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Effects of software-based cognitive bias modification on stress, anxiety, and depression disorders among patients in methadone maintenance treatment: a randomized clinical trial

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Abstract

Objectives: Opioid abuse is one of the most critical problems today, and individuals struggling with this issue often experience stress, anxiety, and depression disorders. This study aimed to investigate the effects of software-based cognitive bias modification on stress, anxiety, and depression disorders among patients receiving methadone maintenance treatment.

Methods: This double-blind clinical trial was conducted in 2022. Eighty-four participants were selected through convenience sampling from individuals undergoing methadone maintenance treatment for opioid abuse at an addiction treatment center in Isfahan city. They were then randomly assigned to either the intervention group (n=42) or the control group (n=42). The intervention involved a four-week program utilizing software-based cognitive bias modification through the dot-probe task, with two sessions per week. Participants in both groups completed DASS21 questionnaires before, immediately after, and two months following the intervention.

Results: The repeated-measures ANOVA test revealed statistically significant differences in the mean scores of stress (P<0.001), anxiety (P<0.001), and depression (P<0.001) disorders in the intervention group before, immediately after, and two months post-intervention.

Conclusion: The findings of this study suggest that software-based cognitive bias modification can lead to a reduction in stress, anxiety, and depression disorders among patients undergoing methadone maintenance treatment. Therefore, incorporating this program alongside other treatment methods for individuals in methadone maintenance treatment is recommended.

Keywords: Cognitive Behavioral Therapy, Stress Disorders, Anxiety, Depression, Methadone.

Introduction

The misuse of opioids is a significant global health concern.[1] A survey conducted in 2019 found that approximately 275 million individuals worldwide have engaged in drug use at least once, with 62 million having used opioids. During this period, over 36 million people suffered from substance abuse, with opioid use accounting for the majority of cases.[2] Substance abuse can harm brain structure and function, hindering treatment and adherence. Successful treatment requires consideration of various factors, including medical, psychological, and social aspects.[3] Treatment options for this disorder include pharmacotherapy, psychosocial interventions, behavioral therapy, peer support groups, and family therapy.[4]

Behavioral therapy is a widely used treatment method that aims to enhance motivation to quit substance use, build resistance to consumption, promote activities, improve problem-solving skills, and facilitate interpersonal relationships.[3,4] Methadone Maintenance Treatment is recognized as one of the most effective treatments for individuals with substance abuse disorders, especially when combined with behavioral therapy.[3] Patients with substance abuse disorders often experience stress, anxiety, and severe depression.[5,6] There is a bidirectional relationship between these psychological disorders and

substance abuse, where substance use can lead to stress, anxiety, and depression, while these conditions can also contribute to continued drug use. Therefore, treatment for substance abuse should also address stress disorders, anxiety, depression, and other psychological issues to improve success rates.[5-7]

Historically, the primary focus of treating individuals with substance abuse and co-occurring mental disorders like stress, anxiety, and depression was on addressing drug dependence. However, recent research suggests that concurrent treatment of these conditions can yield better outcomes.[8] Common pharmaceutical treatments for mental disorders in these patients include selective serotonin reuptake inhibitors (SSRIs), beta-blockers, and benzodiazepines.[9] Non-pharmacological approaches such as motivational interviews and cognitive behavioral therapy (CBT) have also been recommended for managing these mental health issues.[8]

When individuals use addictive substances over an extended period, they develop an unconscious heightened attention to them, known as attentional bias. This phenomenon can lead to physiological arousal and cognitive attraction when faced with external stimuli, prompting reactions.[10] Cognitive bias plays a significant role in sustaining addictive behaviors, and many studies have explored ways to modify this bias.[11] Essentially, cognitive bias involves a systematic deviation in judgment and decision-making that can result in selecting inadequate or incorrect decisions across various domains.[12] In the context of substance abuse disorders, individuals tend to focus more on specific stimuli, potentially leading to errors in decision-making when unable to regulate their emotions towards these stimuli. Cognitive bias is a cognitive error that cannot be rectified solely through increased awareness of the subject matter.[13] Consequently, cognitive bias modification (CBM) aims to alter the processing of stimuli associated with the disorder. For example, the sight of drugs may automatically capture the attention of individuals struggling with substance abuse.[14]

Despite existing research, scholars continue to debate the effectiveness of CBM as a promising treatment for individuals with substance abuse and co-occurring mental disorders.[8,15] While a systematic review by MacLean et al.,[16] highlighted the positive impact of CBM and attention bias modification (ABM) on treating substance-dependent patients, Zhang et al., identified discrepancies and limitations in the positive effects of CBM on addiction, suggesting the need for further investigation.[11,15]

CBM can be implemented through various methods, including computer software. Khodadadi et al., utilized this approach to assess the efficacy of CBM in enhancing intimacy and compatibility in incompatible couples, yielding positive results.[17] Similarly, Mohsenpourian et al., compared the effectiveness of CBM with SSRI medication in treating obsessive-compulsive disorder, concluding that software-based CBM was an effective treatment modality for the disorder.[18] The dot-probe task serves as a standard computer-based behavioral measure to evaluate and modify attentional bias.[19]

Given the challenges faced by individuals with co-occurring stress, anxiety, and depression disorders in treating substance abuse, it has been suggested that addressing both substance abuse and mental health concerns simultaneously may be beneficial.[8,11] CBM, particularly ABM, has been proposed as a potential treatment option for addressing these issues. However, the effectiveness of ABM remains a topic of debate.[15]

Objectives

This study aimed to investigate the impact of a software-based CBM intervention on stress, anxiety, and depression levels in patients undergoing Methadone Maintenance Treatment (MMT).

Methods

This study was a randomized clinical trial conducted in three stages with a one-to-one ratio between two parallel groups.

The inclusion criteria for participation included individuals over 18 years of age who were literate, had a history of opioid abuse for more than six months, had attempted at least one withdrawal, and were currently undergoing Methadone Maintenance Treatment (MMT). Exclusion criteria comprised participants who missed more than one session of the dot-probe task, dropped out of addiction treatment during the intervention, experienced severe physical or mental illness, or passed away during the study.

Based on the study by Seghatoleslam et al., and using the formula

$$[n=\left(z_{1-\frac{\alpha}{2}}+z_{1-B}\right)^2 (s_1{}^2+s_2{}^2)/d^2]$$

with a 95% confidence interval and 80% power, the required sample size for each group (control and intervention) was calculated to be 34 participants. To account for a potential dropout rate of 0.2, the sample size was increased to 42 participants per group, resulting in a total sample size of 84.[20]

Prior to initiating the intervention, eligible participants were randomly assigned by the investigator into either the intervention or control group using a random block method. Blocks of four participants were used, with two individuals allocated to each group within a block. The study design included a two-group randomized clinical trial comprising 21 blocks of four, resulting in two groups of 42 individuals each [Figure 1].

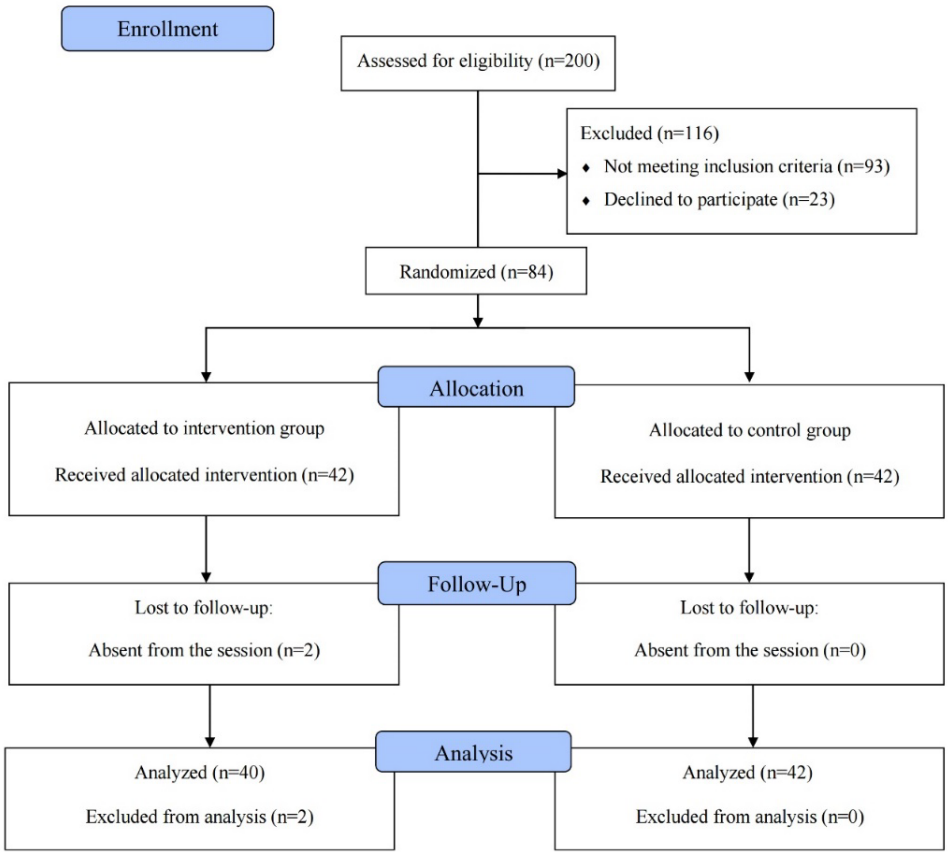

Figure 1. CONSORT flow diagram

The current study utilized various data collection instruments, including a questionnaire that gathered demographic information (such as age, number of opioid withdrawals, duration of opioid abuse, education level, marital status, employment status, and income level) and the DASS21 questionnaire, which assessed stress, anxiety, and depression disorders among participants. The DASS21 questionnaire consisted of 21 questions and evaluated these disorders across seven subcategories. Participants responded using a Likert scale ranging from "not at all" to "very much," with scores ranging from 21 to 84. Higher scores indicated greater severity of disorder. This tool has been validated and shown to be reliable in numerous studies conducted in Iran.[21-23] The Persian version of the questionnaire demonstrated satisfactory internal consistency, with Cronbach's alpha values of 0.78 for stress, 0.79 for anxiety, and 0.77 for depression. Additionally, the tool showed a correlation coefficient of 0.7 with Beck's instrument.[23]

Participants were informed about the study's objectives, methodology, voluntary participation, right to withdraw at any point, confidentiality of information, and absence of participation costs. Written informed consent was obtained from those who agreed to participate. On September 23, 2022, both groups completed a demographic information questionnaire and the DASS21 questionnaire. The DASS21 questionnaire was administered immediately after the intervention ended on October 23, 2022, and again two months later on December 22, 2022.

Prior to the intervention, participants' cognitive biases were assessed using the dot-probe task conducted via software provided by Ravan Tajhiz company. All participants completed the test through a system. This software has been utilized in several studies.[18,24] Following the commencement of the MMT cessation and reception process, the intervention group underwent CBM sessions using the software twice a week for four weeks, with each session lasting between 15 and 30 minutes. After the fourth week, the cognitive bias evaluation was repeated. In contrast, the control group engaged in sessions with neutral images.

Before the initial assessment of attentional bias, both groups were presented with five neutral images to familiarize themselves with and practice the procedure. These images resembled provocative images but were designed not to evoke an emotional response. For example, one image depicted a person holding a cigarette while another showed the same individual holding a pen in a similar pose. A confirmation sign accompanied by an encouraging sound stimulus was provided if a neutral image was chosen, while selecting a provocative image resulted in a cross sign accompanied by an incorrect sound stimulus.[10,25]

The continuous variables were expressed as the mean±SD, and the categorical variables were presented as a percentage and frequency. Data analysis was done with using the independent sample t-tests, chi-square tests, and repeated-measures ANOVA. All statistical analyses were performed with SPSS (version 26.0, SPSS Inc, Chicago, IL, USA). A "P-value" less than 0.05 was considered significant.

This research received approval from the Research Ethics Committee of Isfahan University of Medical Sciences (ethics code: IR.MUI.NUREMA.REC.1401.049, project No. 1400515) and was registered in the Iranian Clinical Trials Registry (code: IRCT20141127020108N3). All participants provided written informed consent, and their rights were upheld in accordance with the Helsinki Declaration.

Results

In terms of demographic information, the majority of participants in both the intervention and control groups were under the age of 40, had experienced more than five opioid withdrawals, had a history of opioid abuse exceeding 17 years, held a primary education level (48.8%), were single (47.6%), self-employed (67%), and reported medium to low income levels (86.6%). The study included 40 individuals in the intervention group and 42 individuals in the control group who completed the study. Independent sample t-test results revealed no significant differences in demographic variables such as age, number of opioid withdrawals, and duration of opioid abuse between the intervention and control groups (P>0.05). Chi-square analysis findings indicated no significant distinctions in demographic characteristics such as education level, marital status, employment status, and income level between the two groups (P>0.05) [Table 1].

Table 1. Comparison of the study groups in terms of participants' demographic characteristics

Characteristics	Groups [a]		P value
	Intervention (n=40)	Control (n=42)	
Age (years)	39.95 ± 9.93	39.64 ± 8.23	0.879[b]
Number of opioid withdrawals	6.67 ± 4.97	5.78 ± 4.89	0.417[b]
Duration of opioid abuse (years)	17.70 ± 9.75	17.33 ± 8.73	0.858[b]
Education level			0.272[c]
Primary	19 (47.50)	21 (50.00)	
Intermediate	12 (30.00)	8 (19.00)	
Diploma	9 (22.50)	10 (23.80)	
Academy	0 (00.00)	3 (7.20)	
Marital status			0.965[c]
Single	19 (47.50)	20 (47.62)	
Married	11 (27.50)	10 (23.81)	
Separation	3 (7.50)	3 (7.14)	
Divorced	7 (17.50)	9 (21.43)	
Employment status			0.572[c]
Employed	1 (2.50)	0 (00.00)	
Freelancer	26 (65.00)	29 (69.00)	
Unemployed	13 (32.50)	13 (31.00)	
Income level			0.813[c]
Lower-Middle	35 (87.50)	36 (85.70)	
Upper-Middle	5 (12.50)	6 (14.30)	

[a]Values are presented as mean ± SD or n (%), [b]The results of the independent sample t-test, [c]The results of the Chi-square test. SD: Standard deviation

The repeated-measures ANOVA results showed a statistically significant decrease in the average stress scores of the intervention group before, immediately after, and two months post-intervention (P<0.001). In contrast, the changes in stress scores for the control group were not statistically significant. Similarly, the average anxiety scores in the intervention group showed a significant difference before, immediately after, and two months post-intervention (P<0.001), while no significant changes were observed in the control group. Additionally, there was a significant decrease in the average depression scores in the intervention group before, immediately after, and two months post-intervention (P<0.001) [Table 2].

Notably, the mean depression score before the intervention was 11.32 (5.01), which decreased to 7.92 (4.86) immediately after the intervention and 7.52 (4.61) two months post-intervention. Conversely, changes in the average depression scores for the control group were not statistically significant, mirroring the patterns seen in stress and anxiety. The t-test results for independent samples revealed significant differences in mean stress (P<0.05) and anxiety (P=0.003) scores between the intervention and control groups immediately after the intervention. However, there was no notable distinction in mean depression scores between the two groups (P>0.05). Similarly, two months after the intervention, the t-test results indicated significant differences in mean stress (P=0.007) and depression (P<0.05) scores between the intervention and control groups, while no significant difference was observed in average anxiety scores between the two groups (P>0.05) [Table 3].

Table 2. Within-group comparisons in terms of the mean score of the stress, anxiety, and depression disorders

Times	Groups		Disorders [a]		
			Stress	Anxiety	Depression
1. Before the intervention	Intervention (n=40)	F	11.58	12.91	13.90
2. Immediately after the intervention		df	1.99	1.92	1.91
3. Two months after the intervention		P-value [b]	0.000	0.000	0.000
	Control (n=42)	F	1.20	1.80	2.03
		df	1.99	1.86	1.88
		P-value [b]	0.304	0.171	0.138

[a] Values are presented as F and df, [b] The results of the repeated-measures ANOVA test. F: The ratio of two variances, df: The degrees of freedom

Table 3. Between-group comparisons in terms of the mean score of the stress, anxiety, and depression disorders

Times	Groups	Disorders [a]		
		Stress	Anxiety	Depression
Before the intervention	Intervention (n=40)	11.10±5.28	9.27±4.52	11.32±5.01
	Control (n=42)	11.83±5.35	9.07±5.36	11.26±5.26
P-value[b]		0.535	0.853	0.956
Immediately after the intervention	Intervention (n=40)	8.00±4.84	5.72±3.59	7.92±4.86
	Control (n=42)	10.66±5.68	8.80±5.27	10.02±5.97
P-value[b]		0.025	0.003	0.086
Two months after the intervention	Intervention (n=40)	8.42±4.57	6.77±4.22	7.30±4.61
	Control (n=42)	10.88±3.44	7.64±5.27	9.52±4.63
P-value[b]		0.007	0.415	0.044

[a] Values are presented as mean ± SD, [b] The results of the independent sample t-test. SD: Standard deviation

Discussion

The objective of this study was to assess the impact of software-based CBM on stress, anxiety, and depression levels in patients undergoing MMT. Recent advancements in experimental psychology have provided a deeper understanding of conscious and unconscious processes, including attention and approach biases, particularly among individuals with substance use disorders.[26] Cognitive bias procedures have largely focused on attentional bias, with ABM being utilized to train patients to concentrate on either positive or negative stimuli. Attentional biases play a crucial role in the development and treatment of stress disorders.[27] While CBM has shown promise in terms of its effectiveness, applying this technique to individuals with substance abuse issues presents several challenges. One such challenge is the absence of attentional and approach bias in CBM, as individual differences in various factors moderate the

extent of biases.[15,26] This limitation has hindered the impact of individual differences on the primary intervention. Researchers also encounter difficulties in selecting an appropriate tool to assess and modify cognitive biases when conducting CBM.[26] The current study effectively utilized CBM software as a suitable tool to reduce stress, anxiety, and depression disorders among participants.

The findings of the study by Gober et al. align with those of the present study, indicating that individuals addicted to opioids exhibit a higher bias towards the drug. However, Gober's review of 18 studies on different addictions revealed inconclusive evidence regarding the reduction of attentional bias through ABM.[27] While randomized clinical trials have demonstrated the clinical efficacy of ABM for anxiety disorders, further research is warranted in other diagnostic domains.[15,27] As evidenced by this randomized clinical trial, the present study showcases that ABM can effectively alleviate symptoms of stress, anxiety, and depression in patients undergoing MMT.

The study did not find a significant difference in the mean of depression scores between the intervention and control groups immediately after the intervention, nor in the mean of anxiety scores between the two groups two months post-intervention. Those considering implementing cognitive bias interventions should be mindful of the potential for adverse or ineffective outcomes and should identify factors that moderate attention bias to establish appropriate entry and exit criteria for such studies.[26] While some studies have suggested that cognitive bias remains relatively stable following any form of treatment,[28] many previous findings are inconclusive due to a lack of clarity on whether researchers effectively targeted bias using suitable instruments.[29] One strength of this study is its regional focus; while CBM has been implemented in various countries,[15] this is the first study to evaluate its impact on stress, anxiety, and depression disorders in Farsi-speaking participants using localized software, thereby confirming its beneficial effects on mental health issues. Participant identification posed challenges in this study due to the concurrent use of multiple substances by most abusers and difficulties in accessing female participants.

Conclusions

Based on the research outcomes, software-based CBM has shown potential in reducing stress, anxiety, and depression in patients undergoing MMT. Therefore, integrating this program with other treatment modalities could be beneficial in alleviating these mental health issues and enhancing the quality of life for MMT patients.

Acknowledgment

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Competing interests

The authors declare that they have no competing interests.

Abbreviations

Methadone Maintenance Treatment: MMT;
Cognitive Bias Modification: CBM;
Cognitive Behavioral Therapy: CBT;
Selective Serotonin Reuptake Inhibitors: SSRIs;
Attention Bias Modification: ABM.

Authors' contributions

MTK and MR contributed to the conception and design of the study, as well as provided critical revisions to the article for important intellectual content. AM and MR were involved in drafting the manuscript. TM and BZ conducted the intervention for the patients. FA and MTK collected and recorded data. AM and FA analyzed the data. All authors read and approved the final manuscript. All authors take responsibility for the integrity of the data and the accuracy of the data analysis.

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Role of the funding source

None.

Availability of data and materials

The data used in this study are available from the corresponding author on request.

Ethics approval and consent to participate

This research was approved by the Research Ethics Committee of Isfahan University of Medical Sciences (ethics code: IR.MUI.NUREMA.REC.1401.049, project No. 1400515) and was registered in the Iranian Clinical Trials Registry (code: IRCT20141127020108N3). All participants signed the written informed consent form and their rights were respected under the Helsinki Declaration.

Consent for publication

By submitting this document, the authors declare their consent for the final accepted version of the manuscript to be considered for publication.

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