Original Article

The Effect of Cognitive Behavioral Therapy on the Burden in Drug Dependent Persons' Caregivers: A Randomized Controlled Clinical Trial

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Abstract

Background: Drug dependence is one of the current problems that leads to the drug dependents persons' suffer and imposes a huge mental burden to their family members. This study aimed investigating to determine the effect of cognitive- behavioral therapy (CBT) on the burden of the caregivers of drug dependent people. In CBT, caregivers discover thought and behavioral mistakes and recover them. **Materials and Methods:** This randomized controlled clinical trial was conducted on 64 caregivers of drug dependent individuals referring to one of the clinical and educational centers in Isfahan, Iran, which were randomly assigned to two equal groups (intervention and control) in 2016. Intervention group under went eight 90-min CBT sessions, whereas control group attended 3 group sessions to express their experiences. Data were collected by Zarit Burden scale and the demographic questionnaire and analyzed by independent t-test, Chi-square, and ANCOVA repeated measure through SPSS 18. **Results:** Before the intervention, no statistical difference was observed among two groups in the mean scores of burden ($t = 0.75$, $p = 0.46$).There was a significant difference between three time points in the intervention group ($F = 3.24$, $p < 0.001$). However, care burden mean score did not show a significant reduction in the control group ($F = 0.17$, $p = 0.96$). **Conclusions:** The CBT can lead to reduction of burden in drug dependent caregivers'. We suggest encouraging nurses to establish educational programs such as CBT to maintain and improve caregiver's mental health.

Keywords: *Burden, caregiver, cognitive therapy, substance-related disorders*

Introduction

Drug dependence is among the existing important problems with regard to vast development worldwide.[1] It is estimated that approximately 260.4 to 360 million people are involved in drug dependence.[2] In Iran, drug dependence is reported approximately 1.325 million people.[3]

Negative effects of drug dependence are not only limited to the drug dependent persons but impose high burden to their families.[4] Negative effects of drug dependence manifest as concerns about drug dependent persons' physical and mental health; negative and hazardous relationships; experiencing higher levels of stress, depression, and anxiety; and lower self-esteem.[5] However, because of the relevant stigma, most drug dependence problems remain hidden.[6] Stigma leads to families' isolation and their social identity destruction and acts as the main barrier in seeking treatment and its continuation, and related rehabilitation.[7] With regard to above-mentioned issues, living in a family with a drug dependent person imposes high burden. Challenging with such problems, therefore, results in high levels of physical and mental signs, and consequently, leads to hopelessness and a negative attitude toward the future.[8] In addition, the level of the burden, imposed to the family, has an inverse association with drug dependent persons' physical and mental health and the longevity of their remaining in treatment.[9] Therefore, some interventions should be conducted in the family to make a more satisfactory life experience for both the drug dependent persons and their families. With regard to the conducted research, whenever family cognitive education is accompanied with routine mental healthcare's, it cannot ably affect the reduction of caregivers' mental problems.[10]

One of the cognitive education techniques is cognitive behavioral therapy (CBT).There

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are numerous evidence supporting the efficiency of such an intervention in a vast domain of mental disorders.[11] The CBT considers unpleasant excitements as a product of illogical thoughts and defines cognitive processes as the main axis for thinking, excitement, and behavior. In such an approach, what families members think and behave are focused.[12] Various researches have investigated the positive effects of such a treatment approach in different groups.[13,14] With regard to existence of few studies on the effect of CBT on drug dependent persons' and their family members' burden and with respect to psychiatric nurses ability in applying such techniques in treatment,[15] the present study aimed to investigate the effect of CBT on the burden of the caregivers of drug dependent persons.

Materials and Methods

The present study was a two group three stage clinical trial (IRCT2017011431927N1) in the July to September 2016. The study population comprised caregivers of the drug dependent individuals referring to Shahid Ayatollah Modares educational center in Isfahan, Iran. The sample size was calculated with regard to similar studies;[16] the sample size for each group was set at 32 participants; Z1 was the confidence interval that was considered to be 95%, Z2 was test's power that was 80%, and, which was the least difference between the mean of changes in score of burden of care between both groups, was considered to be 0.70. The samples were selected (in accordance with the inclusion criteria) by convenience method from 90 family caregivers of the drug dependent individuals referring to the study environment and divided into intervention and control groups. The quadric balanced block randomization method (using a table of random numbers) was used to randomize the participants into the intervention and control groups (n = 32).According to the sample size (64), 16 blocks were needed. Then, the blocks were randomly written on a piece of paper, and the researcher referred to the list of the family caregiver and placed them in the blocks [Figure 1]. Inclusion criteria were being the main caregiver of the drug dependence and accepting all his/her responsibilities, having necessary physical and mental health to give care, being interested in attending the study, being able to communicate verbally and obeying educational sessions regulations, passing atleast 1 year after drug dependence diagnosis, giving care to only one person in the family, not having dependency to drugs or psychiatric medications, not previously attending educational sessions on addiction to drugs, obtaining scores over 30 from Zarit Burden scale, and dependence on substances. Abusing substances was differentiated by a psychiatrist according to the DSM-IV-TR criteria. Exclusion criteria were caregiver's absence in educational sessions for at most two sessions because of some reasons.

Data were collected by Zarit Burden scale and the demographic characteristics questionnaire including age, sex, marital status, employment, education level, family relationship, length of caregiving, and caregivers'income. Zarit Burden scale has been taken from a 22-item questionnaire. The questions refer to the caregiver/patient relationship and evaluate the caregiver's health condition, psychological well-being, and their finance and social life. The Zarit Burden scale was translated to several languages, showing a performance similar to the original version, and its psychometery was measured and confirmed in various studies.[17,18] The caregivers' answers to each item were evaluated in Likert's scale with the lowest score of 0 (no

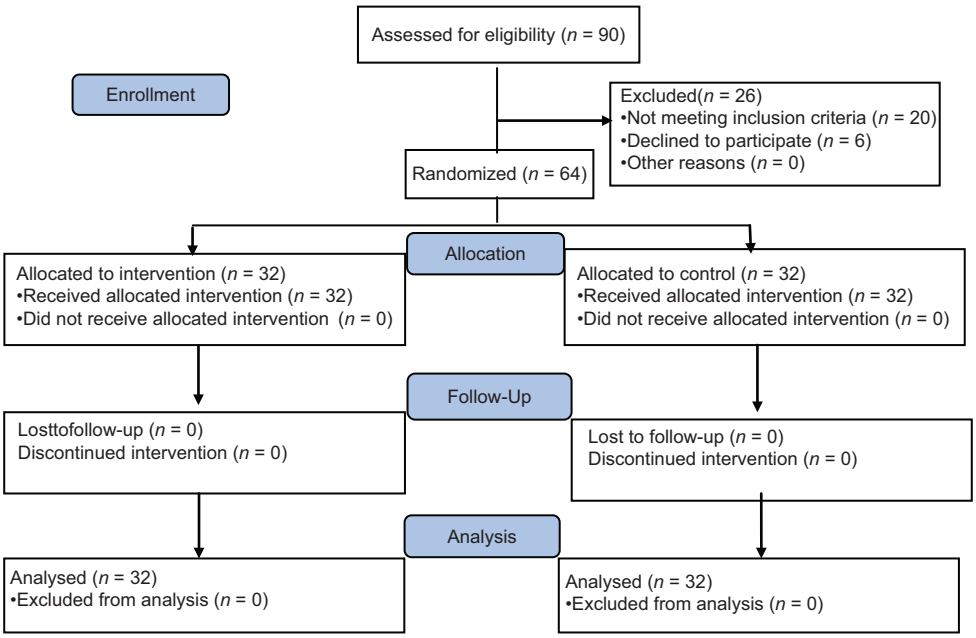

Figure 1: CONSORT flow diagram of the participants

care burden) and the highest score of 88 (the highest care burden).Scores 61–88 showed high burden, 31–60 showed moderate burden, and 30 and lower than 30 showed mild burden. Zarit Burden scale was adopted by Navidian *et al*. in 2004. They confirmed its qualitative content validity after translate of Zarit Burden scale to Persian and reported its reliability through test-retest of 0.94.[19] To calculate the content validity rate (CVR) and content validity index (CVI), the opinions of nine experts including CVR more than 0.62 and CVI more than 0.8 were considered acceptable by the researchers, and all items were accepted. Moreover, in the present study, internal consistency was evaluated in a pilot study on 16 subjects, randomly drown from the study population. The Cronbach's alpha coefficient was 0.86 indicating an acceptable internal consistency.

The treatment sessions were held in the hospital conference room. The intervention groups were classified into 4 groups of eight participants and received intervention that consisted eight 90-min sessions of CBT, which were held twice weekly for 2 months. The presented program was designed to determine, challenge, and change the participants' negative cognitions from ABCD model; A: Activeevents, B: belief, C: consequences, and D: discussion. Each session was designed in a way that each participant, in addition to learning a cognitive technique, would also learn and practice a behavioral technique (muscle relaxation, using diaphragmatic breathing, and visualization) too. At the beginning of each session, previous discussions and participants' homework were reviewed and the sessions ended with questioning and group discussion. In addition, relaxation techniques were conducted at the beginning and at the end of each session. The content of interventional program from CBT was designed with regard to the literatures. It included familiarization with drug dependence disease and its problems, cognitive–behavioral model, cognitive errors, negative automatic thoughts and the techniques to cope with them, empowering communicational skills, problem solving, and anger management.[20] To encourage the subjects to follow educational program, caregivers were telephoned and their questions and obscure points were answered. The control group was asked to only participate in pre-intervention, post-intervention and follow-up stages. A separate place was selected for the control group and 3 sessions were assigned for them to participate and talk about their express and experiences. The members of the two groups were not able to communicate with each other during the intervention. In addition, the participants did not communicate with each other and share information because they had been selected from different parts. It should be noted that the data were analyzed by an individual who was blind to the intervention groups. Absolute blinding was not possible because the intervention was performed by the researcher just in the intervention group. The collected data were analyzed by independent t test and Chi-square test to compare caregivers' demographic characteristics between intervention and control groups. In addition, to compare burden levels in intervention and control groups, and for the time intervals of immediately after and 1 month after intervention by ANCOVA repeated measure. Data were analyzed through SPSS version 18 (IBMSPSS Statistics) with significance level of $p < 0.05$. ANCOVA repeated measure assumptions such as normal distribution of care burden were investigated by Kolmogorov-Smirnov test. The equality of variances and co-variances in the subjects was investigated by Leven's test and Box test, respectively. The results were obtained by the administration of the model with control of confounding demographic variables (age, sex, care length, income level, and baseline care burden values before intervention).Other demographic variables were checked but had no confounding effect.

Ethical considerations

To observe ethical principles, approved by the Ethics Committee of Isfahan University of Medical Sciences (IR.MUI.REC.1394.9.74) and after the researcher received are commendation letter from research council of Isfahan University of Medical Sciences, presented to the related authorities. Moreover, before the interventions, all the participants were informed about the goal and method of the study, voluntary the nature of the research, and the confidentiality of their information. A written informed consent was obtained from all the participants.

Results

This study was conducted on 64participants. Participant characteristics are presented in Table 1. The results of the Chi-square test and independent t test revealed no statistically significant difference between the two groups regarding qualitative and quantitative demographic variables [Table 1].

Prior to the study, the mean score (SD) of the burden of care was 55.43 (11.19) in the intervention group and 53.56 (8.76) in the control group, but the difference was not significant ($t = 0.75$, $p = 0.46$). Pairwise comparisons was not significant between three time points in the control group ($F = 0.17$, $p = 0.985$), but there was a significant difference between three time points in the intervention group ($F = 3.25$, $p < 0.001$) implying that the burden of care before the intervention was higher than those of right after ($t = -9.58$, $p < 0.001$) 95%CI:[−21.43,−13.98] and 1 month after the intervention ($t = -9.13$, $p < 0.001$ 95%CI:[−29.49,−18.88]. However, the results of ANCOVA repeated measure showed a significant difference between the intervention and control group regarding the scores of burden of care immediately and 1 month after the intervention ($F = 15.23$, $p < 0.001$) [Tables 2 and 3]. The results of ANCOVA repeated measure showed a significant difference in care after intervention through controlling the confounding factors (age, sex, care length, income level,

and baseline care burden values before intervention).The effect of time was significant within groups.

Discussion

Care burden is an issue making trouble for both the patients and their families. It leads to numerous physical and psychological sings, which are often ignored as care burden has a hidden nature.[4] The present study aimed to the effect of CBT on the burden in drug dependent caregivers. With regard to the results, burden mean scores showed no significant difference between intervention and control groups before intervention, whereas their values were less immediately after and 1 month after intervention in intervention group, compared to control, and showed a gradual decrease through time. These findings have been supported by those of other studies. A study, conducted to evaluate the effect of anger management group education from the Patrick Reilly's CBT approach, indicated that the group who received intervention had a significant decrease in the level of aggression and developed health promotion among patients abusing substances, compared to the control group.[13] In addition, the results of another study, aiming to evaluate the CBT group approaching on reducing self-stigma for people with mental illness, showed that CBT could be an effective and efficient clinical method to reduce the self-stigma and depressive mood.[14] In addition, there was another study, aiming to evaluate the effectiveness of the CBT on dementia patients' caregiver with an approach on the intervention group participating in the ''Coping with Frustration'' class (this course is a cognitive–behavioral intervention program developed by Gallagher-Thompson and is from a cognitive–behavioral model for the management of frustration and anger). It showed that CBT could be an effective and efficient clinical method to reduce the depression and caring burden and improve satisfaction with life.[21] The results of a study revealed that educating non-professional caregivers with a brief CBT from the problem-solving model of depression could be effective on reduction of depression and caring burden.[22] However, the results of a research on the efficacy of short term strategic family therapy model on interactions of the family members with an addicted child in which subjects were randomly divided into three groups of methadone maintenance treatment (MMT), brief strategic family therapy (BSFT), and transtheoretical model (TTM) providing a CBT, reported that BSFT was more effective on the reduction of family bizarre interactions and the number of relapses, compared to TTM. This issue can be owing to TTM emphasis on the disease of the involved individual and ignoring inefficient interactional model concerning addiction in the family. However, TTM was more effective on familial relations and reduction of relapses, compared to MMT that is merely from medication therapy and ignores interpersonal relations of the drug dependent persons.[23]

Therefore, according to the results of the present study, CBT sessions can educate the caregivers about the cognitive

Table 1:Demographic variables of the participants (*n*=64)

Variables	Intervention (*n*=32) Mean (SD)	Control (*n*=32) Mean (SD)	*p*
Age (years)	42.53 (11.10)	43.31 (10.72)	0.78*
Length of care (years)	5.10 (2.40)	7.04 (1.80)	0.31*
Gender%			
Female	26 (81.25)	25 (78.12)	0.80**
Male	6 (18.75)	7 (21.87)	
Occupation status%			
Working	12 (37.50)	12 (37.50)	0.88**
Homemaker	17 (53.12)	17 (53.12)	
Retired	3 (9.37)	3 (9.37)	
Marital status%			
Single	3 (9.37)	2 (6.25)	
Married	27 (84.37)	25 (78.12)	0.16**
Divorced	1 (3.12)	3 (9.37)	
Widowed	1 (3.12)	2 (6.25)	
Educational level%			
University	5 (15.62)	4 (12.50)	0.92**
High school Diploma	27 (84.37)	28 (87.50)`	
Relationship with the patient%			
Father	2 (6.25)	3 (9.37)	0.86**
Mother	13 (40.62)	15 (46)	
Sister	1 (3.12)	3 (9.37)	
Brother	3 (9.37)	2 (6.25)	
Children	2 (6.25)	9 (28.12)	
Wife	11 (34.37)		
Income%			
Less than needed	20 (62.50)	18 (56.25)	0.86**
Equal to needed	9 (28.12)	11 (34.37)	
More than needed	3 (9.37)	3 (9.37)	

*Independent *t* test, **Chi-square test

Table 2: Comparison of the mean changes in burden at baseline, immediately after and 1 month after the intervention in the intervention and control group

Variable	Time	Intervention	Control	Between group		Within group	
		Mean (SD)	Mean (SD)	F*(df**)	*p*	F (df)	*p*
Burden	Baseline	55.43 (11.19)	53.56 (8.76)	*F* (1,56)=15.23	<0.001	*F* (1,56)=260.80	<0.001
	Immediately after intervention	34.43 (10.53)	53.50 (8.55)				
	1 month after intervention	28.25 (7.61)	54.34 (8.20)				

*ANCOVA repeated measure, **degrees of freedom

Table 3: Comparison of the mean scores of changes in caregivers' burden in intervention group immediately after and 1month after intervention, compared to control group

Variable	Time	Group	B (SE)	*t*	*p**	95%CI
Burden	Immediately after intervention	Intervention	−17.68 (1.84)	−9.58	<0.001	[−21.38;−13.98]
		Control	Reference			
	1 month later	Intervention	−24.18 (2.65)	−9.13	<0.001	[−29.49;−18.88]
		Control	Reference			

ANCOVA repeated measure* (with control of age, sex, care length, income level, and base line care burden values before intervention)

distortions and negative automatic thoughts and strategies so as to encounter these thoughts, and consequently, learn that by using these strategies at different life situations, they could feel more relaxed. Therefore, with regard to the effects of these thoughts in creating social isolation, hopelessness, depression, anxiety, and low self-esteem in caregivers, and consequently, increased level of the burden in caregivers, this therapy was able to reduce the caregivers' burden. The strength of this study was conducting the intervention to reduce families' care burden to achieve a healthy community. The CBT, applied in the present study, was according to a strong theoretical framework. In addition, the intervention program, the assigned homework in each session, letting the caregivers give feedbacks, in addition to conducting the intervention at home were among other strength points of this study. One of the limitations of the present study was its short follow-up period after the intervention. With regard to the fact that the expression of experiences and feelings acted as a placebo in control group, there was no chance to hold more than three sessions in this group. Therefore, inequality of session numbers in intervention and control groups can be considered as a limitation of this study. In addition, due to lack of random access, the sampling method had to be convenience sampling from the inclusion criteria, and this was another limitation of this study. We restricted the effect of these limitations by allocating the caregivers randomly to the control and intervention groups.

Conclusion

The findings of this study show CBT can lead to reduction of burden in drug dependent caregivers'. Therefore, planning and provision of such psychiatric services among caregivers of the chronic diseases as a vulnerable group are essential in mental health provision services. In addition, considering the results of this study, we suggest encouraging nurses to establish educational programs such as CBT to maintain and improve caregiver's mental health.

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Conflicts of interest

Nothing to declare.

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