



Efficacy of a Cognitive-Behavioral Relapse Prevention Model in the Treatment of Opioid Dependence in Iran: A Randomized Clinical Trial

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Abstract

Background: Relapse following abstinence from substance use is common. In this study, we evaluated the effectiveness of training, based on a cognitive-behavioral relapse prevention model in individuals with opiate dependence.

Methods: A total of 50 substance abusers were selected via simple random sampling among the clients of Aftab Center, Tehran, Iran for substance dependence treatment. The subjects were randomly divided into 2 groups: routine addiction treatment program and the developed intervention, plus the routine addiction treatment program. All the subjects completed the questionnaire on demographic variables and addiction history, Inventory of drug-taking situations, and drug avoidance self-efficacy scale at baseline and after the intervention. The patients were followed-up for 3 and 6 months after the intervention. ANOVA, Chi square test, and ANCOVA test were performed for data analysis, using SPSS version 19.

Results: In this study, the mean age of the subjects was 38 ± 11.26 years. Based on the results, social pressure was the most frequent high-risk situation, followed by negative emotional and physical states. In the 3-month follow-up, 8% and 24% of the subjects from the intervention and control groups dropped out, respectively. Nevertheless, no significant difference was found between the groups in terms of the dropout rate. At the end of 6 months, 84% and 48% of the subjects from the intervention and control groups showed abstinence from drug use, respectively. The findings indicated a significant difference regarding self-efficacy between the groups ($P < 0.001$).

Conclusions: Design of interventions based on cognitive-behavioral models, which can improve self-efficacy, may be effective in relapse prevention.

Keywords: Cognitive Behavioral Treatment, Opioid Dependence, Relapse Prevention

1. Background

Relapse following abstinence from substance use is common (1). The rate of relapse has been estimated at 80% - 95% following alcohol or tobacco use cessation (2). Therefore, relapse prevention is a fundamental component of addiction treatment (3, 4). Cognitive-behavioral approaches, such as relapse prevention therapy (RPT), have been proposed for the treatment of addictive behaviors, including relapse, and improvement of coping strategies to maintain abstinence (5, 6). In these methods, risk assessment is carried out, and possible environmental, interpersonal, and physiological factors for relapse are determined.

Then, cognitive and behavioral techniques are employed, which integrate both RP interventions (or relapse management) and inclusive strategies to address lifestyle balance, drug cravings, and cognitive distortions, leading

to exposure to high-risk situations for relapse. Identification of high-risk relapse situations and evaluation of coping abilities in face of these situations (without relapse) are the 1st therapeutic steps in RPT. In some coping situations, it is important to determine if lack of knowledge, skills, and other factors, such as motivation, self-efficacy, and anxiety, can produce these situations (7).

Carroll Irving conducted a meta-analysis of 26 studies with 9,504 participants regarding the impact of RPT on smoking, alcohol use, and poly substance/cocaine use. The results of this review presented RPT as an effective intervention in decreasing substance use and promoting psychosocial adaptation. Particularly, RPT was more effective in the treatment of poly substance/alcohol use. Individuals and groups benefit more from RPT treatments, compared to other methods (8).

Based on a study by Momtazi and Rawson, the fre-

quency of opiate use, particularly opium, ranged from 1.2% to 8.6% in different regions of Iran. Overall, according to epidemiological research in national and international journals, substance abuse is a prevalent mental health problem in Iran. Opioid use in Iranian populations is rooted in the dominant culture, as families support tobacco smoking in the form of a water pipe (9). Moreover, the United Nations Office on Drug and Crime reported that 450 metric tons of opium was consumed in Iran in 2010 (10).

2. Objectives

We aimed to design an integrated RPT group program according to Marlatt's RP model (6) of or individuals with opiate dependence in Iran. The efficacy of the developed program for opiate-dependent individuals was investigated in treatment centers of Tehran, Iran, where illegal drug users received treatment and rehabilitation interventions. Such studies can provide a practical and theoretical framework for implementing long-term psychological treatments for drug use and reducing psychological, social, and physical consequences of drug problems in Iran.

3. Methods

3.1. Design

In this randomized trial, the routine addiction treatment program was compared with the developed program, comprised of an RPT intervention based on the Marlatt's model, besides the routine program (1, 2). The participants were assessed at baseline, after the intervention, and 6 months following discharge from the center.

3.2. Participants

The information of drug users in Aftab center for addiction treatment and rehabilitation was used for selecting the samples (n, 50) during 2012 - 2013.

The sample size was calculated based on the following formula with considering 75% of relapse (11):

$$n = 2 \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta} \right)^2 \overline{pq}}{(P_1 - P_2)^2} \quad (1)$$

P = 35%, $\alpha = 0.05$, Power = 80%, N = 25.

The inclusion criteria were as follows: 1) dependence on 1 type of opiate substance based on the DSM-IV criteria; 2) abstinence from drug use for 2 weeks based on the urine opiate test; and 3) giving a consent form. On the other hand, serious mental and physical diseases were the exclusion criteria. Simple random sampling was used to

classify the subjects into 2 groups: routine addiction treatment program (2) and RPT program plus the routine addiction treatment program; each group comprised of 25 participants. Random allocation in this study comprised the following steps:

1. Providing a list of subjects' names
2. Assigning each subject to a number
3. Luring all numbers in a box
4. The head of center starting to draw a number randomly
5. The first number allocated to the intervention group and the other one to the control group.

This study was blind to the researcher and subjects; all the steps have been done by the head of center.

3.3. Measurements

3.3.1. Drug History

A questionnaire on drug history was developed, consisting of demographic information, treatment history, drug history, and some addiction-related psychosocial factors.

3.3.2. Inventory of Drug-Taking Situations (IDTS)

IDTS, which is a self-report scale with 50 items, presents a profile of high-risk situations by evaluating contexts where one has experienced heavy drug or alcohol use over the last year. In this scale, the RPT classification system consists of 8 classes of high-risk situations, as discussed by Annis, Turnerand, and Sklarin (1997) (12).

3.3.3. Drug Avoidance Self-Efficacy Scale (DASES)

DASES (13), a 16-item self-report scale, was developed to examine self-efficacy, which is described as one's confidence in his/her coping abilities in face of risky situations without drugs. For every item, the person imagines him/herself in a certain situation and rates his/her self-efficacy to refrain from drugs. Every item indicates a situation where one may feel inclined to use drugs. Responses are graded on a 7-point scale, ranging from "certainly yes" to "certainly no". The total score is the sum of scores of all items, indicating the level of self-efficacy.

The study instruments were assessed by 5 specialists (psychologist) content validity after forwards- backwards translation and alpha cronbach was computed for each instruments due to reliability. It was 0.75 and 0.79 for the IDTS and DASES, respectively.

3.3.4. Procedures

The subjects were given questionnaires after obtaining the informed consents. The subjects in the intervention group received 14 weekly skill training sessions, which

helped them reduce drug use. The sessions were held by a psychiatrist and a psychologist. The RPT program based on Marlatt's model included 12 sessions, focused on identifying high-risk relapse situations, self-efficacy improvement, coping strategies, relapse management, and relapse prevention.

During the training sessions, the participants were assisted to identify the possibility of relapse, identify high-risk situations, and control them. The program also focused on increasing awareness regarding emotional, cognitive, and behavioral responses to prevent relapse. Identification of situations associated with drug craving is one of the examples. Moreover, recognition of high-risk relapse situations, behavioral analysis of relapse, use of role-play (for skill development and prevention of high-risk relapse situations), and alternative behaviors to prevent relapse in high-risk situations were incorporated.

The 1st and 2nd sessions included a motivational interview to reduce substance use. The subsequent 12 sessions focused on relapse prevention and cognitive-behavioral coping strategies. In the 3rd session, assistance was provided for the participants to identify risky situations for substance use. In the 4th session, a coping drill was presented with role-play in risky situations. In the 5th session, positive expectancies regarding drug use were examined, and the participants were taught how to overcome social, environmental, and personal problems. The 6th and 7th sessions focused on drug craving by imagining situations where the subject smelled or looked at drugs and then learned to cope with the situation through self-talk and muscle relaxation techniques.

The 8th and 9th sessions emphasized on communication skills in interpersonal relationships and encouraged behavioral techniques and saying "no". In the 10th session, different problem solving and coping strategies in emotional situations were emphasized. The objective of the 11th session was to distinguish anger and its signs and employ anger management. The next session was about relaxation and its different types.

Routine addiction program included giving the Methadone to the client and private consultation regarding addiction complications by psychologist.

All the participants completed IDTS and DASES after the intervention, as well as 3 and 6 months after the intervention. The 1st 2 sessions were approximately 90 minutes, while the other sessions were scheduled for about 60 minutes (Figure 1).

3.3.5. Follow-Up

All the subjects completed the questionnaires at baseline and after the intervention. They were followed-up for

relapse at 3 and 6 months after the intervention. We also interviewed the families to collect reliable information and social support. The subjects who claimed to have abstained from drug use were administered a urine test to confirm their reports. The Ethics Committee of Tehran University of Medical Sciences approved this study. The study goals and methods were explained to the participants before the study. Participation was voluntary in this study. If the samples were willing to cooperate, a consent form was obtained.

3.3.6. Data Analysis

For analyzing the data, descriptive and analytical statistics were measured. ANOVA and Chi square tests (if appropriate) were performed to compare the subjects' characteristics between the groups. For evaluating responses to interventions, changes in self-efficacy from baseline to week 4 were examined (positive values showing an increase in self-efficacy assessment). ANCOVA test was applied to control self-efficacy-related factors, including sex, age, occupational status, marital status, educational level, age at first drug use, duration of substance use, and drug treatments. The assumptions of ANCOVA (normality, homogeneity of variance and random independent samples) were checked.

4. Results

The study sample consisted of 50 substance abusers, referred to Aftab center for addiction treatment and rehabilitation. The mean age of the subjects was 38 ± 11.26 years, and the average education was 3.12 years. In total, 12% of the participants were unemployed. The average drug-use history was 10.84 years in the subjects. In addition, the average age of the participants at first drug use was 27.84 years. Most subjects had received several drug treatments (2.92 ± 3.87 times), and the longest abstinence time was 31.84 ± 13.12 days, 23 individuals (92%) in each group were male (Table 1). Based on the study results, social pressure was the most frequent risky situation, followed by negative emotional and physical states and curiosity (Table 2).

4.1. Relapse in Follow-Up

In the 3-month follow-up, 2 (8%) and 6 (24%) subjects from the intervention and control groups dropped out of the study, respectively. No significant difference was found in the dropout rate between the groups ($P = 0.34$). In the 6-month follow-up, 21 (84%) and 12 (48%) subjects from the intervention and control groups showed abstinence, respectively, as confirmed by the negative results on the urine test. The control group had a higher relapse rate, compared to the intervention group ($X^2 = 7.219$; $P = 0.007$).

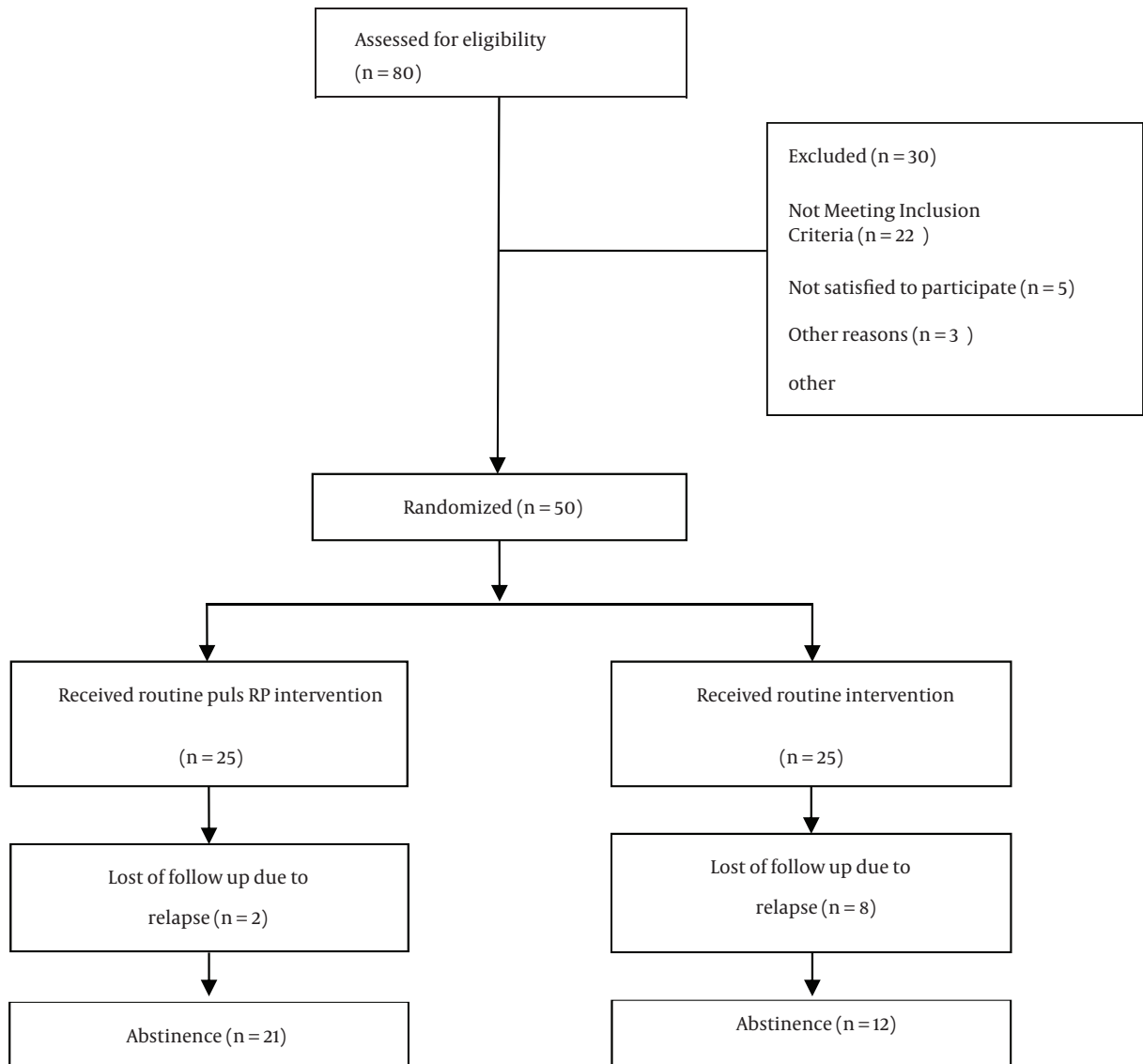


Figure 1. Study Flow Chart

Further data analysis and covariate assessment presented a significant difference between the groups regarding relapse and self-efficacy (Tables 3 and 4).

5. Discussion

In this study, it was assumed that RPT, as a cognitive-behavioral treatment, focuses on post treatment care. This treatment includes the assessment of environmental, interpersonal, and emotional states, which promote risky situations, and improvement of self-efficacy using appropri-

ate coping skills. This model (Marlatt's model) has been supported theoretically and practically in other studies (14, 15). For example, due to Pashaei and colleagues regarding the efficacy of the intervention based on Marlatt model, in Opioid-dependent patients, this model has an effective role in decreasing relapse rate (14). Based on the Witkiewitz and Marlatt overview of the efficacy and effectiveness of relapse prevention based on Marlatt's model in the treatment of addictive disorders, there is empirical support for the elements of the model of relapse (15).

In this study, the aim was to evaluate the RP model in

Table 1. The Characteristics of Study Sample (n = 50)^a

	Intervention (n = 25)	Control (n = 25)	P Value*
Age	34.53 ± 11.15	37.40 ± 9.66	0.33
20 - 29	10 (40)	4 (16)	
30 - 39	8 (32)	12 (48)	
40 - 49	5 (20)	5 (20)	
> 50	2 (8)	4 (16)	
Education			0.36
Illiterate	19	16	
literate	6	9	
Marital status			0.07
Married	20 (80)	14 (56)	
Single/Widowed/divorced	5 (20)	11 (44)	
Employment status			0.58
Employed	13 (52)	11 (44)	
Unemployed	12 (48)	14 (56)	
First drug use age	28.8 ± 9.59	30 ± 11.10	0.68
< 20 - 30	16 (64)	13 (52)	
30 - 40	5 (20)	8 (32)	
> 40	4 (16)	4 (16)	
Duration of Substance use, y	5.52 ± 3.63	5.92 ± 2.96	0.67
< 5	12 (48)	10 (40)	
> 5	13 (52)	15 (60)	
Drug treatment histories, times	2.12 ± 1.13	3 ± 2.72	0.14
< 3	9 (36)	10 (40)	
> 3	16 (64)	15 (60)	

^aValues are expressed as mean ± SD or No. (%).

individuals with opioid dependence. The results showed that training, based on the model, had significant effects on self-efficacy in opiate-dependent individuals. According to a review study, self-efficacy is one of the most consistent predictors, used in alcohol use interventions (16). Based on the literature, self-efficacy was majorly associated with addiction relapse (17). Consistent with the present findings, Dolan, Martin, and Rohsenow (2008) reported improved self-efficacy, leading to a lower rate of drug use after 3 months of intervention; however, unlike our study, this finding was not confirmed at 6 months after the intervention (18). Due to Taghizadeh and Cherati (2015), there is significant relationship between self-efficacy and relapse

Table 2. High Risk Situation from Participant's Point of Views^a

	First Priority	Second Priority	Third Priority
Negative Emotional States	9 (18)	8 (16)	3 (6)
Somatic disorder	9 (18)	2 (4)	8 (16)
Positive emotion	1 (2)	3 (6)	4 (8)
Self control	-	2 (4)	2 (4)
temptation	1 (2)	5 (10)	-
Social pressure	12 (24)	15 (30)	8 (16)
Fun	4 (8)	11 (22)	5 (10)
Loneliness	-	-	1 (2)
Social conflict	3 (6)	3 (6)	-
Curiosity	7 (14)	-	17 (34)
Early Ejaculation	3 (6)	-	-
Sleep Avoidance	1 (2)	-	-
Not Mention	-	1 (2)	2 (4)
Total	50 (100)	50 (100)	50 (100)

^aValues are expressed as No. (%).

(19).

Another study from Iran (2014) also showed that individuals with higher self-efficacy could cope with abstinence for longer periods in comparison with addicts with low self-efficacy (20). According to a study by Nikmanesh (2016), non-relapse individuals showed higher self-efficacy and had better social support in comparison with those with relapse. In addition, the eta-squared statistics revealed that social support of 0.22 and self-efficacy of 0.17 could predict addiction relapse (21). However, in a study by Burling et al., no significant association was found between self-efficacy and abstinence from drug use; also, specific situations may present affirmative results in individuals with low self-efficacy (22).

According to a meta-analysis of self-efficacy and smoking interventions, evaluation of self-efficacy following abstinence and its association with abstinence depend on the study population and time of self-efficacy evaluation (23). In our study, self-efficacy was assessed several times (baseline, 3 months after the intervention, and 6 months after the intervention). The results indicated that integration of RP programs into routine interventions of healthcare centers could produce better results in comparison with the routine programs alone; moreover, it was effective in reducing the relapse rates (52% vs. 16%). Kelly and Daley (2013) also indicated treatment improvement (24).

In the present study, application of routine treatment programs plus RP interventions could lead to efficient

Table 3. Comparison of Self Efficacy Between Two Groups^a

	Before		P Value	After		P Value
	Intervention Group	Control Group		Intervention Group	Control Group	
SE	36.35 (6.46)	38.64 (6.70)	0.219	52.65 (7.19)	40 (6.49)	< 0.001

^aValues are expressed as mean (SD).

Table 4. Analysis of Covariance of SE and Relapse

Source of Variance	Type III Sum of Square	df	Mean Square	F	Sig
Intercept	272.229	1	272.229	14.800	0.000
Group	2541.960	1	2541.960	138.196	0.000
Pretest	909.378	1	909.378	49.439	0.000
Age	11.115	1	11.115	0.604	0.441
Occupation	98.409	1	98.409	5.350	0.026
First drug use age	42.805	1	42.805	2.327	0.134
Duration of Substance use	121.699	1	121.699	6.616	0.014
Drug treatment histories	19.702	1	19.702	1.071	0.306
Error	790.939	43	18.394		

treatment and enhance treatment efficacy. In some previous studies, the majority of the subjects showed relapse during 6 months (80%) (25), and the relapse rate was higher in females, compared to males (26). In our study, the relapse rate was 52% for 6 months, and no significant difference was found between females and males in terms of relapse rate, considering the small size of female population in the study.

In the present study, most subjects were males and 20 - 29 years old. The majority of the participants were illiterate, married, and unemployed, while another study from India (27) showed that 10.2%, 40.8%, and 10.9% of the addicts were illiterate, unmarried, and unemployed, respectively. Based on the results, most abusers had experienced their first drug use at the age of < 30 years. In a study by Sau et al. (27), the majority of the abusers initiated drug use at the age of 18 - 25 years. Therefore, we should focus on these age groups for planning prevention programs.

Based on the results, social pressure was the most frequent risky situation, followed by negative, physical, and emotional states as well as curiosity. In a study by Sau et al. the most frequent trigger was social pressure, followed by curiosity. Overall, use of opiate in the treatment of negative physical state has a long history in Iranian culture and dates back to the era of Avicenna. Today, opiate use is common in small towns and villages for alleviating pain.

In a study by Dennhardt and Murphy (2011), alcohol use and depression were examined in college students, and

depression was found to cause an increase in alcohol use problems (28). Accordingly, policymakers should pay attention to these factors in their programs. It seems that insufficiency of entertainment facilities for young people is the main factor in this area.

The present study had some limitations. The majority of the participants were males, and the sample size was relatively limited. Moreover, the duration of RP program and follow-up was relatively short. In addition, due to budget restrictions, post treatment support was inadequate, which might be the reason why the rate of short-term relapse was higher than our expectations. Overall, further research on improved RP programs is recommended among males and females.

5.1. Conclusions

The present findings indicated that RPT could reduce the rate of relapse among opioid abusers. To help addicts remain abstinent, this study advocates self-efficacy improvement. Finally, RPT can be regarded as a complementary treatment in opioid addicts.

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Footnote

Authors' Contribution: Leili Salehi designed and conducted the study and prepared the draft of the manuscript. Leila Alizadeh performed the data analysis.

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