Original Article

Effectiveness of Cognitive-Behavioral Therapy on Improving Mental Health and Quality of Life of Spouses of Patients under Methadone Maintenance Treatment, a Double-Blind Randomized Clinical Trial

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Abstract

Introduction: Drug abuse by a family member is associated with adverse psychological consequences for other family members. Existing literature indicates the effectiveness of cognitive-behavioral therapy (CBT) on the psychological components of addiction. This study was conducted to evaluate the effectiveness of CBT on improving mental health and quality of life (QOL) of the addicted spouses.

Methods: In a double-blind randomized clinical trial, 30 patients under methadone maintenance treatment (MMT) were selected through respondent-driven sampling (RDS) and randomly assigned into experimental and control groups by block randomization. CBT was presented to the experimental group in the form of a classic protocol in eight weekly sessions and the control group was merely received routine treatments of the center. Data were collected by two mental health and QOL questionnaires. The collected data was analyzed using covariance analysis.

Results: The outcomes showed that the mental health index was significantly improved in the experimental group. Also, the secondary outcomes showed an increase in the scores of QOL (all p's<0.000).

Conclusion: CBT counselling is effective in Improving Mental Health and QOL of spouses of patients opiate-dependent patients in MMT. This findings can be used in designing of treatment interventions in the field of addiction. However, further studies are needed in this regard.

Introduction

Addiction is a chronic and recurrent disease, which various psychological, social and environmental factors are contributing in its emergence and continuity (1). Addiction is considered as one of the most harmful phenomena that have been associated with damages in recent decades, not only in Iran but also in most countries of the world (2).

Opioids are widely used around the world. The findings show that the use of opioids in the United States has quadrupled between 1999 and 2014 (3).

The statistics of the United Nations Office on Drugs and Crime (UNODC) shows that the

number of opioid users was approximately 500,000 people in 1996. This figure reached to 710,000 addicts in 1998 and reached 3,761,000 people in 2001 (3). In Iran, substance users are estimated to be between 1.8 and 3.3 million people, most of them being opioid users (4). Studies have shown that chronic drug abuse is associated with psychological and behavioral damages (5). The extent of the damages caused by the drug abuse affects the endocrine functions, and this process can affect all cognitive actions (6). In recent years, the necessity of designing therapeutic strategies in opioid dependent individuals has been proposed more (7).

On the other hand, in a systematic look, studies show that spouses of drug users are more prone to mental illness (8). Approximately 10 million people in Iran are directly or indirectly involved with the problem of addiction, if the communication circle of each person dependent on drug is considered as 5 people (fathers, mothers, siblings, spouses and children) (9). New research suggests that the complications of drug abuse affect people who are directly in contact with these people, and most likely, the wives and children of the addicted people are at risk of injury (10). Intergenerational transmission of risk factors may reflect the genetic factors that have emerged in the form of educational components and encourage addictive behavior (9).

Drug abuse by one member of the family affects the mental health and quality of life of people around them, especially their wives. The World Health Organization considers quality of life as an individual's perception of the cultural status and value system in relation to goals, expectations, criteria and affairs (11). Quality of life (QOL) is a broad-based concept that encompasses physical, mental, social and environmental dimensions (11). Studies show that drug abuse is associated with a decline in the quality of life in consumers (12).

On the other hand, mental health can be defined on the basis of well-being. Therefore, mental health is not only a lack of mental illness, but also refers to a level of performance that a person is comfortable with himself/herself and easy to live with and there

is not any problem (13). In the past decades, mental health has been replaced by more comprehensive features that directly concern public health (13). The components of mental health include emotional well-being, quality of life, and psychological and social well-being. Addiction disorders are one of the major factors in causing damages to the mental health of the patient. These damages can emerge in two dimensions of internalized and extracted disorders (14).

Today, the use of psychological interventions in the field of drug abuse is considered as an inevitable necessity. Since these interventions help patients avoid slipping or relapse, they are used as primary or complementary therapies (15).

Cognitive-behavioral therapy (CBT) is one of the main psychotherapy methods in the field of addiction. CBT is used in a wide range of addictive disorders (16). Research has shown that the use of CBT has been associated with improving the quality of life of patients (17). Also, the results of the study by Lee et al. (18) show that CBT can improve the mental health of patients by reducing basic anxiety.

Given that today the phenomenon of addiction is changing from an individualistic and one-factor framework to ecological and multifactorial approaches, this transformation of the attitude is the bedrock of the emergence of a holistic view that embraces the family (9). Considering the importance of the role of QOL and mental health, and in light of the emergence of new therapeutic approaches and existing research gap in Iran, the present study was conducted aimed to investigate the effectiveness of CBT on improving the mental health and QOL of the spouses of the addicted individuals under methadone treatment.

Methods

The present study was a double-blind randomized clinical trial that was conducted from April to September 2016. In this regard, 30 wives of the patient under methadone maintenance treatment were selected from responders to five addiction treatment centers in Tehran using a respondent-driven sampling (RDS). RDS is a combination of chain sampling and a mathematical model (Markov

chain theory and networks bias) and is being considered today in the world's major health organizations. After a structured clinical interview and obtaining informed consent, they entered the study process and randomly assigned to experiment and control groups through block randomization method. The inclusion criteria were: 1) diagnosis of addiction based on DSM-5 criteria; 2) the age range of 18-60 years in spouses; 3) 2-5 cc methadone daily intake (syrup, Daropakhsh) in men 4) the ability to read and write. The exclusion criteria for mothers and children were: 1) lack of normal intelligence; 2) more than three months of using psychiatric drugs in spouses because of the possibility of affecting the psychological syndrome; and 3) more than 2 sessions of absenteeism in theraputic sessions.

Group therapy was conducted in the form of eight weekly one-hour sessions based on the classic manuel.

Active control groups were only received motivational interview and did not have knowledge of the educational content of the experimental group, and the teacher of the experimental group did not play any role in data analysis. Two indices of quality of life and mental health were evaluated at two intervals of before and after treatment. Data were analyzed using multivariate covariance analysis in SPSS software version 22 (SPSS, Inc., Chicago, IL, USA) and significance was considered as 0.05. All stages of the study were conducted after obtaining informed consent and based on the latest version of the Declaration of Helsinki (DoH). DoH is the World Medical Association's (WMA) best-known policy statement. DoH has developed as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

1. Demographic Checklist: This questionnaire was prepared by the researcher to collect personal information such as age, education, and time of avoidance from drug use.

2. The Structured Clinical Interview for DSM-4 (SCID-4): It is a clinical interview that is used to diagnose axial disorders based on DSM-IV (19). The reliability coefficient for assessors for SCID is reported to be 60% (20). The diagnostic agreement of this instrument in Persian was favorable for most of the specific and general diagnosis with reliability greater than 0.6. Kappa coefficient for all current diagnoses and life expectancy diagnosis was obtained equal to 0.52 and 0.55, respectively (21).

3. The Symptom Checklist-90-R (SCL-90-R): This test consists of 90-item in a 5-point Likert scale. This tool evaluates the 5 dimensions of psychiatric symptoms (physical complaints, obsessive-compulsive disorder, interpersonal sensitivity, depression, anxiety, hostility, aggression, anxiety, paranoid thoughts and psychosis). On this scale, there are 7 additional items that are not classified in any of the abovementioned dimensions and are referred to as others, and the evaluation and scoring of the test are based on 3 general indices. Psychometric properties of mental health questionnaire in Iranian society have been evaluated and the mentioned indices have been reported to be desirable (22).

4. The 36-Item Short Form Health Survey (SF-36): This questionnaire was developed by the International Organization for Quality Assessment of Life (ILO), which includes 36 items in two main physical and mental domains that include eight health-related subscales including physical function, physical pain, general health, Social function, emotional role, physical role, vitality, mental health. The total score of questions is from 0 to 100. The level of quality of life is favorable (between 71 and 100), somewhat favorable (31 to 70) and undesirable (zero to 30). The results of the study by Salim et al. (23), show that the validity and reliability of the tool is acceptable.

Statistical analysis
To analyze the data, the covariance analysis test was used and the effect of pre-test was eliminated. Before applying the parametric test of covariance analysis, its assumptions were examined. The assumption of normal distribution of the data was evaluated by Shapiro–Wilk test ($p < 0.05$). Also, the results of the Leven test indicated the equalization of variances ($p > 0.05$).

Results

In the present study, the majority of participants had an average age of 32.3 + 2.21 years. Also, the level of education of diploma had the highest frequency. The mean of drug abuse was 2.11 years and the mean duration of avoidance from drug abuse was 1.3 years. The mean and standard deviation of scores of the mental health and quality of life for the participants in the study are presented in table 1.

Table 1. Mean and standard deviation of the scores of mental health and QOL

Variable	Index	Experiment		Control	
		Pre-test	Post-test	Pre-test	Post-test
		Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	Physical complaints	25.11 ± 5.29	22.47 ± 5.11	24.79 ± 3.29	24.31 ± 4.82
	Obsessive-compulsive disorder	22.91 ± 4.31	19.61 ± 4.32	23.42 ± 4.15	23.09 ± 4.12
	Interpersonal sensitivity	18.51 ± 3.76	15..3 ± 3.22	19.32 ± 4.08	19.22 ± 4.82
	Depression	29.72 ± 4.39	27.02 ± 3.81	30.42 ± 5.23	29.93 ± 5.42
Mental health	Anxiety	20.93 ± 3.11	17.43 ± 3.52	19.39 ± 3.54	19.32 ± 3.74
	Hostility	13.42 ± 2.31	11.08 ± 2.81	14.37 ± 3.22	13.74 ± 2.93
	Anxiety to *morbidity*	15.52 ± 3.42	12.83 ± 3.09	16.32 ± 4.11	15.97 ± 3.59
	Paranoid thoughts	12.93 ± 2.85	10.08 ± 2.48	12.84 ± 2.64	12.31 ± 2.84
	Psychosis	21.14 ± 3.91	19.74 ± 3.55	20.39 ± 3.71	20.85 ± 4.11
	Physical function	54.11 ± 8.22	57.29 ± 8.91	53.31 ± 7.23	53.78 ± 7.93
	Physical pain	64.73 ± 9.52	67.14 ± 9.88	63.22 ± 7.31	62.88 ± 6.91
Quality of life	General health	63.11 ± 10.52	65.74 ± 9.21	61.37 ± 8.11	62.73 ± 8.29
	Social function	51.27 ± 7.92	53.39 ± 9.11	52.31 ± 7.72	51.83 ± 8.22
	Emotional role	42.38 ± 6.11	45.82 ± 6.91	41.32 ± 5.84	40.79 ± 5.58
	Physical role	52.74 ± 7.09	55.22 ± 8.32	53.29 ± 7.48	52.39 ± 6.51
	Vitality	65.31 ± 9.13	67.72 ± 9.52	64.38 ± 8.79	64.88 ± 8.94
	Mental health	51.12 ± 6.32	53.84 ± 6.93	50.41 ± 6.12	51.48 ± 7.32

As the results of table 1 show, the scores of participants in the study increased in both mental health and QOL in post-test. The covariance analysis was used to determine the changes in the indices. The results of this test are presented in table 2.

Table 2- Multivariate tests in mental health and QOL

Test name	Magnitude	Assumption DF	Error DF	F	Significance level	Eta root
Pillai's trace	0.915	2.00	25	133.7	0.0001	0.915

The results of table 2 indicate a significant difference in the linear composition of mental health and QOL (F = 133, DF = 25, P <0.01). Also, 91 percent of variance of dependent variables is explained by the grouping (test and control) variables. The results of the

effects between subjects are presented in table 3.

Table 3. Effects of the results between the subjects

Source		Sum of squares	DF	Mean of squars	F	Significance	Eta root
Group	Mental health	2139.58	1	2139.58	196.37	0.0001	0.833
	QOL	9480.71	1	9780.1	65.93	0.0001	0.717
Error		283.27	26	10.89			
		3738.76	26	143.79			
		338050.0	30				
Total modified		2442.967	29				
		13570.0	29				

As shown in **table 3**, there is a significant difference between the experimental and control groups in mental health and quality of life scores. The size of modified effect of mental health is 0.83 and QOL is 0.71. It can be acknowledged that cognitive-behavioral therapy has been effective in improving mental health and QOL of addicted wives. Also, the results of three-month follow-up showed that the changes were maintained during the follow-up period (0.05).

Discussion

This study was conducted aimed to evaluate the effectiveness of cognitive-behavioral therapy on improving mental health and QOL of the addicted spouses. The primary outcomes indicated that the mental health index improved significantly after CBT. Secondary outcomes also showed an increase in QOL scores in spouses of patients undergoing methadone treatment. In line with the results of this study, the results of the study by McHugh et al. (24) showed that the use of CBT in drugs use patients is associated with improving psychological indicators, learning strategies, and improvement of motivational components. The results of McKay et al. study (25) can be used to reduce the obsessive-compulsive disorder (OCD) signs. Also, the findings study of Kaczkurkin & Foa (26) was showed that CBT appears to be both efficacious and effective in the treatment of anxiety disorders. Furthermore, the findings study of (27) provide preliminary evidence for the utility of CBT as a feasible treatment for anxiety and comorbid depressive symptoms.

Also, the results of (28) showed that CBT benefits for depression symptoms. Pot-Kolder et al. (29) showed that CBT could reduce paranoid ideation and momentary anxiety in patients with a psychotic disorder.

In this regard, the results of study by Sugarman et al. (30) showed that the use of cognitive-behavioral, computer-based therapy has been associated with improvement of adaptive skills in outpatient patients under addiction treatment. Also, the results of the systematic study of Rice et al. (31) suggest that the use of CBT as a complementary intervention along with treatment with opioid agonists is associated with more favorable therapeutic outcomes. The use of cognitive-behavioral interventions in patients undergoing methadone maintenance therapy has the support of research. In this regard, the results of Pirnia and Pirnia (32) showed that CBT improved mood syndrome. However, patients undergoing methadone maintenance therapy had favorable responses to supplemental or alternative therapies as well (19).

In this regard, the results of the study by Reno and Aiken (33) showed that the QOL after drug abuse treatment (psychological interventions) increased in many areas. For example, the patient experience less physical pain or spends more time with family members. This can have a significant effect on other aspects of a person's life. Also, McHugh et al. (24) showed that cognitive-behavioral

techniques, alone or in combination with medication, play an important role in managing anxiety and depression and intimacy with others, and increase individual satisfaction from their level of life and ultimately general health of the person. The results of the study by Bennebroek Evertsz' (34) showed that CBT is effective in improving QOL and in decreasing anxiety and depression in patients. Also the results of meta-analysis study by Linardon & Brennan (35) showed that CBT led to significant and modest improvements in subjective QOL.

This study was had some limitations during the implementation process. The most important limitation of the present study was the inability to follow-up the results of the treatment. Also, the use of self-reporting tools on specific topics such as addiction can be biased. It is suggested that evaluation of biological indicators along with the questionnaire be used in the future studies. Also, the use of CBT along with opioid antagonist drug treatments can be a good route for future studies. The results of this study can be used in designing of treatment interventions in the field of addiction. However, further studies are needed in this regard.

Conflict of interest
The authors did not report any conflicts of interest.

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