

Comparing Effectiveness of Mindfulness-Based Relapse Prevention with Treatment as Usual on Impulsivity and Relapse for Methadone-Treated Patients: A Randomized Clinical Trial

Mehdi Yaghubi MSc¹, Fatemeh Zargar PhD², Hossein Akbari PhD³

Original Article

Abstract

Background: Impulsivity is one of the causes of relapse that can affect treatment outcomes. Studies have shown that addiction treatments can reduce impulsivity in drug-dependent individuals. Studies also have suggested that mindfulness is associated with impulsivity. However, no study has investigated the effectiveness of the mindfulness-based intervention on impulsivity in opioid-dependent individuals. This study aimed to compare the effectiveness of mindfulness-based relapse prevention (MBRP) with treatment as usual (TAU) in terms of impulsivity and relapse for methadone-treated patients.

Methods: The present randomized controlled clinical trial was performed in Kashan, Iran, in 2015. The study population was opioid-dependent patients referred to Maintenance Treatment Centers. Seventy patients were selected by random sampling and were assigned in two groups (MBRP and TAU) randomly. The participants of two groups filled out Barratt impulsivity scale (BIS-11) as a pre-test and 8 weeks later as post-test and 2 months later as a follow-up. Both groups received methadone-therapy. The MBRP group received 8 sessions of group therapy, while the control group did not receive any group psychotherapy session. Finally, data from 60 patients were analyzed statistically.

Findings: The MBRP group had decreased impulsivity significantly ($P < 0.001$). The mean impulsivity score was 74.76 ± 4.72 before intervention that was significantly decreased to 57.66 ± 3.73 and 58.86 ± 3.57 after the intervention and follow-up ($P < 0.001$), respectively. In addition, significant differences were observed between MBRP and TAU groups for relapse frequency ($P < 0.050$).

Conclusion: This study showed that MBRP compared to TAU can decrease the mean impulsivity score in opioid-dependent and reduce relapse probability. These findings suggest that MBRP is useful for opioid-dependent individuals with high-level impulsivity, and relapse prevention.

Keywords: Mindfulness; Impulsivity; Relapse

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1- Department of Clinical Psychology, School of Medicine, Kashan University of Medical Sciences, Kashan, Iran

2- Assistant Professor, Behavioral Sciences Research Center AND Department of Psychiatry, School of Medicine, Isfahan University of Medical Sciences, Isfahan, Iran

3- Assistant Professor, Department of Biostatistics and Epidemiology, School of Public Health, Kashan University of Medical Sciences, Kashan, Iran

Correspondence to: Fatemeh Zargar PhD, Email: fatemehzargar@gmail.com

Introduction

Substance abuse is known as a chronic disease, which is one of the most challenging health problems. It can cause problems at different levels of individual, family and society.¹ In Iran, the recent national survey of drug abuse has estimated that about 1.2 million of drug dependents need treatment services.² Studies have reported that opioids are the main drug of abuse among all the drugs.^{2,3} The literature review demonstrated that 60-90% of addicts who receive treatment are relapsed.⁴ Studies have shown that several factors are involved in drug use.⁴ To design effective programs on drug prevention, understanding the etiology of this phenomenon and its related factors is essential.⁵

Core Substance use symptoms include increased motivation for substance (craving) control disorders (impulsiveness and obsession), difficulty in regulating emotions (negative mood) and increased reactivity to stress.⁶ Evidence suggests that impulsivity contributes to the more prevalence of substance use disorders, leading to consequences such as cognitive impulsivity, motor impulsivity and lack of planning.⁷ Impulsivity is defined as behaviors such as hurry, incontinence, impatience and lack of attention to the consequences of an action.⁸ According to the research, four dimensions of personality associated with different dimensions of impulsive behaviors have been introduced: 1) Lack of planning: the tendency to engage in urgent actions instead of applying with careful thought and planning. 2) Urgency: difficult to resist strong impulses and a tendency to act out of ignorance on emotional experiences, positive or negative. 3) Sensation: seeking tendency to seek adventure and excitement. 4) Lack of stability: the difficulty in keeping attention on tasks or failure in distress tolerance. Studies have shown that due to lumbar lesion damage, executive function and control ability in people with high impulsivity are significantly weak; therefore, they are widespread in behavioral and self-regulatory behaviors.⁸

On the other hand, it seems that different aspects of impulsivity are linked to different aspects of risky behavior^{9,10} and the consequences of poor treatment outcomes of drug abuse.¹¹⁻¹³ In addition, negative emotions are related to severe problems and engaged in a variety of risky

behaviors such as alcohol, gambling and pathological eating.⁹ The problems associated with impulsivity, such as poor inhibition, failure in planning and making decisions can be a major obstacle in the treatment of people with substance abuse disorders, especially at the beginning, compliance, and continuation of treatment. In clinical samples, impulsivity is linked with the factors that are involved in relapse such as craving and severity of drug use. This is a potential mediator in the responsiveness and effectiveness of the treatment of substance use disorders.¹¹ Also, impulsivity is a very important goal for experimental studies and clinical trials of individuals who seek treatment for substance use disorders.¹² In addition, recent research in the non-clinical samples has shown when impulsivity is reduced in a person, the substance abuse and related problems are also likely to be reduced.¹⁴

People participating in substance abuse treatment programs have reported decreases in impulsivity.¹⁵ Impulsivity is a mediator of the relationship between treatment process and reducing the problems associated with alcohol use.¹⁶ Therefore, the potential mechanisms of change in successful interventions for substance abuse disorders may reduce the level of impulsivity.¹⁶ Various approaches have been used for substance abuse treatment including supportive therapy, cognitive behavioral therapy and interpersonal. Regarding the effectiveness of mindfulness techniques in the treatment of mental and physical disorders, these interventions have been considered. One of these interventions is mindfulness-based interventions. Mindfulness-based relapse prevention (MBRP) is one of the newest psychological interventions in the treatment of addiction that integrates mindfulness techniques¹⁷ with traditional behavioral therapy.¹⁸ Studies have indicated that mindfulness-based interventions are effective on relapse prevention and treatment of substance use disorders.¹⁹⁻²¹ However, few studies have examined the effectiveness of mindfulness-based interventions on impulsivity.²² Studies have shown that mindfulness is negatively correlated with impulsivity, depression, and anxiety.²³ Mindfulness and awareness of thoughts and behavior can reform emotional processing methods and events associated with the drug.^{24,25} Combined with previous research, we can say

impulsive aggressive tendencies are related to a lack of self-control.²⁶ In another word, mindfulness is associated with improved self-control.^{22,26} In this field, it was not found a study to investigate the effectiveness of mindfulness-based interventions on impulsivity in opioid dependents. This study aimed to compare the effectiveness of MBRP and treatment as usual (TAU) on impulsivity and relapse for methadone-treated patients.

Methods

This randomized controlled clinical trial was performed in 2015. The study population included all man patients, aged 20-45 years and opioid-dependent referred to Maintenance Treatment Centers from May to July 2015 in Kashan, Iran.

The sample size was calculated based on a previous research. According to the study conducted to compare the groups in terms of MBRP with the control group, the effect size index between the two groups on the addiction severity index of 65% was reported. According to 95% confidence interval and test power of 90%, using Cohen's formula, 26 subjects were estimated to be needed in each group. But, we included 35 patients in each group to achieve more reliable results.¹⁹

After sample size calculation, 70 patients who met the inclusion criteria, were selected by random sampling, and then were invited to participate in the study. Group sessions were offered to the willing patients to participate, while the patients with the same condition were replaced with the unwilling patients. Then, patients were assigned to MBRP and TAU groups using the table of random numbers. Inclusion criteria were age between 20 to 45 years, psychiatric or medical references regarding the original diagnosis and diagnostic criteria for substance dependence according to the Diagnostic and Statistical Manual of Mental Disorders-5th edition (DSM-5), not having severe psychiatric disorders (schizophrenia, depression and bipolar disorder), and having the least degree of junior high school. Exclusion criteria also included not wanting to continue the meetings, the absence of more than two sessions, participate in other health programs simultaneously, and having a long-term dependence on simultaneous multi-drug.

Demographic information form: This form contained five questions about demographic information, which was related to demographic

variables including age, education level, marital status, employment status, and use-history of substance.

Barratt impulsivity scale (BIS-11): This questionnaire is a useful tool for evaluation of impulsive behavior. The structure of the questionnaire, indicating the dimensions of impulsivity was fast decision-making and lack of foresight. The index had 30 questions and evaluated the following three factors: 1. Cognitive impulsivity that included severe making cognitive decision. 2. Motor impulsivity which included acting without thinking. 3. Lack of planning which determined by immediate orientation or lack of foresight. Questions have been formulated in a 4-point Likert scale and highest scores would be 120. Barratt et al. reported inter-rater reliability for the total score of 0.79 to 0.83.²⁷ Naderi and Haghshenas in a study for the first time in Iran, validated the Barratt impulsiveness scale and compared the correlation with the community Zuckerman sensation seeking scale students. The correlation coefficient (r) was 0.28 ($P < 0.005$), the Cronbach's alpha reliability coefficient was 0.72, and split-half was 0.60.²⁸

Morphine test: Relapse frequency was assessed by morphine kit by measuring the amount of morphine in the urine. The positive urine test indicated the relapse.

After being randomly assigned to the intervention and control groups, the participants agreed with the objectives, issues and how to run and the time of hold sessions. Also, Participants completed consent form to participate in the study. After pre-test, mindfulness training sessions were held for the intervention group by a clinical psychologist in 8 sessions during 2 months and 1 week, 2 hours each session in two 45-minute parts with a 30 minute-break and catering. A meditation training CD, exercises, guided imagery and manual entries of each session were distributed among the MBRP group participants and feedback forms were collected. The control group did not receive a regular training program. In fact, questionnaires were completed only in the pre-test and post-test. After the sessions, the test was performed in both groups. Also, two months after completion of therapy sessions, both groups of MBRP and TAU were followed. In this study, the intervention of mindfulness-based on MBRP method³⁴ was trained to the subjects. The summary of MBRP training sessions is listed in table 1.

Table 1. Curriculum for sessions of mindfulness-based relapse prevention (MBRP)

Session	Content
1	Express the rules of the group, introducing automatic pilot or by raisin exercise, body scan practice.
2	Continuing body scan practice, practice awareness of physical, emotional and cognitive reaction to triggers of substance use, mindfulness of a daily activity.
3	Expanding mindfulness in other sense: awareness of hearing (focusing on hearing without judgment), expand awareness to your whole body and surroundings and respond mindfully.
4	Increase awareness of high-risk situations, mindful walking, breathing-space practice (especially in the challenging situation).
5	Discussing of acceptance and skillful action.
6	Introducing the role of thoughts in relapse and relapse cycle.
7	Discussing self-care and lifestyle balance.
8	Discussing the importance of support network as a way of reducing risk and maintenance recovery, Practice Review, reflection on the course.

This study was investigated in the Ethics Committee of Medical Sciences and Health Services, Kashan University of Medical Sciences, and a registry number has been reviewed and approved (Ethical approval NO: IR.KAMUS.RES.1394.45 and Iranian Registry of Clinical Trials No: 2016010525870N1). Each participant also completed the informed consent form. In addition, all participants were aware of their rights to withdraw from the study at any time and assured that their personal information will remain confidential. Also,

after completion of the sessions, the treatment sessions were held for the TAU group members.

Results

Among 70 subjects, 5 participants in the MBRP group were excluded because of irregular attendance at MBRP sessions and not completing BIS-11. Moreover, 5 participants of TAU group were excluded because of not completing BIS-11 in post-test and follow-up. Therefore, data analysis was performed on 60 patients (Figure 1).

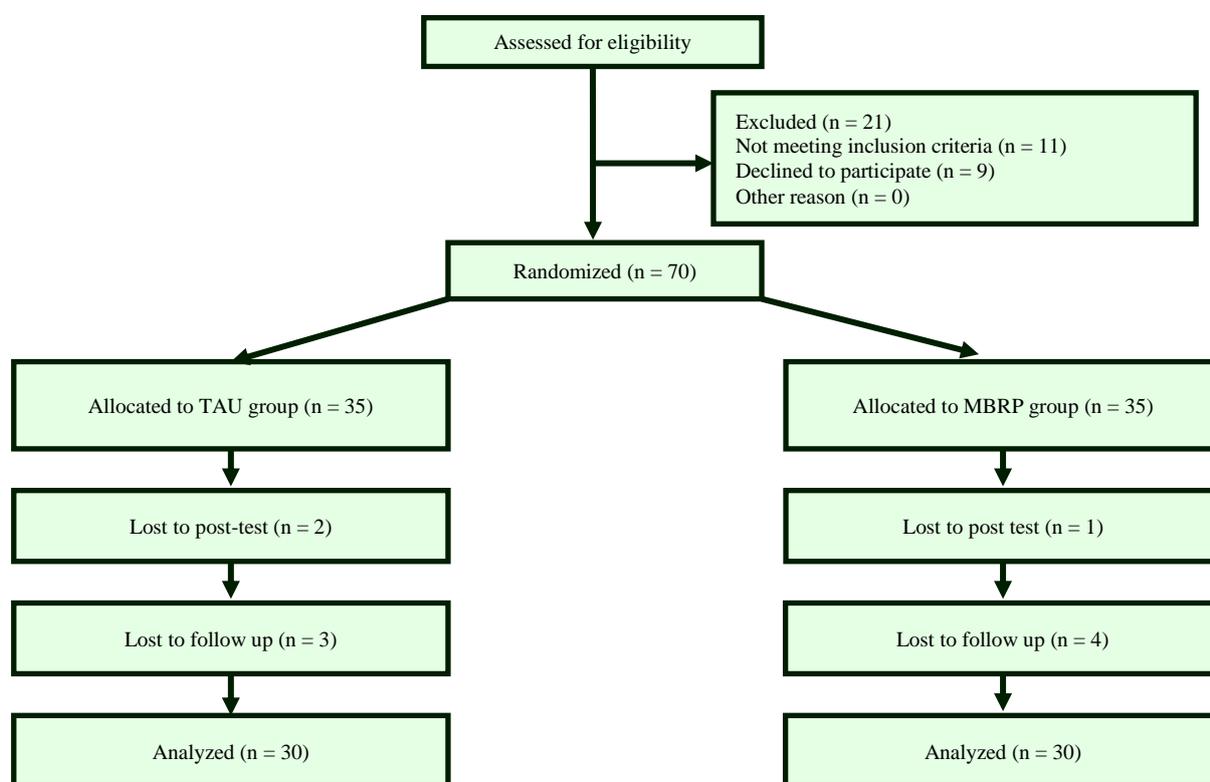


Figure 1. The CONSORT flow diagram of study
MBRP: Mindfulness-based relapse prevention; TAU: Treatment as usual

Table 2. Demographic characteristics of participants in both groups

Variable	MBRP	TAU	P*
Age (year) (mean ± SD)	31.73 ± 4.32	30.43 ± 4.25	0.78
Job [n (%)]			0.740
Employed	23 (76.7)	24 (80.0)	
Jobless	7 (23.3)	6 (20.0)	
Education level [n (%)]			0.640
Under diploma	19 (63.3)	23 (76.7)	
Diploma-undergraduate	11 (36.7)	7 (23.3)	
Use history [n (%)]			0.860
Use < three years	8 (26.7)	10 (33.3)	
Use: Between 3-5 years	19 (63.3)	18 (60.0)	
Use: More than five years	3 (10.0)	2 (6.7)	
Marital status [n (%)]			0.680
Married	21 (70.0)	23 (76.7)	
Single	9 (30.0)	7(23.3)	

*Student's independent t-test or chi-square test

MBRP: Mindfulness-based relapse prevention; TAU: Treatment as usual; SD: Standard deviation

In this study, Student's independent t-test was used to compare the significance of mean age between the MBRP and TAU groups. Chi-square test was used to compare the other demographic variables such as education level, marital status, employment status, and use-history as well as the frequency of relapse in both groups. Also, in order to compare the changes in MBRP and TAU impulsivity scores in three evaluation phases (pre-test, post-test, and follow-up), repeated measures ANOVA was used. Mauchly's Test of Sphericity showed that the uniformity of matrix variance-covariance was not confirmed ($W = 0.414$, $P < 0.001$). However, Hayling test ($F = 1.05$, $P < 0.001$) showed that there is a relationship between membership in the group and the treatment stage (time). Table 2 shows the demographic characteristics of the participants. No significant difference was observed between the two groups of demographic characteristics (Table 2).

The difference of the relapse frequency in two

groups was significant at post-test (Table 3). The number of people who had a relapse in the TAU group was significantly more than MBRP group. Furthermore, the hypothesis related to the effectiveness of MBRP on reducing relapse in the intervention group at post-test was confirmed. In addition, the difference between the two groups in terms of relapse in the follow-up phase was significant. In other words, the effectiveness of MBRP after two months of follow-up remained constant.

Mean scores of impulsivity and its subscales (cognitive impulsivity, motor impulsivity, planning) and comparison of the pre-test, post-test and follow-up (two months after the implementation of the post-test) are shown in table 4, showing the mean score of the intervention group. On the other hand, the TAU group had no significant difference in impulsivity score. The changes in impulsivity score in three phases of evaluation in both groups are shown in figure 2.

Table 3. Relapse frequency in mindfulness-based relapse prevention (MBRP) and treatment as usual (TAU) groups

Treatment phase	Relapse	Group		P*
		MBRP [n (%)]	TAU [n (%)]	
Pre-test	Relapse	7 (23.33)	6 (20.00)	0.614
	No relapse	23 (76.66)	24 (80.00)	
Post-test	Relapse	3 (10.00)	10 (33.33)	0.012
	No relapse	27 (90.00)	20 (66.66)	
Follow-up	Relapse	4 (13.33)	11 (36.66)	0.010
	No relapse	27 (86.66)	19 (63.33)	

*Chi-square test

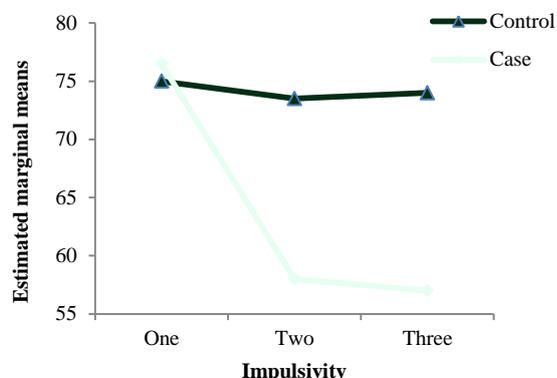
MBRP: Mindfulness-based relapse prevention; TAU: Treatment as usual

Table 4. The comparison of impulsivity at pre-test, post-test, and follow-up in both groups

Outcome measure	Pre-test	Post-test	Follow-up	P*	
				Time	Time × Group
Cognitive (mean ± SD)				< 0.001	< 0.001
MBRP	19.50 ± 2.27	15.60 ± 1.79	15.83 ± 2.19		
TAU	18.23 ± 1.93	17.5 ± 1.57	17.40 ± 1.73		
Motor (mean ± SD)				< 0.001	< 0.001
MBRP	27.13 ± 2.96	21.50 ± 1.89	21.23 ± 1.83		
TAU	26.46 ± 2.84	25.56 ± 3.13	25.33 ± 3.17		
Planning (mean ± SD)				< 0.001	< 0.001
MBRP	29.70 ± 2.62	20.76 ± 2.47	21.80 ± 2.62		
TAU	30.06 ± 3.42	29.86 ± 2.35	30.16 ± 2.49		
Total score (total impulsivity) (mean ± SD)				< 0.001	< 0.001
MBRP	76.33 ± 4.65	57.66 ± 3.73	58.86 ± 3.85		
TAU	74.76 ± 4.71	72.93 ± 4.68	72.90 ± 4.87		

*Repeated measures ANOVA

MBRP: Mindfulness-based relapse prevention; TAU: Treatment as usual; SD: Standard deviation

**Figure 2.** Changes in impulsivity mean score in treatment as usual (TAU) and mindfulness-based relapse prevention (MBRP) groups

Discussion

The study showed MBRP compared with TAU can reduce the probability of relapse in opioid-dependent. This finding is consistent with findings of previous studies.¹⁹⁻²¹ For example, Witkiewitz et al.¹⁹ found that individuals who received MBRP had significantly lower levels of craving following treatment, in comparison to a TAU control group. In addition, the findings showed that MBRP can reduce impulsivity levels in opioid-dependent men that is consistent with the result of the previous studies.^{22,29} Tang et al.²² found that promoting emotion regulation and decreasing impulsivity in brain activity can enhance addiction prevention and improve treatment.

MBRP can reduce impulsivity levels and probability of relapse in an opioid-dependent manner by multiple mechanisms of mindfulness-based interventions. These mechanisms are as

follows: 1. Neurological effects: Studies have shown that addiction is associated with defects in the network of self-control that itself is associated with the prefrontal cortex.³⁰ Thus, improving the function of the prefrontal cortex may increase emotional regulation, self-regulation and in this way help to the treatment of addiction.³⁰⁻³² Previous studies have suggested that behavioral training, such as meditation, can improve self-control level, emotional regulation, and therefore may be a promising treatment for addiction.^{22,30} 2. The distance between themselves and their thoughts by becoming aware of body and sensation can increase the level of awareness during the experience of negative emotions associated with relapse that reduces vulnerability to relapse.³³ 3. Mindfulness meditation can be used to increase the awareness of the body and sensation. For example, stop, observe, breath, expand, respond (SOBER) breathing space³⁴ helps patients to break the stimulus-response habitual patterns such as seeking immediate relief. 4. Providing a pool of alternative behaviors to respond to signs of craving.³⁴ Difficulty aspects of impulsivity problems such as poor inhibition, lack of decision-making and planning can be a major obstacle for substance use disorder patients throughout the process of improvement.¹¹ Using drugs continuously can create a cycle of repetitive behavior, stereotypes, and minimal consciousness automatically. Mindfulness helps to break this cycle, by adapting the automatic processing of information and ideas and allocating awareness shunted from memory that has been biased due to drug use.²⁴ 5. Attention regulation skills: In the

case of addiction, it has been shown that drug users have the impaired motor skills are less able to interact with their strategic processes. In another hand, ignoring attentional-bias leads the patients toward the stimulus that is related to drug use.³⁵ Mindfulness may adapt the analysis of information related to the relapse process by memory and attention and plays an important role in both positive and negative emotional processing.³⁶

6. Accept emotional experiences: Avoidance coping is one of the causes of drug use initiation and its continuation.³⁶ Mindfulness exercises raise awareness to detect individual high-risk situations, triggers, and cognitive, emotional and physiological processes lead to drug abuse and reducing the risk of relapse. In mindfulness training, raise awareness to detect individual high-risk situations, controversial triggers and cognitive, emotional and physiological processes, that lead to drug abuse are reduces the risk of relapse.³⁷

7. Increasing self-control: Mindfulness is associated with increased self-control.²² Mindfulness training leads to reduced negative emotions, conflict and stress, and reduced use, as well as the changes in judgment and stress which results in the self-control improvement.^{26,34} Awareness of the present moment, being non-judgmental and accepting during mindfulness lead to self-control increase.^{22,29,34} Mindfulness skills help to control behaviors that are automatically triggered by stimulants with negative emotional content that is associated with signs of craving.³⁶ These skills are used to increase awareness of emotional,

behavioral and physical sensations.³⁴ In summary, mindfulness skills can be helpful by self-awareness improvement,⁶ acting with awareness³⁷ decreasing the reactivity to craving signs³⁸ eliminating the negative emotional states,²⁶ and preventing the relapse.¹⁹

Conclusion

The findings of this study showed that mindfulness-based interventions can reduce the levels of impulsivity by MBRP and reduce the probability of relapse in opioid-dependent patients. In addition, mindfulness-based interventions are suggested as a treatment for reducing the impulsivity levels and relapse probability. This intervention can be used as an effective low-cost treatment for opioid-dependent men. Limitations of the present study were using only men for, and short duration of follow-up. Further studies are recommended to raise the generalization and reliability with longer follow-up and both man and women patients.

Conflict of Interests

The Authors have no conflict of interest.

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مقایسه اثربخشی پیشگیری از عود مبتنی بر ذهن آگاهی با درمان معمول، بر تکانشگری و عود در افراد تحت درمان با متادون

مهدی یعقوبی^۱، دکتر فاطمه زرگر^۲، دکتر حسین اکبری^۳

مقاله پژوهشی

چکیده

مقدمه: تکانشگری یکی از عوامل مؤثر در عود می‌باشد که نتایج درمان را تحت تأثیر قرار می‌دهد. پژوهش‌ها نشان داده‌اند که درمان‌های مرتبط با اعتیاد می‌توانند سطح تکانشگری را کاهش دهند. علاوه بر این، تحقیقات پیشنهاد می‌کنند که ذهن آگاهی با تکانشگری ارتباط دارد. با این وجود، هیچ مطالعه‌ای اثربخشی آموزش mindfulness-based relapse prevention (MBRP) را بر تکانشگری افراد وابسته به مواد مخدر تحت درمان با متادون بررسی نکرده است. پژوهش حاضر با هدف مقایسه اثربخشی پیشگیری از عود مبتنی بر ذهن آگاهی با درمان معمول، بر تکانشگری و عود در افراد وابسته به مواد مخدر تحت درمان با متادون انجام شد.

روش‌ها: این کارآزمایی بالینی تصادفی در سال ۱۳۹۵ در کاشان انجام گردید. ۷۰ نفر از مردان وابسته به مواد مخدر تحت درمان با متادون به صورت تصادفی انتخاب شدند و در دو گروه شاهد و آزمایش قرار گرفتند. بیماران هر دو گروه در شروع مطالعه، ۸ هفته پس از آن و یک ماه پس از پایان، مقیاس Barratt impulsivity scale (BIS) را تکمیل نمودند و میزان بازگشت آن‌ها با استفاده از کیت مورفین بررسی گردید. گروه آزمایش ۸ جلسه آموزش MBRP دریافت کرد؛ در حالی که گروه شاهد هیچ مداخله منظم روان‌شناختی را دریافت نکرد. در نهایت، داده‌های ۶۰ بیمار مورد تجزیه و تحلیل آماری قرار گرفت.

یافته‌ها: میانگین نمره تکانشگری گروه آزمایش به طور معنی‌داری کاهش یافت ($P < 0/001$). میانگین نمره تکانشگری قبل و بعد از مداخله به ترتیب $4/72 \pm 74/76$ و $3/73 \pm 57/66$ به دست آمد و در مرحله پیگیری، $3/57 \pm 58/86$ را نشان داد ($P < 0/001$). بر اساس نتایج آزمون χ^2 ، تفاوت معنی‌داری بین فراوانی عود در دو گروه وجود داشت ($P < 0/050$).

نتیجه‌گیری: آموزش MBRP در مقایسه با روش درمان معمول، می‌تواند میزان تکانشگری را در مردان وابسته به مواد مخدر تحت درمان با متادون کاهش دهد و از عود پیشگیری نماید. بنابراین، آموزش MBRP برای افراد وابسته به مواد مخدر که تکانشگری بالایی دارند، مفید است و می‌تواند به پیشگیری از عود کمک کند.

واژگان کلیدی: ذهن آگاهی، تکانشگری، عود

ارجاع: یعقوبی مهدی، زرگر فاطمه، اکبری حسین. مقایسه اثربخشی پیشگیری از عود مبتنی بر ذهن آگاهی با درمان معمول، بر تکانشگری و عود در افراد تحت درمان با متادون. مجله اعتیاد و سلامت ۱۳۹۶؛ ۹ (۳): ۱۶۵-۱۵۶.

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۱- گروه روان‌شناسی بالینی، دانشکده پزشکی، دانشگاه علوم پزشکی کاشان، کاشان، ایران

۲- استادیار، مرکز تحقیقات علوم رفتاری و گروه روان‌پزشکی، دانشکده پزشکی، دانشگاه علوم پزشکی اصفهان، اصفهان، ایران

۳- استادیار، گروه آمار زیستی و اپیدمیولوژی، دانشکده بهداشت، دانشگاه علوم پزشکی کاشان، کاشان، ایران

Email: fatemehzargar@gmail.com

نویسنده مسؤول: دکتر فاطمه زرگر