The effect of cognitive-behavioral group therapy on depressive symptoms in people with type 2 diabetes: A randomized controlled clinical trial

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ABSTRACT

Background: Diabetes mellitus is considered as the most common metabolic disorder. The patients with diabetes are likely to be affected by mental distress, especially depression. Nurses should pay attention to the psychological needs of depressive patients by participating in an application of non-pharmacological treatment such as cognitive-behavioral therapy. This study aimed to assess the effect of cognitive-behavioral group therapy on depression in patients with diabetes.
Materials and Methods: This randomized controlled trial was performed in 2010 in the diabetes clinics affiliated to Shiraz University of Medical Sciences, Shiraz, southern Iran. In this study, 60 eligible patients suffering from depression were randomly divided into two groups by convenience sampling method, using random block allocation. The experimental group was randomly subdivided into three groups of 10 each and received eight sessions of cognitive-behavioral group therapy. The level of depression was checked before as well as 2 weeks, 4 weeks, and 2 months after the intervention in both groups. Glycosylated hemoglobin (HbA1c) level was also checked before and 2 months after the intervention.
Results: Both groups were demographically homogeneous with no statistically significant difference. The trend in depression scores before as well as 2 weeks, 4 weeks, and 2 months after the intervention was statistically significant in the experimental group ($P \leq 0.001$), but not in the control group ($P = 0.087$). The results showed that HbA1c variation was statistically significant before and after the intervention in both groups ($P \leq 0.001$). However, the mean variation of HbA1c was not statistically significant between the groups ($P = 0.473$).
Conclusions: Cognitive-behavioral group therapy was effective in reducing depression in patients with diabetes. Therefore, this method can be recommended for such patients.

Key words: Cognitive-behavior therapy, depression, diabetes, group

INTRODUCTION

Diabetes is the most common disease caused by metabolic disorders, which is accompanied by an increase in blood sugar. The treatment costs and

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also the rate of disability are high in diabetes, making it one of the main health care issues of patients.[1] Diabetes is caused by various complex factors such as genetic and environmental factors. The metabolic disorders caused by diabetes mellitus result in secondary pathophysiological changes in different body organs. With the ever increasing incidence of this disease all over the world, diabetes mellitus is the leading cause of morbidity and mortality.[2] Since the complications of diabetes often affect individuals in their active years of life, it has a large number of socioeconomic consequences.[3] According to the predictions made by the World Health Organization (WHO), the prevalence of diabetes in Iran will be 6.8% of the population or 5.1 million individuals in 2025.[4] The patients with diabetes are in danger of mental distress, especially depression.[5] Research shows that the risk of depression in type 2 diabetes is twice that in the general population.[6] Some studies report that 15-20% of the individuals suffering from type 1 and 2 diabetes have depression.[7] Also, some studies have reported a prevalence of 71.8%[8] and 43.4%[9] for depression among patients with diabetes in Iran. Depression

interferes with the metabolic control of the disease.[10] It also leads to weak control of blood sugar and decrease in acceptance of the treatment as well as its compliance.[7] In most cases, depression is limited in terms of time. The untreated periods usually diminish after 3-6 months. However, the probability of recurrence is high and approximately 15-20% of the patients suffer chronically. Therefore, the treatment has to aim at improving the current status of the patients, creating consistency in improvement, and if possible, reducing the possibility of recurrence. This has led to the emergence of special psychological treatments in which the patients are taught how to control depression through active skills.

Cognitive-behavioral therapy is an active, organized, and time-limited approach.[11] Individuals who suffer from depression generally have negative thoughts and do not participate in activities. In addition, they are isolated because of interpersonal relationship as well as communication problems. Cognitive-behavioral therapies are structured treatments which focus on teaching the patients how to use cognitive techniques for recognizing negative destructive thinking and replace them with healthy, positive, and constructive thinking patterns. This method is also focused on behavior and the patient feels better when participating in enjoyable activities. This treatment helps the patients to be their own therapists and use self-management[5] skills to effectively control their behavior and decrease depression. In this regard, Rossello and Jimenez-Chafey conducted a study in Puerto Rico to assess the effect of cognitive-behavioral group therapy on depression in the adolescents suffering from diabetes (type 1) during a 12-session intervention. The results of the study showed that depression was cured after the interventions and the participants who had moderate depression did not have any symptoms of depression after the interventions ($P = 0.05$). The results of this study also showed that cognitive-behavioral therapies did not have any effect on the patients' blood sugar [glycosylated hemoglobin (HbA1c)].[10]

Cognitive-behavioral therapies are unique therapies for depression in which the patient and therapist are actively involved. This type of therapy is structured, has a specific plan and program for each session, and encourages the patients to actively participate in groups through homework.[12]

In a study assessing the efficacy of individual cognitive-behavioral therapy on depression in patients with diabetes type 2, the results indicated that the level of depression considerably decreased in the patients undergoing cognitive-behavioral therapy ($P < 0.001$). After a 6-month follow-up, the case group showed a 70%

recovery while the control group's recovery was 33.3%. During the follow-up period (6 months after intervention), the glucolized hemoglobin level was statistically significant in both groups ($P = 0.03$).[7]

Since nurses pay attention to psychological needs from a general point of view, it is necessary for them to apply techniques, such as cognitive-behavioral therapies, for any patient with physical complications. In medical centers, nurses can use these types of treatments in different situations, especially in situations related to stress. These issues prove the beneficence of non-pharmacological treatments, such as psychotherapy, for controlling depression. These treatments have not yet been studied systematically.

In Iran, according to the assessments, it seems that similar studies have not been done yet. With consideration of cultural differences and controversial results of previous studies, we aimed to assess the effect of cognitive-behavioral group therapy on depression in patients with diabetes. The novel point of this study, as compared with other studies on cognitive group therapy, is that we wanted to evaluate the levels of HbA1c after intervention in these patients.

MATERIALS AND METHODS

The study was a randomized controlled clinical trial involving pre- and post-tests. All eligible patients were randomly allocated to either experimental or control group by block randomization. Approval for the study was obtained from the Shiraz University Research and Ethic Committee. Informants were provided with a complete explanation about the study, and informed written consents were obtained from the participants.

Initially, the patients were selected using simple random sampling with a table of random numbers from the list of diabetic patients, and then they were divided into case and control groups using block randomization. Afterward, the case group was randomly divided into three groups (with 10 participants in each group) because the intervention would be more effective in smaller groups. A total of 60 diabetes type 2 patients who had referred to diabetes clinics affiliated to Shiraz University of Medical Sciences, Shiraz, Iran participated in this study. The sample size based on the power of 90% and significance level at 0.05 was estimated to be 19. In order to increase the accuracy and also considering the possible decrease in the number of the p atients, the sample size was decided to be 30 in each group. During the study, two subjects dropped out (one from the experimental group and one from the control group). Therefore, a total of 58 patients completed the study (29 patients in each group) [Figure 1].
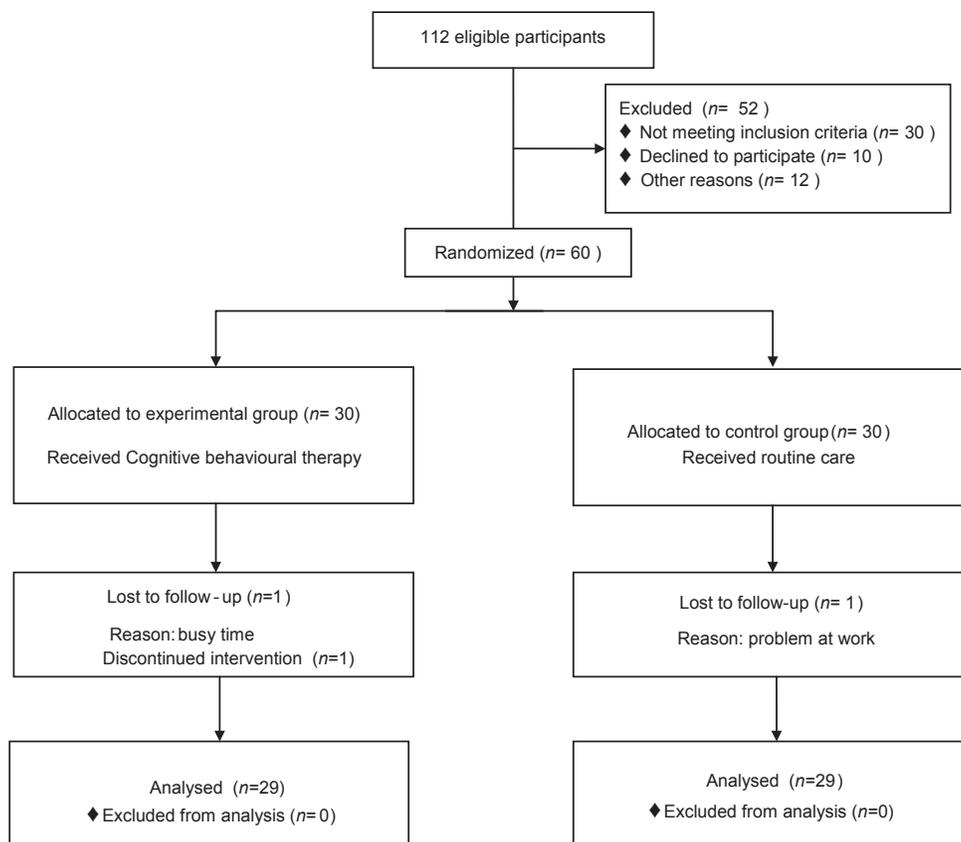
Figure 1: Flow diagram of the participants

The inclusion criteria of the study participants were as follows:

- Having primary school education or higher
- Suffering from diabetes type 2 and willing to participate in the study
- Not having severe depression based on Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) diagnostic criteria
- Having a history of diabetes for more than 1 year
- Having no background of committing suicide, mental disorders, or drug abuse
- Not consuming psychiatric drugs.

The demographic data of the participants were recorded in related forms, and Beck's depression questionnaire was also used. Data were collected by an assistant who was blinded to the groups and the intervention during the study. In addition, the lab tests were performed using a double-blinded method. The technician did not know the patients and the patients did not know the technician.

Beck's questionnaire is one of the most widely used tools for measuring the severity of depression and consists of 21 questions. Each question has four choices and a score of 0-3 is given for each choice.[13] The validity and reliability of this test in Iran were evaluated and its reliability coefficient was reported to be 0.78.[14]

Based on the DSM-IV diagnostic criteria, these patients did not suffer from very severe major depression and had a score of 9-30 in Beck's depression inventory.[15] An expert psychiatrist interviewed the patients clinically. For each of the three case groups, eight sessions of cognitive-behavioral group therapy were conducted. A psychiatrist, a trained psychiatric nursing student, and a professor in the field of mental health nursing were responsible for the cognitive therapy. Two sessions were held every week, lasting for an hour and a half. The level of depression was evaluated before the intervention, 2 weeks after the intervention (after session 4), 4 weeks after the intervention (after session 8), and 2 months after the intervention. Also, the patients' HbA1c was evaluated before and 2 months after the intervention. The control group patients did not receive any intervention and were examined by a physician at the clinic. Patients suspected of having depression in the control group were referred to psychiatrists. However, after the completion of the study, educational pamphlets were given to the control group patients. Moreover, all the patients maintained a stable medical treatment during the study, with respect to anti-diabetic drugs and anti-depressants.

The data collected from the questionnaires and examinations were analyzed using the SPSS statistical software, version 11.5. Independent *t*-test and Chi-square tests were used to test for group differences in the demographic characteristics and outcome measures. The mean score of depression between the groups was evaluated both before and after the training with Mann–Whitney and Wilcoxon statistical tests. Moreover, in order to separately determine the changes in depression before as well as 2 weeks, 4 weeks, and 2 months after the intervention in the case and control groups, repeated measurement statistical test was used. The comparison of the mean HbA1c level between the two groups before and after the training was done using *t*-test and paired *t*-test. In the case group, one individual could not participate in the study because she had to take care of her mother. Likewise, in the control group, one individual could not participate in the study due to problems at work.

Group meetings were held based on the cognitive-behavioral group therapy protocol. In each session, conferences and lectures were presented and the participants asked questions when necessary. Besides, at the end of each session, they were given some homework which had to be completed by the next session.

In the first session, after introductions, the advantages and benefits of the sessions were discussed and the rules were set. Then, depression and its symptoms were explained, the relationship between behavior and thought was discussed, and the difference between a depressed mind and a non-depressed mind was clarified.

In the second session, various aspects of thought and cognitive errors were explained through various examples.

In the third session, initially, the patients' improvement process was evaluated by assessing their daily attitude scale as well as thought list, and feedback was given to them individually. Then, a short overview on depression and its symptoms (which had also been presented in the first session) was given. Afterward, the methods for increasing healthy thoughts were explained through examples.

In the fourth session, the relationship between activity and depression was discussed, and in order to control the improvement process of the patients, a questionnaire was handed to them. In the fifth session, the participants discussed the methods for regulating the goals for overcoming depression, time management, and stress.

In the sixth session, the previously discussed topics were reviewed with the patients' help. Then, some points were mentioned on the healthy management of reality. Also, Benson's relaxation method was performed for the patients as a method for reducing stress.

In the seventh session, the relationships and their effect on mood were discussed. In addition, some examples were presented by the patients and they talked about the relationship between depression and the mentioned relationships. Finally, the patients were asked to record and write down the relationships they had during the week.

In the last session, assertiveness was discussed. In the end, the patients received feedback about the progression and improvement of their disease.

RESULTS

The results of the present study showed no significant difference between the patients in the case and the control groups regarding demographic characteristics such as age, gender, education level, job, and marital status. Besides, both groups were homogeneous [Table 1]. Moreover, the mean depression scores in both groups were significantly different before and 2 weeks after the intervention ($P \leq 0.001$), before and 4 weeks after the intervention (mean score in the case group changed from 18.20 to 7.62 with the SD from 5.92 to 5.16) ($P \leq 0.001$), and before and 2 months after the intervention (mean score changed from 18.20 to 12.39 with the SD from 5.92 to 7.15) ($P = 0.014$) [Table 2]. A significant difference was also observed in the changes in the depression level before, 2 weeks after, 4 weeks after, and 2 months after the intervention ($P \leq 0.001$). However, no significant difference was seen in the control group. Mean score in the control group was 16.89 before intervention with SD 17, the mean score 2 weeks after intervention was 19.46 with SD 16, the mean score 4 weeks after intervention was 17.03 with SD 15, and the mean score 2 months after intervention was 16.27 with SD 16 ($P = 0.087$) [Table 3]. Furthermore, the results showed that blood sugar changes in the control and case groups were statistically significant both before and after the intervention (case group: Mean score of 9.32 before intervention to 8.23 after intervention, with SD from 1.29 to 0.99; control group: Mean score of 8.91 before intervention to 8.04 after intervention, with SD from 1.30 to 1.38; $P \leq 0.001$) [Table 4]. However, the mean variation in HbA1c was not statistically significant between the groups. Mean difference was -1.10 before intervention and -0.92 after intervention, with SD from 0.95 to 0.88 ($P = 0.473$).

DISCUSSION

The present study aimed to evaluate the effect of cognitive-behavioral group therapy on depression in

Table 1: Frequency distribution of the participants based on their demographic characteristics

Group item	Control		Case	
	Number	Percentage	Number	Percentage
Sex				
Women	26	89.70	21	72.40
Men	3	10.30	8	27.60
Total	29	100	29	100
Educational level				
<Diploma	19	65.60	18	62.10
Diploma	8	27.60	8	27.60
Associate degree	1	3.40	1	3.40
Bachelor's degree	1	3.40	2	6.90
Total	29	100	29	100
Occupation				
Self-employed	0	0	3	10.30
Housewife	23	79.30	18	62.10
Retired	6	20.70	6	20.70
Employee	0	0	2	6.90
Total	29	100	29	100
Marital status				
Married	24	82.75	25	86.20
Widowed	5	17.25	4	13.8
Total	29	100	29	100
Age, years				
≥50	7	24.1	7	24.1
51-60	14	48.3	16	55.2
≤60	8	27.6	6	20.7
Total	29	100	29	100

Table 2: Mean comparison of depression scores before and 2 weeks after, before and 4 weeks after, and before and 2 months after the intervention in case and control groups

Group	Number	Mean difference	Median	Standard deviation	Z	P value
Before and 2 weeks after						
Case	28	8.07	8.00	6.39	−4.67	0.001
Control	26	−2.61	−1.00	8.00		
Before and 4 weeks after						
Case	29	10.58	11.00	6.10	−5.18	0.001
Control	29	−0.13	0.00	6.93		
Before and 2 months after						
Case	28	5.60	6.00	6.98	−2.45	0.014
Control	29	0.62	1.00	6.38		

patients with diabetes. We found that the interventions were effective in reducing depression in patients with diabetes.

These findings are consistent with other studies. Rossello and Jimenez-Chafey's study showed that cognitive-behavioral group therapy was effective in reducing the signs of depression in diabetic patients.[10] Also, the results of Lustman *et al.*'s study showed that the reduction of depression signs and the percentage of the patients who were relieved from depression were both higher in the group which participated in cognitive-behavioral therapies.[7]

Sheikholeslami performed a study on 22 individuals to assess the effect of group therapy on depression in patients suffering from stroke. In this study, Beck's questionnaire was used before, immediately after, and 1 month after the intervention in selected hospitals affiliated to Isfahan University of Medical Sciences. The findings of this study showed that in comparison to the rate of depression before the intervention, the rate of depression in these patients had a considerable decrease immediately after and 1 month after the intervention ($P \leq 0.0001$).[16] Also, another study was performed by Van Der Van *et al.* in Amsterdam to assess the short-term effect of cognitive-behavioral group therapy on controlling the blood sugar in the adults with diabetes type 1 who had a weak and long-term control of blood sugar.[12] The case group consisted of 45 patients and the control group consisted of 43 patients, and the interventions lasted for 6 weeks. The results showed no significant change in controlling glucolized hemoglobin after the treatment. However, regarding the reduction of blood pressure ($\leq 0.75\%$), there was a significant difference between the groups after cognitive-behavioral group therapy training, and there was a considerable increase in HbA1c levels after knowing about HbA1c level.[17]

A great number of medical complications can lead to destructive emotional distress and further deteriorate the initial medical complications. Hence, nurses must understand that the patients' emotional needs are the key to their prognosis and can influence the treatment results.[16] The high incidence of diabetes in the world and also in Iran and the fact that the patients may not be able to use medication should be taken into account. Moreover, common medications for behavioral disorders, such as some anti-depressants and shock therapy, could lead to problems in treating the patients with diabetes since they can cause changes in the patients' HbA1c level.[17]

The statistical results confirmed the long-lasting effect of the intervention since Beck's depression test was done before and 2 months after the intervention. The mean score difference before and 2 months after the intervention was statistically significant in both case and control groups,

Table 3: The changes in depression scores before, 2 weeks after, 4 weeks after, and 2 months after the intervention in case and control groups

Group	Number	Mean	Median	Standard deviation	Minimum	Maximum	*P* value
Case							
Before	29	18.20	18.00	5.92	9.00	30.00	0.001
2 weeks after	28	10.35	9.00	5.71	1.00	24.00	
4 weeks after	29	7.62	6.00	5.16	0.00	20.0	
2 months after	28	12.39	12.50	7.15	0.00	27.00	
Control							
Before	29	16.89	5.44	17.00	10.00	30.00	0.087
2 weeks after	26	19.46	10.49	16.00	8.00	43.00	
4 weeks after	29	17.03	8.71	15.00	6.00	47.00	
2 months after	29	16.27	8.62	16.00	4.00	36.00	

Table 4: Comparing the blood sugar (hemoglobin) changes before and after the intervention in case and control groups

Group	Case		Control	
Blood sugar changes	Before treatment	After treatment	Before treatment	After treatment
Mean	9.32	8.23	8.91	8.04
Median	9.26	8.14	8.60	7.82
Standard deviation	1.29	0.99	1.30	1.38
Minimum	6.93	6.76	6.07	5.43
Maximum	11.79	11.23	11.43	11.97
P value	0.001		0.001	
Percentage of changes	11.65		9.75	

which shows that the effect of cognitive-behavioral treatments can last and continue after the treatment. In the research performed by Lustman *et al.*, a statistically significant difference was observed in the depression level of the cognitive-behavioral treatment group and the control group 6 months after the study.[7] Moreover, Sheikholeslami's study revealed that 1 month after the treatment, the depression level had considerably reduced in the case group.[13]

On the contrary, some studies do not confirm the lasting effect of cognitive-behavioral treatments. In the study conducted by Edilman *et al.*, for instance, treatment endurance was not maintained in the cognitive-behavioral intervention group.[18]

In this study, blood sugar changes (glucolized hemoglobin) were significant in both study groups after the intervention. However, the mean difference of blood sugar before and after the intervention did not have a statistically significant difference in both groups. Considering the significance in blood sugar changes after the intervention in both groups, we cannot certainly claim the significance in

the case group to have resulted from the interventions. Researchers believe that one of the intervening factors which may have been effective on blood sugar results is the patients' knowledge of their blood sugar results before the interventions. The blood sugar results were given to the patients before the intervention due to ethical considerations; therefore, they might have controlled their diabetes-related diet and, as a result, their blood sugar had been controlled. Another potentially influential factor is the patients' participation in educational classes regarding diabetes. Moreover, another important factor is the small sample size in this study and, statistically, it has been shown that by increasing the number of samples, a better conclusion can be reached.

Of course, most studies conducted on the issue showed that cognitive-behavioral therapies were effective on psychological variables and they did not have any effect on the blood sugar of patients with diabetes.[10,19-21]

In this regard, Van Der Van *et al.*'s study shows that cognitive-behavioral therapies are not effective on the patients' blood sugar.[19] In addition, no significant difference was observed in the patients' blood sugar after therapy in Lustman *et al.*'s study. However, during 6 months, the glycolized hemoglobin level had a statistically significant difference in both groups.[7] Also, Markowitz *et al.*'s study performed with the aim of finding the effect of cognitive-behavioral therapy on depression and its adherence in patients with type 1 diabetes showed a clinically meaningful decrease in depression severity score but possible improvement in glycemic control.[22]

Two months of follow-up, as in our study, might not be adequate for assessing the effect of cognitive-behavioral therapy on blood sugar and more time is needed for evaluating the effect of cognitive-behavioral disorders on blood sugar.

Cognitive-behavioral therapies are among the effective treatments for depression. However, they have been poorly used in depression related to physical illnesses. The results of this study, which are consistent with some similar studies, show that cognitive-behavioral therapies are effective on depression in diabetes patients and can be a harmless therapeutic approach.

One of the limitations of our study could be its small sample size. Also, we did not perform any sham intervention in the control group. Moreover, further studies are needed to be conducted on the issue because during this study, some conditions were out of the researcher's control; for instance, the patients' attitudes in both groups were influenced by their current family conditions, their past, the environment, and their disease, and could not be controlled. Also, information exchange was possible between the patients in the class; of course, it should be noted that the case group was advised not to exchange information with the control group.

The results of this study can be used in various educational studies and therapeutic fields. Also, the researchers hope that this study will provide a foundation for studies on psychological treatment methods with a more accurate view on mental-psychological problems in chronic physical patients. Also, nurses should pay attention to the needs of chronic patients, such as diabetic patients, by participating in the psychiatric team while applying non-pharmacological treatment such as cognitive-behavioral therapy.

CONCLUSION

Cognitive-behavioral treatments can be suitable for treating depression in patients with diabetes. Also, our study showed that 2 months follow-up might not be adequate for assessing the effect of cognitive-behavioral therapy on blood sugar. Of course, further studies need to be conducted with more patients and sessions. Also, it is suggested that the study be repeated with more participants in order to get a better effect of cognitive-behavioral therapy on blood sugar in diabetic patients.

ACKNOWLEDGMENTS

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ERRATUM

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Author name 'Akram Arabi'
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