

THE EFFECT OF GROUP COGNITIVE-BEHAVIORAL THERAPY ON DEPRESSION IN MENOPAUSAL WOMEN: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Psychological and cognitive consequences of menopause such as irritability, stress, anxiety, feelings of sadness, mood changes, and depression affect quality of life of women in this period. Doing consultation with female patients to help them to cope with these changes can be useful. The current study was done to assess the effect of cognitive behavioral therapy (CBT) on depression in menopausal women in Tooserkan, Iran. In this randomized clinical trial, 76 menopausal women who presented to health centers of Tooserkan, Iran from September to December 2016 were included. Six CBT sessions were held. The Depression, Anxiety, and Stress Scale (DASS-21) was applied. After completing six CBT sessions, and also one month later the measurements were done. The data were analyzed using the Mann-Whitney and Friedman tests. Comparisons of depression scores between the two groups before initiating CBT was not significant ($P > 0.05$). Within-group comparisons of depression scores before and after CBT and one month later showed significant changes in CBT group ($P < 0.001$). These changes in control group were not significant ($P > 0.05$). It is suggested to use CBT for menopausal women to improve the quality of life of this group.

KEYWORDS: *Depression; menopause; cognitive-behavioral therapy*

INTRODUCTION

Menopause is defined retrospectively as the last menstrual period followed by 12 months of amenorrhea. Average age at menopause is 51 years¹. In Iran, average menopause age is 47.8 years². Despite the rise in life expectancy for women, menopause age has remained constant. Therefore, with the increased life expectancy, women spend nearly one-third of their life span after menopause. According to the latest population and housing census by the Statistical Center of Iran in 2011, there were 8,070,430 women in the age range of 50 to 65 years (10.74% of the total population)³. Since after menopause, the ovaries stop producing significant amounts of estrogen, so the symptoms and diseases associated estrogen deficiency become important in women health¹. Along with the

menopause and reverse metabolic changes that occur during the transition from pre-menopause to post-menopause phase, women are susceptible to various diseases such as osteoporosis, osteopenia^{4,5}, high blood pressure, and cardiovascular diseases^{6,8}. Also, psychological and cognitive consequences of menopause can affect quality of life of women. These include sleep disturbances, fatigue, impaired short-term memory, irritability, stress, anxiety, feelings of sadness, anger, lack of motivation, difficulty concentrating, mood changes and depression². Many women report difficulty in concentrating and emotional instability during this period¹. Research shows that depressive symptoms occur more frequently the perimenopausal period⁹, as 26 to 33% of women experience their first depressive episode in their menopause¹⁰. In Jung et al. study¹¹ it was reported that the risk of depression increased linearly with decreasing

menopausal age. Inna study by Rabiei and colleagues¹², it was shown that 9.2% of menopausal women had depression and 4.2% had anxiety. The prevalence of depression in women is 2-3 times higher than in men. Some women are susceptible to mood disorders during hormonal changes. Considering physical and psychological problems that threaten women in this period, it seems that therapies that can help women cope with these problems, especially psychological ones, will be useful. One of the effective ways is cognitive-behavioral therapy (CBT). This therapy helps individual to think differently and as the result of this new thinking, he/she can confront undesirable events with more acceptable behaviors¹³. Nowadays, CBT is used in the management of many conditions such as anxiety, depression, phobia, and stress¹⁴. There is limited attention to menopausal women in health centers and in the orders of the Ministry of Health and Medical Education. Considering and the effect of mood changes in menopausal transit time on the quality of life of affected women, this study was performed to assess the effect of CBT on depression in menopausal women in Toosierkan, Iran in 2016.

MATERIALS AND METHODS

This was randomized clinical trial. The participants were sampled using the convenience sampling method. The study population consisted of menopausal women who presented to Health Centers of Toosierkan, Iran. The inclusion criteria consisted of normal menopause (not as the result of medication or removal of the ovaries), age range of 47 to 57 years, the time passed from beginning of menopause as 1 to 4 years, no acute or chronic systemic condition in the past 12 months so severe resulting in the inability of the participant to attend the sessions, no grief for a family member in the past 3 months, no stressful factor such as severe disease of spouse or children, no use of hormonal therapy to reduce menopausal symptoms, able to speak Persian, not having severe mental diseases or use of psychotropic medications, not being addicted to drugs, not having suicidal thoughts, not having previous history of psychosis or suicide, not attending relaxation, yoga and similar classes. Exclusion criteria were not attending two or more CBT sessions, using hormonal therapy during the study, occurrence of an unexpected stressful event during the study, and no willingness to resume the study. The sample size was calculated as 90 subjects (45 in each group) using the formula of comparing a quantitative variable between two

groups and similar study¹⁵. Randomization was done by writing numbers on separate piece of papers and then asking the subjects to pick a paper. Ninety numbers were written on the papers and put in a bowel. Those who picked even numbers were assigned to control group. Those who picked odd numbers were assigned to intervention group. To ensure that randomization is done at its best form, a colleague who was midwife and blinded to the process was asked to manage group assignment and randomization. After getting informed consent, the Depression, Anxiety, and Stress Scale (DASS-21) was applied. Those who had high numbers on this scale which indicated severe depression or anxiety were referred to psychiatrists. Blinding was done for both examiner and the subject. The participants were blinded to control or intervention group. Also, the subjects in the groups were identified by codes (for example, 1 and 2), and the colleague who performed analyses was blinded to the subjects. As the intervention was done by the researcher and he was aware of the intervention type and the groups, blinding was not done for the researcher. The DASS-21 is a standard scale and its reliability and validity have been verified in Iran. In a previous study, it was shown that correlation coefficient between stress and depression was 0.48, a coefficient of 0.53 between anxiety and stress, and coefficient of 0.28 between anxiety and depression¹⁶. In a study to determine reliability of this scale in Iran, Cronbach's alpha for depression, anxiety, and stress was respectively 0.81, 0.74, and 0.78¹⁷. In another study, correlation between the DASS subclasses with Beck's Depression Inventory was 0.70, between stress subscale of the DASS and Zung Anxiety Scale was 0.67, and between Stress subscale and the Perceived Stress Scale was 0.49¹⁸. Each subscale of the DASS has 7 questions and the total score is the sum of scores to the related questions. Each question is scored from 0 (not true about me at all) to 3 (true about me always). The total score of each of these subscales should be doubled. Then the severity of symptoms can be determined¹⁸. The next tool used was a data collection form which contained 19 questions about demographic data and obstetrics data. This form was developed by the researcher and was approved by the faculty of the School of Nursing and Midwifery, Kermanshah, Iran. For in intervention group, CBT sessions were performed in group sessions consisting of 11-12 subjects. The total number of sessions was six and each session lasted from 60 to 90 minutes. The sessions were held in the consultation room of the Welfare Center of Toosierkan. This location was selected as this place

was very quiet, well lit with enough appliances. The gathered data were analyzed using the SPSS software (ver. 23.0) applying independent t test, chi-square, Kolmogorov-Smirnov, Mann-Whitney, Friedman, analysis of variance, Tukey's, and Kruskal-Wallis tests. Significance level was set at 0.05. The contents of each session were as follows

Session one

Welcome, introduction of members and being familiar with each other, emphasis on confidentiality of the issues discussed in each session, describing the physiology of menopause

Session two

Discussion about the effect of thought on emotions, social supports and related relations, discussion about the effect of activities on mood, relaxation training by both lecture and practical method (gradual relaxation of muscles, respiration techniques, etc), providing subjects with assignments to be done at home

Session three

The review of previous session assignments and group feedback, becoming familiar with negative thoughts and opinions and the ability to separate them from reality, being familiar with evaluating emotions and the degree of belief in negative thoughts about menopause, doing 10 minutes of relaxation, raising positive thoughts and avoiding negative thoughts in self-care, providing assignment at home

Session four

Review of the previous session assignment and group feedback, being familiar with automatic thoughts and cognitive errors, decreasing anxiety about not being supported by others, becoming familiar with respiratory relaxation techniques, providing home assignment

Session five

Review of previous session assignment and group feedback, becoming familiar with confirmatory and rejecting evidence of negative beliefs about menopause, performing relaxation for 10 minutes using respiratory techniques, providing home assignment

Session six

Reviewing the previous session assignment and group feedback, encouraging the participants to talk about the stress and anxiety as a result of menopausal symptoms and discussing about them,

developing positive thoughts and decreasing negative thoughts in doing physical activity, exercise, and adhering to healthy diets through becoming familiar with exercise benefits and diet. Discussing about the side effects of unhealthy diets and sedentary lifestyle, solving misinterpretations through group discussion and Socrates communication, and final conclusion after completing the sessions, the measurements were done by the research team in both groups, and repeated once more 1 month later. For ethical purposes, control group received one session of consultation after completion of the second-stage measurements.

RESULTS

In this study, 76 menopausal women in two groups of intervention (38 subjects) and control group (38 subjects) were studied. Mean (\pm SD) age of the sample was 53 ± 2.86 years. The proportions of married subjects in intervention and control groups were 81.6% and 97.4%. In intervention group, 100% was housewife and in control group, 94.7% was housewife (Table 1). Mean time passed from menopause was 2.65 years in both groups. The chi-square test was used to determine whether two groups are matched regarding demographic variables such as marital status, educational level, occupation, body mass index (BMI), number of children, number of deliveries, exercise activity, and income. The results showed that except for income, other factors were comparable in two groups (Table 1). The results showed that mean values for depression in intervention and control groups before CBT were 9.63 (\pm 3.7) and 8.5 (\pm 3.42). After the study, this score decreased to 2.63 (1.97) in intervention group and 7.81 (3.97) in control group. One month after completion of the study, this score decreased to 2.35 (1.66) in intervention group and 7.44 (2.66) in control group (Table 2). The Friedman test analyses showed that CBT in intervention group resulted in change in mean depression scores at different time points (Table 2). However, such changes were not significant in control group ($P= 0.583$). In addition, the analyses showed that significant difference existed between intervention and control groups regarding mean depression score ($P<0.001$). A significant difference also was found one month after CBT between the two groups ($P< 0.001$); Fig. 1. The Kruskal-Wallis test analyses showed that no significant difference existed regarding mean depression score in intervention group when comparisons were made within subgroups including

marital status, educational level, BMI, number of children, number of deliveries, and exercise activity. But, significant difference existed regarding this score at different income groups.

Pairwise comparisons with Mann-Whitney test showed that depression was more severe in those with lower income levels ($P < 0.005$); Table 3.

Table 1
Comparison of demographic variables between Intervention and control groups

Variable		Intervention group	Control group	X ²	df	P value
Marital status	Married	31 (81.6%)	37 (97.4%)	5.19	2	0.074
	Single	5 (13.2%)	1 (2.6%)			
	Divorced/widower	2 (5.3%)	0			
Education	Primary school	11 (28.9%)	5 (13.2%)	2.87	2	0.238
	Secondary school	26 (68.4%)	32 (84.2%)			
	High school diploma and university	1 (2.6%)	1 (2.6%)			
Occupation	Housewife	38 (100%)	36 (94.7%)	2.05	1	0.152
	Clerk and retired	0	2 (2.6%)			
BMI	18.5 to 24.9	9 (23.7%)	6 (15.8%)	1.04	2	0.592
	25 to 29.9	18 (47.4%)	22 (57.9%)			
	> 30	11 (28.9%)	10 (26.3%)			
Number of children	No child	5 (13.2%)	1 (2.6%)	4.82	3	0.185
	1 to 2	5 (13.2%)	9 (23.7%)			
	3 to 4	21 (55.3%)	24 (63.2%)			
	≥ 5	7 (18.4%)	4 (10.5%)			
Number of deliveries	No delivery	6 (15.8%)	1 (2.6%)	2.09	3	0.069
	1 to 2	3 (7.9%)	9 (23.7%)			
	3 to 5	24 (63.2%)	25 (65.8%)			
	≥ 5	5 (13.2%)	3 (7.9%)			
Exercise activity	No exercise	9 (23.7%)	7 (18.4%)	0.341	2	0.843
	Regular exercise	8 (21.1%)	8 (21.1%)			
	Sporadic exercise	21 (55.3%)	23 (60.5%)			
Income	Good	7 (18.4%)	4 (10.5%)	7.76	2	0.021
	Moderate	20 (52.6%)	31 (81.6%)			
	Poor	11 (28.9%)	3 (7.9%)			

Table 2
Comparison of depression scores in intervention and control groups before and after the cognitive-behavioral therapy

Variable	Group	Before intervention Mean (±SD)	Immediately following intervention Mean (SD)	One month after intervention Mean (SD)	P value*
Depression	Intervention group	9.63 (±3.72)	2.63 (±1.97)	2.35 (±1.66)	0.001
	Control group	8.50 (±3.42)	7.81 (±3.97)	7.44 (±2.66)	
P value		0.211	0.001	0.001	

*Friedman test

Table 3
Comparison of depression in intervention group based on demographic subgroups

	Variable	Depression			
		Mean (\pm SD)	t	df	P value
Marital status	Married	2.45 (\pm 2.09)	2.79	2	0.247
	Single	3 (\pm 1.4)			
	Divorced/widower	3.6 (\pm 1.14)			
Education	Primary school	2 (\pm 3.09)	0.736	2	0.692
	Secondary school	2.46 (\pm 1.98)			
	High school diploma and university	3 (\pm 0.001)			
BMI	18.5 to 24.9	2.5 (\pm 2.45)	0.438	2	0.803
	25 to 29.9	2.55 (\pm 1.97)			
	> 30	2.8 (\pm 1.7)			
Number of children	No child	3.6 (\pm 1.14)	4.61	3	0.201
	1 to 2	3.6 (\pm 2.07)			
	3 to 4	2.4 (\pm 2.2)			
	\geq 5	1.8 (\pm 1.3)			
Number of deliveries	No delivery	3.16 (\pm 1.5)	1.14	3	0.767
	1 to 2	2.33 (\pm 1.5)			
	3 to 5	2.62 (\pm 2.2)			
	\geq 5	2.2 (\pm 1.9)			
Exercise activity	No exercise	3.11 (\pm 2.08)	0.775	2	0.679
	Regular exercise	2.6 (\pm 1.9)			
	Sporadic exercise	2.4 (\pm 2.01)			
Income	Good	1.57 (\pm 0.975)	6.61	2	0.037
	Moderate	2.35 (\pm 1.2)			
	Poor	3.8 (\pm 1.2)			

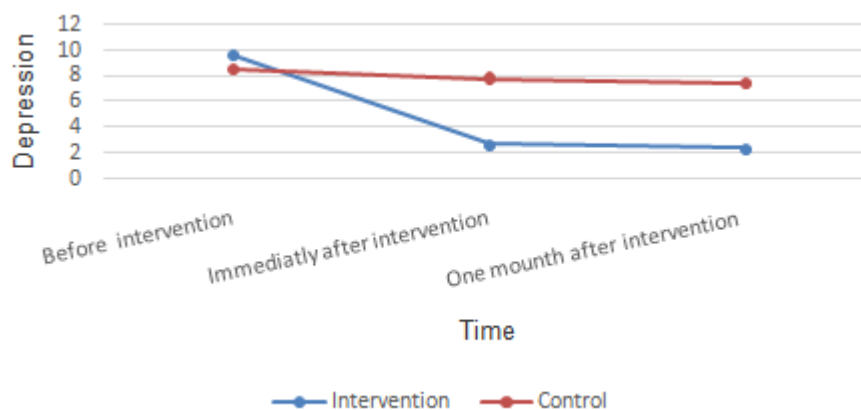


Figure 1
Changes in depression scores at different time points in intervention and control groups

DISCUSSION

The current results showed that the mean scores of depression in the group that received CBT decreased more significantly when compared to the control group. This indicates the effectiveness of CBT. These results are in agreement with a

previous study¹⁹ in 2014. They reported that CBT significantly decreased depression, anxiety, and stress in women with breast cancer. The results of Asghari et al.²⁰ study in 2015 showed a significant decrease in depression scores in the CBT group. Azizi et al.²¹ in 2015 found that group CBT was effective on decreasing depression and evident and hidden anxiety in elderly women. The results of

Yoo et al²² in 2009 showed that CBT significantly reduced depression. Valsaraj and colleagues²³ in 2016 confirmed the effectiveness of this type of counseling on depression. In explaining the reasons for the effectiveness of CBT in reducing anxiety, depression and stress it can be said that a variety of cognitive techniques used help people to recognize negative automatic thoughts detect and learn skills to challenge cognitive distortions. Also, behavioral techniques used in this project such as relaxation and respiratory techniques have been shown to improve disorders such as stress and depression²⁴. As depressed patients exaggerate the risk of danger, these techniques make these patients think logically in such situations. On the other hand, when these techniques are employed in group sessions, this let the patients understand that they are not alone and other patients have similar problem. This results in reduction of loneliness, blame, and shyness feelings. This enables them to exchange constructive communications regarding solutions or coping strategies. This intellectual and empathy experience for problem of others helps restore their self-esteem. The results of this study revealed that no difference was noted regarding depression score when compared in subgroups including marital status, education, body mass index (BMI), number of children, number of deliveries, and exercise in postmenopausal women in the intervention group after CBT. But significant difference was seen regarding depression score within different income levels. Pairwise comparison with the Mann-Whitney test showed that in this group of women following CBT, depression was more pronounced in those with lower income level. In a former study²⁵, depression amongst menopausal women correlates with income, but did not correlate with marital status. According to the findings of another study, educational level, occupation, and BMI did not have significant association with depression, but a significant association existed between depression and marital status²⁶. This study reported that married women had less severe depression. To adjust thus discrepancy between the results of different studies, it can be said that traditional culture in small cities like Tooserkhan where families are usually populated can have important role. In such families, when a member dies, other members try to compensate the lack of that

particular person and therefore family members will face less anxiety. Also, the low percentage of single subjects in this study is another contributing factor. The current study faced some limitations. Firstly, The DASS is used to measure depression, anxiety, and stress. This scale cannot diagnose these conditions as ICD or DSM can do. On the other hand, the group CBT cannot address each condition with details. Therefore, it is advised that in the future studies where group therapies are done, the individual problems be addressed as well. As this study was a randomized clinical trial, it is possible that when implementing CBT, the researcher be biased. It is advised that in other clinical trials, in order to prevent bias, the person who does CBT will not be the main researcher. It is suggested that more accurate diagnostic scales be used that incorporate diagnostic criteria for measuring depression, anxiety, and stress. According to the obtained findings, CBT was effective in reducing depression, anxiety, and stress in menopausal women. It is advised to authorities and health planners to use CBT as an effective tool to improve the quality of life of menopausal women and as a tool for completion of services provided to these women. Considering the results, it is suggested to use this method in management of other conditions such as anxiety.

CONCLUSION

As a pragmatic suggestion, it is useful to add CBT as an effective tool for improvement of quality of life among menopausal women in the services provided by the Ministry of Health.

ACKNOWLEDGEMENT

This study was registered (No. IR.KUMS.REC.1395.327) in the Ethics Committee of Kermanshah University of Medical sciences, Kermanshah, Iran; this trial was also registered at Clinical Trial Center No. IRCT2016081624753N2.

CONFLICT OF INTEREST

Conflict of interest declared none

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