Research Paper: Neuroscience-Informed Psychoeducation for Recovery: A Program to Promote Metacognition in People With Substance Use Disorders

Tara Rezapour[1], Mohammad Barzegari[2], Elham Sharifi[3], Nastaran Malmir[4], Hamidreza Ghiasvand[5], Mohammad Salehi[4,6], Alireza Noroozi[4], Hamed Ekhtiari[4,7]

1. Department of Cognitive Psychology, Institute for Cognitive Science Studies (ICSS), Tehran, Iran.
2. Department of Psychology, Faculty of Education and Psychology, Shahid Beheshti University, Tehran, Iran.
3. Department of Sociology, Faculty of Social Science, University of Tehran, Tehran, Iran.
4. Iranian National Center for Addiction Studies (INCAS), Tehran University of Medical Sciences, Tehran, Iran.
5. Department of Educational Psychology, Faculty of Social Science, Islamic Azad University, Saveh, Iran.
6. Department of Neuroscience and Addiction Studies, School of Advanced Technologies in Medicine, Tehran University of Medical Sciences, Tehran, Iran.
7. Laureate Institute for Brain Research (LIBR), Tulsa, OK, USA.

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ABSTRACT

Introduction: A brief neuroscience-informed psychoeducation program (Neuroscience-Informed Psychoeducation for Recovery [NIPER]) was developed to promote awareness (metacognition) in the main cognitive domains affected by drug and alcohol use to increase willingness to invest time and effort in the brain and cognition recovery process. The primary aim of this pilot study was to determine the feasibility and acceptability of the NIPER program and its potential effectiveness in increasing metacognition, psychological wellbeing, and willingness for the brain and cognition recovery programs among patients with Substance Use Disorders (SUDs).

Methods: A total of 56 patients with SUDs were recruited from four outpatient treatment centers in Tehran City, Iran. They participated in four 90-min weekly sessions delivered adjunct to their routine treatment. The program's effectiveness was measured in terms of metacognition and psychological wellbeing at baseline and the end of the program. The rate of adherence and participation and willingness to continue with brain and cognition recovery programs were measured as feasibility outcomes.

Results: A total of 51 participants completed the study. Compared to the baseline assessments, patients reported more problems in dimensions of attention, memory, inhibitory control, decision making, motor/speech, interoception, insight, and a higher level of psychological wellbeing ($t=4.66$; $P<0.001$). In terms of feasibility outcomes, the adherence and participation rates were found above 85%. Most participants expressed their high willingness to continue the brain and cognition recovery programs (86.2%) and would introduce NIPER to their peers (98%).

Conclusion: Considering the pilot results in terms of feasibility and preliminary effectiveness of NIPER in the clinical context of addiction treatment, we think that NIPER is a potentially beneficial intervention to be offered to people with SUD. It would increase their awareness and engage them in the brain and cognition recovery process. However, the clinical efficacy of the intervention should be tested in future randomized clinical trials.

*** Corresponding Author:**
Hamed Ekhtiari, MD, PhD.
Address: *Laureate Institute for Brain Research (LIBR), Tulsa, OK, USA.*
Tel: *+1 (918) 5025120*
E-mail: *hekhtiari@laureateinstitute.org*

Highlights

- Using the developed neuroscience-informed psychoeducation program increased subjective complains about cognitive problems in people with substance use disorders.

- Using the developed neuroscience-informed psychoeducation program increased psychological wellbeing in people with substance use disorders.

- Using the developed neuroscience-informed psychoeducation program increased willingness to attend brain and cognition recovery programs in people with substance use disorders.

Plain Language Summary

Neurocognitive deficits are common among people with substance use disorders that may hamper the recovery process in this group. One important cognitive function that may also be negatively affected by these neurocognitive alterations would be mental awareness or metacognition. Impairments of this ability cause individuals to underestimate their cognitive deficits (e.g., attention, memory) as well as to recognize their need for treatment. Therefore, improvement in metacognition may remove motivational barriers to invest time and effort in the brain and cognition recovery process and improve treatment outcome. In the present study, we shared the results of a feasibility data of a new neuroscience-informed psychoeducation program developed to promote metacognition in people with substance user disorders.

1. Introduction

As a brain disorder, addiction is characterized by a broad range of apparent and subtle cognitive deficits in areas of attention, episodic memory, and executive functions (e.g., inhibitory control, flexibility, planning) (Rezapour, Aupperle, Paulus, & Ekhtiari, 2020; Verdejo-Garcia et al. 2019). These deficits in substance users are clinically important, as they may contribute to poor treatment outcomes indicated by a high risk of dropout, low treatment compliance, and shorter abstinence (Bruijnen et al., 2019). Besides, cognitive deficits may affect an individual's self-efficacy and interfere with psychosocial, occupational, and daily living functioning (Bruijnen et al., 2019; Weber et al., 2012).

Studies considering cognitive functions in substance users reveal that chronic use of drugs and alcohol may adversely affect another cognitive function component termed as awareness or metacognition (Balconi, Finocchiaro, & Campanella, 2014). Metacognition is defined as an individual's ability to understand his/her cognitive functions and use this understanding to regulate them (Balconi et al., 2014; Wasmuth, 2015). Impairment of this ability has been reported in previous studies among substance users using neuroimaging, self-reports, and behavioral measurements (Goldstein et al., 2009; Jung, Kim, Kim, Oh, & Kim, 2011; Maremmani et al., 2012; Williams, Olfson, & Galanter, 2015). For example, it has been shown that functional and structural alterations in regions, such as the rostral anterior cingulate, anterior insula, and precuneus in people with SUDs, are associated with a lack of self-awareness. Behavioral and self-report measures also indicate discordances between individuals' self-assessments and their actual performance on cognitive tasks (Moeller et al., 2010) or their informant report on the existence of cognitive problems in people with SUDs (Verdejo-Garcia & Perez-Garcia, 2008).

These experimental results of metacognitive deficits become increasingly important when they contribute to the lack of insight and affect treatment outcomes. Substance users with poor metacognition are more reluctant to initiate or continue treatment and more likely to underestimate the need for changing behavior (Dean, Kohno, Morales, Ghahremani, & London, 2015). Thus improvement in metacognition may remove motivational barriers to invest time and effort in the brain and recovery process and improve treatment outcomes. Despite the importance of metacognition in the recovery process in substance users, there is a lack of intervention to target this function.

The Neuroscience-Informed Psychoeducation for Recovery (Niper) program has been designed as the first package in the field of drug addiction to raise an individual's awareness about cognitive deficits (metacognition)

associated with using drugs and alcohol. The program also motivates patients with SUDs to invest time and effort in their brain and cognition recovery process (Ekhtiari, Rezapour, Aupperle, & Paulus, 2017). To determine whether the intervention can be delivered to patients with SUDs who are receiving routine treatment, we conducted a one-arm open-label pilot trial in SUDs patients recruited from outpatient treatment centers. We assumed that providing patients with NIPER may improve their metacognition and increase their willingness to invest time and effort in the brain and cognition recovery programs.

2. Methods

Study setting

This is a single-arm, four-center trial conducted to assess the feasibility of a psychoeducation program designed for patients with SUDs in Tehran, Iran, between July and October 2019. To identify the interested outpatient centers, we advertised on the social media channels related to drug and alcohol addiction professionals. We provided information about the content and duration of the program. After initial expression of interest to participate, 4 centers (one academic and three private centers) agreed to take part in this study by providing 56 volunteer patients. Of these participants, 16 were recruited from center A, 17 from center B, 8 from center C, and 15 from center D. Then, they were trained in groups of up to 15. We had six groups (two groups from center A, two groups from center B, one group from center C, and one group from center D). In these centers, various models of addiction treatment, including opioid agonist pharmacotherapies with methadone, buprenorphine, and opium tincture, were provided for patients, as well as intensive outpatient psychosocial interventions for the treatment of stimulants use disorder.

Study participants

Since this research is a feasibility study, the sample size was not calculated. Instead, it was determined as 56 participants, based on the guidelines suggested for feasibility studies (Billingham, Whitehead, & Julious, 2013). We recruited the medically stable participants, those who could speak and write in Farsi, were between 18-65 years old, were diagnosed with opioid and or stimulant use disorders based on the Diagnostic and Statistical Manual of Mental Disorders (DSM–5). They had received a Standard Treatment Program (STP) based on the Iran Ministry of Health protocols and guidelines for more than 2 weeks and less than 24 weeks and were willing to participate in the research. The participants were excluded if they could not perform assessments and comprehend intervention-related information or were concurrently participating in another study receiving similar types of intervention besides STP, which might interfere with our program. Finally, they were excluded if they had major uncontrolled psychiatric disorders (including depression, bipolar or psychotic disorders) or had a history of suicidal attempts during last year. Eligibility criteria were assessed using self-reported data. All participants signed the written informed consent after providing all the necessary research-related information. Those participants who remained in the program and completed pre- and post-assessments were compensated at the end of the study for the time they spent in research and received a certificate of course completion. This study was approved by the Research Ethics Committee of Tehran University of Medical Sciences (Code: IR.TUMS.VCR.REC.1398.771).

Intervention

The intervention used in the present study was the Neuroscience-Informed Psychoeducation for Recovery (NIPER) program developed to promote an individual's metacognition as well as compensatory strategies and healthy lifestyle, which may support brain healing during addiction recovery (Ekhtiari et al., 2017). NIPER is a paper-based program consisting of four group sessions: each session is estimated to last 90 minutes (two 45-min parts, separated by a 10-min break). NIPER translates knowledge from the neuroscience of addiction into an individual's everyday life within three modules.

Part I: Brain literacy module

Some questions that may be raised by patients with SUDs planning for their recovery are as follows: What did drug/alcohol do to my brain? What are the signs of brain injuries caused by drugs/alcohol? How do you experience these brain injuries in everyday activities? To answer these questions, NIPER applies the Addictions Neuroclinical Assessment (Kwako, Momenan, Litten, Koob, & Goldman, 2016) and Research Domain Criteria (Insel, 2010) frameworks to define the most affected brain functions by using drug/alcohol. According to these frameworks, patients with SUDs experience various impairments in the areas of negative valence, positive valence, cognitive control, attention, memory, perception, understanding of self/others, arousal, and motor functions. Each system is composed of different subcomponents depicted as the circles in Figure 1.

Each session starts with a first-person narrative of a subjective experience of cognitive deficits associated

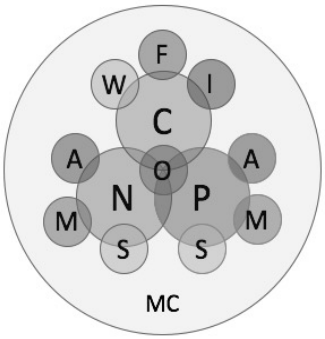

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Figure 1. Main cognitive domains addressed in the Neuroscience-Informed Psychoeducation Program for Recovery (NIPER) The three main cognitive systems (bigger circles) include: N= negative valence, P= positive valence, C= cognitive control. The subcomponents are Working memory (W), Saliency processing (S), Inhibition (I), Flexibility (F), Interoception (O), Attention (A), Memory (M), Metacognition (MC) to self (insight) and others (social cognition).

with drug and alcohol use and colorful cartoons depicting the relevant sign that emerges in real life. Figure 2 illustrates all of the cartoons used for this module, as well as the related scenario for each main domain of cognitive deficits. Brain literacy modules encourage individuals to share their personal experiences of having similar cognitive deficits and their associated problems in their daily lives with others in the group. After group discussion, the participants are provided with a series of paper-pencil exercises that demand the discussed cognitive functions (e.g., "spot the difference" exercise for attention and the different Stroop exercises for inhibitory control). By practicing this part, the participants gain a deeper understanding of the discussed cognitive functions. This module takes around half of the time in each session.

Part II: Brain recovery-supporting activities module

The second half of each session provides ideas on the recovery supporting activities that engage the cognitive functions addressed in the brain literacy module. For this module, the patients are asked to practice these activities regularly and talk about their personal experiences in the next session. These activities can be easily embedded in daily life activities and do not need particular tools. For example, to reinforce memory function, participants are trained to record daily events in a notebook, named as brain book, and try to visualize events as they record. These activities are selected from routine exercises practiced in cognitive rehabilitation programs.

Part III: Healthy brain lifestyle module

Each session ends with triggering the curiosity of individuals by asking this question: "What can we do to help the process of brain healing?" Before initiating this module, it is imperative to explain the duration and speed of the brain healing process during addiction recovery. NIPER uses "a broken hand" metaphor for the brain in the recovery process to explain how the brain needs active support to gradually obtain the normal cognitive functions (similar to the range of motion for a broken hand). A set of evidence-based recommendations which may foster the brain healing process are provided in the form of "to-dos" to improve a recovery-supporting lifestyle. These recommendations emphasize the components such as a healthy diet, physical activities, social communications, mental activities, and sleep quality and their importance for brain recovery.

Therefore, NIPER provides patients with SUDs with critical information about brain functions that are affected by drug and alcohol use, as well as activities and strategies that may promote the brain healing process during addiction treatment. NIPER has been developed to help patients with SUDs know more about addiction as a brain disease and use this awareness in their real life. The content of the three NIPER modules is described in more detail in Table 1. NIPER was initially developed in a grayscale version and consisted of a 116 A-5 size booklet.

In this study, NIPER was delivered by four trained providers (MB, ES, NM, HG), each communicating with one clinical site constantly during the study. All providers had at least a bachelor's degree in psychological or social sciences and prior clinical experiences working with patients with SUDs. To improve treatment fidelity, providers had been trained about the intervention through several online meetings before this study, and sessions were supervised weekly by the program developers (HE and TR). They were also asked to record the exact amount of time spent for each training session and reported the extra time

Cognitive Functions	A Part of Narrative scenario	Cartoons	Cognitive Functions	A Part of Narrative scenario	Cartoons
Attention	I often experience that environmental triggers can produce an inability in me to control my desire to use my drug of preference, even when I do not want to use because using is all I can think.		Decisions & Control	I can make a decision to refrain from using but many times, I am unable to follow-through with my decision. I feel powerless over my ability to not use, even when I don't want to. especially if I have recently used.	
Memory	I believe my memory has been negatively affected by my drug use. I am experiencing lapses in short-term memory, forgetting things as recent as what I had for lunch or if I returned a phone call. I feel like this may cause others to loose trust in me.		Motor	I often find myself searching for the right words in conversations, words I used to know in the context for which I seek them. I feel very limited in my vocabulary resources. I also feel like my coordination and dexterity have diminished.	
Negative valence	I often experience negative feelings like a dramatic sense of guilt, becoming stuck in the self-debasement, and a profound fear of abandonment. Experiencing these feelings around my drug use creates a great deal of anxiety.		Awareness & Insight	Despite what some of my friends, relatives, and co-workers might say, I do not see myself as someone who has a disease, needs medical care or other treatment. I only drink and use recreationally and can stop anytime I want to.	
Interoception	I do not feel like I am in touch with my bodily senses anymore. When I am stressed, craving, depressed or anxious I do not feel like my mind and body communicate; therefore, I am not aware what my body may need at certain times. such as when I need to hydrate.		Social Cognition	I have difficulty identifying and expressing my emotions, clearly and understandably. I realize that I cannot accurately pick-up on cues coming from other people about how they see me or interpret my behavior, so I have lost my ability to empathize.	
Arousal & Sleep	I have a difficult time falling asleep and staying asleep. I wake-up startled and anxious. I can feel my heart beat too loudly, remain anxious, excitable and easily aroused. I find it very hard to become calm once I am experiencing these states. In contrast, sometimes I feel drowsy and sleepy.		Positive valence	The seduction of drugs for me is highly rewarding and beckons me, loudly and frequently. The rewarding experience begins with simply thinking about my drug or obtaining it. It induces a kind of pleasure for me that even thinking about them not just seeing, causes this change. I seem to avoid doing things that I used to enjoy.	

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Figure 2. The brain literacy modules of NIPER, including cognitive domain, narrative scenario and cartoons designed in 10 domains and distributed in 4 sessions

spent for participants individually. Moreover, to ensure that the training materials were delivered equally for all training groups, NIPER was offered a structured booklet, given similarly to all training groups (Bellg et al., 2004).

Study measures

Training providers collected self-report data from participants at baseline (week 0) and the end of the intervention (week 4), including basic information, metacognition, and psychological wellbeing. Data about feasibility outcomes were also collected in terms of adherence and participation rate, as well as the participants' opinions about the program.

Patients' basic information

Basic information, including sociodemographic (age, years of education) and addiction-related data (main substance use, age of onset, years of use, previous addiction treatment experience), were collected at baseline.

Metacognition

Metacognition was evaluated using a developed instrument based on the NIPER's cognitive domains inspired by the "measure of insight into cognition" (Saperstein, Thysen, & Medalia, 2012). This instrument includes 10 self-report items asking individuals whether they have perceived cognitive problems rating on a 5-point Likert scale (0=not at all to 5= a lot). The items are adjusted to tailor cognitive functions in the NIPER program. They consist of difficulty with attention and concentration, a decline in memory function, diminished behavioral control, difficulties in decision making, difficulties in speech and movement, distorted brain-body connection, sleep problems, increased negative emotions, decreased positive emotions, difficulties in social interactions, and decline in self-awareness and insight. A higher score for each item represents a higher level of perceived impair-

Table 1. An overview to the content of the three modules in the NIPER program during 4 sessions

Session	Brain Literacy Module	Brain Activities Module	Healthy Lifestyle Module
First	1. Attention 2. Memory	1. Do word exercises 2. Be your "present-moment" attention coach 3. Train your brain to be flexible 4. Journal in your brain book 5. Play "memory games" 6. Reduce "brain clutter"	1. Be more mentally active 2. Be a healthy foodie
Second	1. Negative valence 2. Interoception 3. Arousal & sleep	1. Use positive language 2. Live in gratitude 3. Volunteer for charity work 4. Practice body-presence 5. Observe your heart rates 6. Practice mindfulness 7. Create a sleep heaven 8. Pamper yourself occasionally 9. Enjoy the benefits of warmth/heat	1. Be Calm and relaxed 2. Be in Tune with Your Emotions 3. Be a Healthy Sleeper
Third	1. Decision & control 2. Motor	1. Set daily goals 2. Track your money 3. Practice patience 4. Practice paraphrasing 5. Enjoy the "artist in you" 6. Improve dexterity	1. Commit to abstinence from intoxicants 2. Be more physically active
Forth	1. Positive valence 2. Social cognition 3. Self-awareness	1. Observe your brain processes 2. Attend to your posture 3. Live weight-conscious 4. Use compassion and understanding 5. Allow yourself to be transparent 6. Be a voice analyzer 7. Be a member of the happiness club 8. Be a "hobbyist" 9. Detox your brain from negative memories by making positive ones	1. Be a healthy friend to yourself 2. Be a more socially active 3. Be patient and hopeful

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ments. The participants were asked to fill out the instrument at baseline and the end of the intervention.

Psychological wellbeing

To assess the program's effect on psychological wellbeing, we used the World Health Organization quality-of-life scale (Nejat, Montazeri, Holakouie Naieni, Mohammad, & Majdzadeh, 2006). This subset includes six items that focus on the ability to concentrate, self-esteem, body image, spirituality (i.e., the extent to which they feel their life is meaningful), and the frequency of positive or negative feelings (i.e., blue mood, despair, anxiety, depression). The participants were asked to rate each item on a 5-point scale (0= not at all to 5= extremely amount). The total score was then transformed on a 0–100 scale, in which higher scores indicate higher psychological wellbeing. In the present study, we used the Persian version of the scale validated by Karimlou , Zayeri and Salehi (2011).

Feasibility outcomes

To collect data about the feasibility of the program, the rate of adherence and participation was evaluated by the number of participants who remained in the intervention (who completed pre-assessment and post-assessment and attended to at least three from four sessions), and the number of participants took part in each session, respectively. They were also asked to rate their willingness to introduce the NIPER to their peers and continue investing time and effort in the brain and cognition recovery process (e.g., cognitive training/rehabilitation). These questions were asked after the intervention.

3. Results

Sample characteristics

Of 56 patients who participated in the NIPER intervention and completed the baseline assessments, 51 remained and were re-assessed at the end of the intervention. Five participants dropped out after the first session due to uncertain reasons. All participants were men and were recruited during their early abstinence phase (the first month of abstinence). Table 2 indicates the descriptive characteristics of the samples.

Table 2. Demographic and substance use related data of the retained sample (n=51)

Variables		Mean±SD/No. (%)
Age		38.04±9.97
Years of education		11.45±3.34
Days of abstinence		23.91±10.3
Main substance used	Opioids	40(78.4)
	Stimulants	11(21.5)
	Age of main substance use onset	22.94±6.54
	Years of main substance use	9.86±6.15
Previous addiction treatment experiences	Yes	42±82.3
	No	8±17.6
History of injection	Yes	6±11.8
	No	44±86.3

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Metacognition

To compare metacognition from baseline to post-intervention, two paired-sample t test was used for each item. As shown in Table 3, the participants reported significantly higher impairments in the domains of attention, memory, control, decision making, motor and speech, interoception, and insight. While participants' mean scores increased for the other dimensions, they were not statistically significant (P>0.05).

Psychological wellbeing

At baseline, the Mean±SD psychological wellbeing score was 36.14±15.17, and at the end of the intervention, this score increased to 43.39±16.01, indicating a significant improvement (t_{50}= -4.66, P<0.001, 95% CI: -10.37, -4.13).

Feasibility outcomes

The adherence rate was 91% (51 of 56 participants completed the intervention and pre-assessment and post-assessment). The participation rate was calculated for each session regarding the total number of participants who attended. The results were as follows: 96% (n=49) in the first session, 94% (n=48) in the second session, 96% (n=49) in the third session, and 98% (n=50) in the fourth session. Regarding the willingness to continue with brain and cognition recovery programs, 1 participant (2%) rated his response as very low, 6 (11.8%) as medium, 17(33.3%) as high, and 27(52.9%) as very high. Finally, most participants (n=50, 98%) said that they would introduce the NIPER to their peers.

4. Discussion

This pilot study aimed to test the feasibility of a new neuroscience-informed psychoeducation program in the context of addiction recovery. The results indicated that the intervention is feasible and acceptable for patients with SUDs. In other words, the program can improve their understanding of deficits related to attention, memory, behavioral control, decision making, motor and speech, interoception, and insight. These results should be interpreted with caution since we did not have a control group, and these changes could also be related to the progress in the standard treatment program during the one month of the intervention. Regarding feasibility measures, we found an acceptable rate of adherence and participation throughout the intervention and a high rate of willingness to continue the program.

We did not find any significant difference between an individual's self-report on sleep, negative feeling, positive feeling, and social interaction problems between before and after assessments. These deficits might be more apparent to the individual to perceive and detect in the everyday functioning even before receiving the NIPER (e.g., extended sleep onset latency, more nighttime awakenings) (Hasler, Smith, Cousins, & Bootzin, 2012).

Table 3. Changes in perceived cognitive impairments from baseline to post-intervention (n=51)

Domain	Mean±SD		t	P	95%CI
	Pre- intervention	Post- intervention			
Having problem with attention	2.69±1.5	3.63±1.3	-4.39	<0.001	-1.36, -0.51
Having problem with memory	2.80±1.4	3.32±1.2	-2.05	0.04	-1.02, -0.01
Having problem with inhibitory control	2.73±1.8	3.29±1.2	-1.77	0.08	-1.17, 0.07
Having problem with decision making	2.61±1.4	3.17±1.1	-2.40	0.02	-1.09, -0.09
Having problem with motor and speech	2.42±1.6	3.34±1.1	-3.37	0.001	-1.47, -0.37
Having problem with interoception	2.64±1.4	3.4±1.03	-2.79	0.008	-1.31, -0.21
Having problem with sleep	2.94±1.5	3.26±0.9	-1.54	0.12	-0.73, 0.09
Having problem with negative feeling	2.66±1.5	3.08±1.1	-1.84	0.07	-0.88, 0.03
Having problem with positive feeling	3.08±1.4	3.27±1.1	-0.73	0.46	-0.68, 0.31
Having problem with social interaction	3.06±1.3	3.35±1.1	-1.17	0.24	-0.77, 0.20
Having problem with awareness and insight	2.60±1.3	3.38±1.3	-3.15	0.003	-1.26, -0.27

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NIPER is one of the first attempts to translate the brain-related topics in addiction into a stand-alone psychoeducational program with therapeutic intention. In parallel to our study, similar neuroscience-based approaches were used to develop prevention programs to reduce the risky use of drugs and alcohol in young students by providing neuroscience-based information on addiction (Debenham, Birrell, Champion, Askovic, & Newton, 2020).

Following this feasibility study, further studies are necessary to conclude the efficacy of the NIPER in addiction medicine. Future studies should be designed in the form of randomized clinical trials with larger sample sizes and control groups. These trials should consider the clinical outcomes and monitor potential changes over a follow-up period. However, the expectations should not exceed the potentials for a 4-session brief intervention.

The impact of improved metacognition on the recovery process has been broadly investigated in different psychiatric disorders (e.g., schizophrenia, bipolar disorder). This relation has been investigated through measures, including medication acceptance and therapeutic alliance (Moritz et al., 2018). Improved metacognition may also affect outcomes of brain and cognition recovery programs (e.g., cognitive rehabilitation) in two ways. First, patients with SUDs who acquire this awareness may perceive these interventions as more meaningful and necessary for addiction recovery. Thus, they become more motivated to participate in the cognitive training/rehabilitation programs actively and less likely to drop out, which is a challenging part of the addiction treatments. Secondly, this neuroscience-informed look towards addiction and its brain deficits and potentials for brain recovery may benefit individuals who deny their current deficits and are not hopeful for brain recovery even when they are aware of these brain deficits. This new metacognitive awareness may reduce resistance to therapeutic interventions. In conclusion, this pilot study demonstrates the feasibility and acceptability of implementing a neuroscience-informed psychoeducational intervention for substance users. We hope that providing such an educational program for patients with SUDs who are commonly suffering from a lack of proper understanding about their cognitive deficits could enable them to recognize their problems, assign them to their drug use disorder and perceive the need for appropriate treatment. Offering these types of metacognition enhancing programs may be even more crucial at the early stage of addiction treatment (Maremmani et al., 2012) when individuals are more ignorant about their addiction-related problems, particularly the cognitive ones.

Ethical Considerations

Compliance with ethical guidelines

All ethical principles are considered in this study. The participants were informed of the purpose of the research and its implementation stages. They were also assured about the confidentiality of their information. They were free to leave the study whenever they wished, and if desired, the research results would be available to them. Written consent has been obtained from the subjects. Principles of the Helsinki Convention were also observed. The study was approved by the Ethics Committee of the Tehran University of Medical Sciences (Code: IR.TUMS.VCR. REC.1398.771).

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Authors' contributions

All authors equally contributed to preparing this article.

Conflict of interest

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