Original article / *Araştırma*

Lapse and craving prevention in methadone maintenance treatment, applying continuous care model: a randomized clinical trial

Moloud RADFAR,[1] Haleh GHAVAMI,[2] Javad NAMAZPOOR,[3] Hamid Reza KHALKHALI[4]

ABSTRACT

Objective: *Although, the lapse and relapse are synonymous with the return to substance use disorder but they have different meanings. Lapse is suddenly return to substance use but relapse is reuse of substance after substance use quitting. Lapse does not have to lead to relapse. Lapse is one of the major challenges in methadone maintenance treatment (MMT). Lapse is the stage that occurs before relapse. Craving is the most important factor for lapse after the treatment periods, too. The aim of this study was to determine the effectiveness of applying continuous care model on lapse and craving prevention in patients on MMT.* ***Methods:*** *This parallel randomized controlled trial was conducted on 95 patients who were selected through the convenience sampling and randomly assigned to intervention (n=48) and control (n=47) groups. Continuous care model which consisted of four stages (orientation, sensitization, control and evaluation) was conducted on intervention group over a period of 3 months. At the end, two groups were compared. Craving Questionnaire and Lapse-and-Absence Check List were used to collect data.* ***Results:*** *At the end of third month, the mean of the lapse in the experimental group decreased to 1.57±1.1 times (from 2.07±0.89 times) and the mean of craving score decreased to 50.47±15.1 (from 53.73±13.58) that showed a significant difference comparing to the control group.* ***Discussion:*** *Continuous care model is effective to reduce lapse and craving in male patients on MMT. Therefore, it is suggested that this model should be implemented along with a medical treatment to prevent lapse and craving in male substance abuse disorder.* ***(Anatolian Journal of Psychiatry 2019; 20(2):117-124)***

Keywords: *continuous care model, craving, lapse, methadone maintenance treatment*

Metadon sürdürüm tedavisinde, sürekli bakım modeli uygulanarak lapse ve aşermeyi önleme: Bir randomize klinik çalışma

ÖZ

Amaç: *Tekrar madde kullanımı (lapse) ve depreşme (relapse), madde kullanım bozukluğuna geri dönüş ile eş anlamlı olmakla birlikte, farklı anlamlar taşır. Lapse aniden madde kullanımına geri dönmektir, ancak depreşme madde kullanımını bıraktıktan sonra madde kullanımının tekrarlanması anlamına gelir. Lapse, her zaman depreşmeye yol açmaz, ancak metadon sürdürüm tedavisindeki (MST) başlıca zorluklardan biridir. Lapse, depreşmeden önceki aşamadır. Ayrıca madde aşermesi, tedavi dönemlerinden sonra lapse için en önemli etkendir. Bu çalışmanın amacı, MST hastalarında sürekli bakım modeli uygulamasının lapse ve aşermeyi önlemeye etkisini belirlemektir.*

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[1] PhD Assoc. Prof.; [2] PhD, Assist. Prof.; [3] MSc Nursing and Midwifery Faculty of Urmia University of Medical Sciences, Urmia, Iran

[4] PhD Assoc. Prof., Patient Safety Research Center, Department of Biostatistics and Epidemiology, Urmia University of Medical Sciences, Urmia, Iran

Correspondence address / *Yazışma adresi:*
Assist. Prof. Haleh GHAVAMI, Nursing and Midwifery Faculty-Pardis Nazlou, 11 km of Nazlou Road, Urmia, Iran
E-mail: haleh_ghavami@yahoo.co.uk

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Yöntem: *Bu paralel randomize kontrollü çalışma, uygun örnekleme ve rastgele seçilerek müdahale (s=48) ve kontrol (s=47) gruplarına randomize olarak atanan, toplam 95 hasta üzerinde gerçekleştirildi. Üç aylık süre boyunca müdahale grubunda dört aşamadan (oryantasyon, duyarlılık, kontrol ve değerlendirme) oluşan sürekli bakım modeli uygulandı. Araştırmanın sonunda iki grup karşılaştırıldı. Veri toplanmasında Madde Aşerme Ölçeği, Lapse ve Ayıklık Kontrol Listesi kullanıldı.* ***Bulgular:*** *Üçüncü ayın sonunda, deney grubundaki lapse ortalaması 2.07±0.89 kezden 1.57±1.1 keze düştü. Aşerme puan ortalaması 53.73±13.58'den 50.47±15.1'e düştü. Müdahale ve kontrol grubu arasındaki fark istatistiksel yönden anlamlı bulundu.* ***Tartışma:*** *Sürekli bakım modeli, MST hastalarında lapse ve aşermeyi azaltmada etkilidir. Bu nedenle, tekrar madde kullanımını ve aşermeyi önlemek için bu modelin tıbbi tedavi ile birlikte uygulanması önerilmektedir.* ***(Anadolu Psikiyatri Derg 2019; 20(2):117-124)***

Anahtar sözcükler: *Sürekli bakım modeli, aşerme, lapse, metadon sürdürüm tedavisi*

INTRODUCTION

Substance use disorder (SUD) is a worldwide problem which has been a source of concern to many human societies and its prevalence is increasing rapidly in the world.[1-5] SUD not only affects physical, emotional and social aspects of patient, but also can lead to psychosocial problems in their community and families.[6] The United Nations Office on Drugs and Crime (UNODC) reported in 2016, 247 million people used substance in one year ago that 29 million are in serious condition.[7] In many countries, the opioid agonists, buprenorphine and methadone, are licensed for maintenance treatment of opioid dependence.[8] Methadone stops opioid receptors and thereby prevents withdrawal symptoms and reduce craving for use and so becomes effective in the treatment of addiction.[9] Despite the effectiveness MMT, some patients experienced several lapses and relapse.[10] Most of the patients who are under treatment, trends again for substance use disorder during the 90 days after treatment.[11]

Although, the lapse and relapse are synonymous with the return to substance use disorder but they have different meanings. Lapse is suddenly return to substance use but relapse is reuse of substances after substance use quit. Lapse does not have to lead to relapse.[12] Lapse is one of the major challenges in MMT and it is the stage that occurs before relapse. Lapse means one positive test or absence in rehabilitation center for less than a week and relapse defined by two consecutive positive tests during two weeks or absence in rehabilitation center for more than one week.[13] Since the lapse causes several problems such as continuing high risk behaviors, transmission of infection to the general population, intoxication, contacting with substance sellers, no adherence to treatment and no achievement of treatment goals, it is necessary to pay attention to lapse prevention by supportive, psychological and social interventions.[14] One of the most important causes of lapse is craving or a strong psychological need to use the substance.[12] Craving is a persistent and strong desire for substance use[15] which is the most important factor in returning to substance use disorder after the treatment period and also known as the main cause of substance dependence.[16] Craving can be considered as a cause of mental and physical withdrawal symptoms.[17] Without complementary and psychosocial interventions, drug maintenance treatments have poor effectiveness.[18] The best treatment outcomes are achieved when the drug maintenance treatment is combined with psychosocial interventions.[13]

Continuous care model (CCM) is a supportive intervention which was designed and implemented by Ahmadi for managing patients with chronic coronary artery disease in Iran. CCM considers the client as an active and effective factor in the continuous care and health process.[19] CCM is a regular process for effective, interactive, and consistent communication between clients and care facilitators in order to identify the needs and problems of clients and it can help them in maintain, improve and promote their health.[20] The main purpose of CCM is to design and provide a plan that facilitates acceptance, heightened insight, and appropriate behavior, as well as control of the underlying disease and its complications.[21] CCM includes four stages of orientation, sensitization, control, and evaluation.[22] Several studies conducted on applying CCM in chronic and recurrent diseases such as diabetes,[20,23] heart failure,[24] obstructive bronchiolitis,[25] schizophrenia,[26] hemodialysis[27,28] in Iran. They showed that applying of CCM had a significant impact on quality of life and prevention of recurrence of disease in these mentioned studies. Regarding above-mentioned outcomes of CCM, and considering substance use disorder as a chronic disease we aimed to evaluate the effect of this model in patients on methadone maintenance treatment.

As craving is the most important cause of lapse

and relapse and they are the main challenges in MMT, the aim of this study was to determine the effectiveness of applying continuous care model on lapse and craving prevention in patients on methadone maintenance treatment.

METHODS

Design and ethical approval

This study is a randomized clinical trial (IRCT2016042816564N6). The hypothesis of this study was: participation in the intervention group can significantly prevent laps and craving in patients on MMT. The Ethics Committee of Urmia University of Medical Sciences approved the study proposal (Reference no: IR.umsu.rec.1395.95). Written informed consent was obtained from each participant before the study.

Participants

Participants were selected from male patients who were on methadone maintenance treatment (MMT) referred to rehabilitation unit of the Razi Psychiatric Treatment-Educational Center of Urmia. Inclusion criteria for this study were: the age range between 18-48, having substance use disorder according to psychiatrist diagnosis, having methadone maintenance treatment for at least three months and residence in Urmia. Exclusion criteria included; having other mental disorders during treatment that requires hospitalization, taking antipsychotics and antiepileptic drugs and clients who were unable or *unwilling* to attend in continuous care counseling sessions.

At first, 212 active cases in the rehabilitation unit of Razi Treatment-Educational Center were assessed, of which 117 cases were excluded because, they did not meet inclusion criteria and sample size was 95. These 95 sample were randomly assigned into two groups; control and intervention group, using sealed envelopes. During this study, some of samples refused to participate in study. Therefore, the number of participants in each group fell to 42.

Measures

Data collection tools were Craving after Substance Use Quit Questionnaire, and Lapse and Absence Check Lists. *Craving After Substance Use Quit Questionnaire* was made by Salehi, Barrafan and Ziaee in Iran.[29] This is Likert scale consisting of 20 items that assess thoughts and feelings about the substance and drug craving that was experienced after substance use quit. The item responses domain from 5 ‘not at all correct’ to 0 ‘perfectly correct’, with a total possible score of 0-100. A score lower than 40 shows low craving, between 40 and 60 shows a modest craving and above 60 shows, a high craving.[29] This instrument has an internal consistency of Cronbach's alpha equal to 0.94. The validity of the questionnaire was demonstrated by the criterion method.[29]

The ‘Lapse and Absence Check List’ measured the number of lapses based on the positive urine test and the number of absences recorded in the rehabilitation center. Urine test was done for all patients weekly during the study. Lapse average was calculated in two periods, first time was three months before the intervention, and the second time was three months after beginning of Continuous Care Model. This checklist has been adjusted based on the definition of Methadone Drug Dependence Treatment Protocol[13] and is approved by psychiatrists and specialists.

Intervention

The CCM was implemented on the intervention group individually and face-to-face during 3 months. Forty-seven people received continuous care consultations every day, depending on the model steps and the number of clients. All sessions were held in a room at the center. Interviewer was a master's psychiatric nursing student who passed clinical mental health counseling and patient education courses before this study.

CCM was implemented in four steps:

1. Orientation: The goal of this step is introducing the client and nurse with each other, explanation the stages of the model, creating motivation about the necessity of continuing their participation, explaining the goals and manner of the implementation of CCM and the time and place of the next meetings. This step was carried out during one session lasted about 20-40 minutes. This session was held for both intervention and control groups but it differed in terms of time and type of expectations and plans. The control group received their routine care in the rehabilitation center. At this stage, personal information including age, gender, marital status, educational level, lapse, and Absence Check Lists were collected for all samples. In addition, craving questionnaires were completed in both intervention and control groups.

2. Sensitization: The goal of this stage is giving information about the nature of the substance use disorder and its consequences. This stage is

conducted in the form of four counseling sessions that conducted weekly. Each session lasted 20 to 40 minutes for each patient individually. The researcher discussed with the patients on the following items; the characteristics of SUD, the symptoms of deprivation and poisoning, the temptation factors, the need for regular referral to the rehabilitation center, the importance of nutrition, regular physical activity, healthy relationships, social activities, using the experiences of treated individuals, the necessity of safe environment, and continuity of healthy behaviors in order to increase the patient's self-esteem.

3. Control: This step was performed in four sessions each of him or her lasted 20-40 minutes that conducted weekly for each patient. The goal of this stage was to continuity of health behaviors in order to maintain and enhance the trend to quit the substance use. Consultations continued at these sessions and the patients were monitored for acquired knowledge at the sensitization step. At this stage, considering the care needs, and new care issues and feedback to previous sessions, the consultations continued to maintain mutual interaction. The process of continuity of health behaviors and adherence to treatment was monitored by observation, questioning, and review of checklists and results of periodic urine tests. The researcher followed up topics that discussed before and new health related problems were discussed.

4. Evaluation: Although this stage was final step of the model, but it was considered at all stages. This step was performed for each patient in one session lasted 20-30 minute. At this stage craving, lapse and absence were evaluated again.

Since the continuity of care is dynamic and it is specific for each patient, the flexibility is significant feature of this caring model.

Statistical procedures

For statistical analysis, we used paired sample/ dependent t-test and Independent t-test, chi-square and Pearson's correlation test. The level of significance was set at $p<0.05$. All statistical analyses were carried out using SPSS Software (version 15).

RESULTS

Demographic characteristics

All of 84 men that included in two groups of study were compared to each other regarding demographic variables such as age, marital status, and education level that might affect the results of the research.

Mean and standard deviation of age in experimental and control groups were respectively 37±6.26 and 38.35±7.22. Based on t test results, two groups were similar each other regarding age (t=-9.20, p=0.36).

57.1 % of patients in experimental group, and 64.3% of them in control group were married. Based on chi-squared test results, two groups were similar each other regarding marital status (χ^2=0.44, df=1, p=0.5).

9.5% of patients in two groups of study were illiterate. 14.3% of patients in experimental group, and 23.8% of them in control group had primary level education. 9.5% of patients in two group had academic education at university level. Based on Chi-squared test results (χ^2=2.87, df=4, p=0.57) two groups were similar each other regarding educational level.

No baseline differences existed between the two groups of study, considering these demographic characteristics and groups were similar together.

Intervention impact measurement

Kolmogrov Smirnov test was used to determine the normal distribution of craving and lapse in two groups of study, before or after the intervention (Table1).

Mean of lapse and craving scores

Independent t-test showed that the mean of lapse score before intervention in the intervention group was 2.7±0.89 and in the control group was 2.2±1.04 which was not significant (p=0.82) at the error level of 0.05. The mean score of craving before intervention was 53.73±13.58 in the intervention group, and it was 51.38±15.18 in the control group, which was not significant (p=0.45). In other words, there was similarity in the mean of craving and lapse scores between the two groups of study before the intervention (Table 2).

Paired sample/dependent t-test showed that the mean score of lapse in the control group before intervention was 2.02±1.04 times and after intervention was 1.83±0.96 times that was not significant (p=0.16). But in the intervention group, the mean score of the lapse that was 2.7±0.89 times before the intervention, decreased to 1. 57±1 times after the intervention, which was significant (p=0.001) (Table3).

Paired sample /dependent t-test showed that the

Table 1. Kolmogrov Smirnov test to determine the normal distribution of lapse and craving in two groups of study, before or after the self-care intervention

Variable	Before or after the intervention	z	p
Lapse	Before the intervention	0.098	0.095
	After the intervention	0.093	0.091
Craving	Before the intervention	0.083	0.075
	After the intervention	0.079	0.063

Table 2. Results of Independent t-test in comparison with the mean score of lapse and craving before intervention in study groups

Variable	Groups	Mean±SD	t	p
Lapse	Intervention	2.07±0.89	0.22	0.82
	Control	2.02±1.04		
Craving	Intervention	53.73±13.58	0.75	0.45
	Control	51.38±15.18		

Table 3. Paired sample t-test results in comparison of mean score of lapse before and after intervention in study groups

Groups	When	Mean±SD	t	p
Experimental	Before intervention	2.07±0.89	3.43	0.001
	After intervention	1.57±1.1		
Control	Before intervention	2.02±1.04	1.43	0.16
	After intervention	1.83±0.96		

Table 4. Paired sample t-test results in comparison of mean score of craving before and after intervention in study groups

Groups	When	Mean±SD	t	p
Experimental	Before intervention	53.73±13.58	2.70	0.008
	After intervention	50.47±15.1		
Control	Before intervention	51.38±15.18	2.03	0.049
	After intervention	49.52±12.79		

Table 5. The relationship between craving and lapse

Variable	Correlation amount	n	R^2	p
Craving and lapse after intervention	0.56	84	31%	<0.001

R^2=equals the square of the Pearson correlation coefficient

mean score of craving in control group decreased to 49.52±12.79 (from 51.38±15.18 baseline) which was significant (p=0.049). The mean score of craving in the intervention group was 53.33±13.58 before intervention, that decreased to 50.47±15.1 after the intervention which a significant difference (p=0.008) in comparing with the control group (Table 4).

Pearson's correlation test was used to evaluate the relationship between craving and lapse. This test showed that the obtained correlation coefficient is significant and there is a positive relationship between craving and lapse(R=0.56, p<0.01). In other words, the degree of craving and lapse 31% are explained and interpreted by each other and 69% are related to other factors (R^2=31%) (Table5).

DISCUSSION

This randomized controlled trial study was planned to determine the effects of the effectiveness of applying continuous care model on lapse and craving in patients on MMT. Numerous studies have indicated that applying continuous care model in chronic disease can improve physical functioning, quality of life, quality of sleep, blood sugar control, blood pressure control, and disease-related symptoms in patients.[20,22-28]

Regarding above mentioned outcomes of CCM, and considering substance use disorder as a chronic disease we aimed to evaluate the effect of this model in patients on methadone maintenance treatment. The results of our study provided partial support for our priori hypothesis that applying continuous care model among men on methadone maintenance treatment can decrease their lapse and craving for substance use.

Our results are consistent with a study did by Ilgen et al.[30] which focused on continuous care for psychiatric and substance use disorder. They used treatment records from all caregivers with co-occurring substance use disorder and psychiatric disorders whom discharged from an inpatient psychiatric ward, in the 90 days after discharge. Their findings showed that; receiving continuing care was associated; with a lower likelihood of re-hospitalization over the first year after discharge.[30]

In our study continuing of care like Ilgen's study lead to prevention of lapse and craving that may contributed in decreasing re-hospitalization.

Review study of Ayu et al., provided a summary of publications on addiction medicine training programs that confirmed during the past fifteen years. They concluded; faculty development and a clear policy concerning (international) certification of addiction medicine curricula are essential to further improve addiction medicine training and improve the care for patients with substance use disorder.[31] Reimer et al. conducted a review study on misuse and diversion of opioid substitution treatment medicines. They concluded; although treatment of opioid use disorder is a crucial need, it is essential to reduce misuse and diversion while ensuring the best possible care.[32]

Furthermore, our study is consistent with the research of Ögel et al, on the effectiveness of a structured treatment program in patients with substance use disorder. Their study showed alcohol and drug dependence treatment program (SAMBA) is an increasing factor for adherence to treatment in patients with substance use disorder, who were directed to treatment.[33]

In our study Pearson's correlation test showed that there is a significant positive relationship between craving and lapse. In other words, decreasing craving can lead to reducing lapse. So, applying caring measures such as CCM to reduce craving, may have contributed to avoid lapse, and ultimately to prevent relapse of substance use disorder in patients on MMT.

In present study, decline in the mean of craving and lapse after the intervention in the control group can be due to the supports and psychological counseling that have been done for all patients, by psychologists and care providers at the Razi Psychiatric Center. These supports and counseling are parts of the routine caring and treatment as usual in this center, which is carried out to all clients.

Among other causes; the intervention group's influence on the control group may be due to the close relationship and association of the patients between these two groups of study.

Another reason could be the impossibility of completely separating the intervention group from the control group and inevitably visits of these two groups before and after medical examinations, or taking their daily methadone in the waiting room, as well as indirectly transmits and exchanges information (about counseling sessions, and follow-ups of CCM process) out of the center, between the two groups of study.

This study had some limitations, so the study findings could not be generalized because of the following reasons: 1) All of participants were male, 2) Participants were enrolled only from one hospital, 3) Relatively small sample size, short duration of our study, location of program, scheduling, and transportation conflicts, 4) Although the effectiveness of the CCM on craving and lapse was significant compared to control group, effect of this caring model on the other health outcomes in substance use disorder, had not evaluated in our study.

It is suggested that; other studies with larger sample sizes on both genders, considering other health outcomes in substance use disorder be conducted.

CONCLUSION

Current study showed that men on methadone maintenance treatment may decrease their lapse and craving participating continuous care program. Also this simple, effective, comfortable, and low-cost program may apply to other types of addictive behaviors. The results of this study may contribute to the growing body of knowledge supporting the feasibility and effectiveness of continuous care model as a non-pharmacologic option in the prevention of substance use disorder.

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