Development and Psychometric Assessment of Lapse Management Program and Educational Content After Quitting in Patients with Substance Use Disorders

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Abstract

**Background:** Despite advances in the treatment of substance abuse disorders, some clients experience lapse and relapse after treatment. As a stage before relapse, the lapse is a major challenge in the treatment of addiction.

**Objectives:** This study attempted to develop and psychometrically assess a lapse management program and its educational content after quitting in patients with substance use disorders.

**Methods:** This study was performed in two parts. In the first part, the program and its educational content were designed, and in the second part, it was validated using the opinions of 10 experts in two phases. For program validation, face validity and content validity were used both qualitatively and quantitatively.

**Results:** The lapse management program and its educational content were designed based on self-awareness skills in eight sessions. The validation results showed that the minimum and maximum CVR values for each component of the program were calculated as 0.8 and 1, respectively. Also, the minimum and maximum CVI values were 0.86 and 1, respectively. Moreover, the average content validity index for the entire program was 0.94.

**Conclusions:** The results showed that the lapse management program and its educational content had a good face and content validity for recovering clients and enjoyed the necessary validity for educational, clinical, and research applications.

**Keywords:** Lapse Management, Validation, Self-awareness, Substance Use Disorders

1. Background

Substance use disorder is a chronic, relapsing condition that is difficult to treat (1). Despite advances in the treatment of substance abuse disorders, it has been observed that some clients experience lapse and relapse shortly after treatment (2). The lapse is a major challenge in the treatment of addiction that occurs before relapse (3).

Studies show that 80 - 95% of people who complete the addiction treatment course will have a relapse within one year after treatment (4). Researchers indicate that lapse and relapse are influenced by various factors such as the severity of stressors, extreme craving for consumption, impaired coping skills, low self-efficacy (5-7). Besides, studies with two-year or longer follow-up periods have shown that 25 - 50% of participants move between abstinence and consumption periods (8). On the other hand, lapses during the treatment process increase the risk of relapse and, thereby, the chance of treatment withdrawal and permanent return to drug use (9). This is associated with more negative consequences such as the possibility of consuming larger amounts of the substance, more severe drug dependence, multidrug dependence, increased criminal behaviors, and the imposition of additional costs on the health care system (10).

Various studies have emphasized the importance and role of self-awareness in the successful prevention and control of addiction (11-13). Researchers such as Ahmed et al. and Sevari et al. have shown that self-awareness interventions can improve self-efficacy (13, 14). On the other hand, high self-efficacy creates a strong barrier to recurring behaviors such as lapses. Koohestani et al. concluded that education and intervention about the factors affecting the lapse and strengthening coping skills will reduce lapses in...
addicts (15).

Some studies have proposed different interventions to prevent relapse, including the cognitive-behavioral model of relapse prevention (16), and mindfulness-based interventions (17). In these models, the issue of lapse is discussed only briefly, and none of them directly uses self-awareness skills. As long as the person does not reach the point of self-awareness in his treatment, there should be little hope of survival of the treatment. Due to the importance and high impact of self-awareness on abstinence self-efficacy, it is necessary to pay the self-awareness skill directly in the lapse management program. In this program, the self-awareness skill is taken from the self-awareness part of the WHO life skills program, and the concepts of lapse and craving are taken from the Marlatt cognitive-behavioral model.

2. Objectives

According to the search results in various databases (Pubmed, Scopus, ISI, Science Direct, Google Scholar, ISC, and SID), no study or content was found to use self-awareness skills in lapse management. Thus, the present study was done to design and validate a lapse management program and educational content after quitting of addiction.

3. Methods

This study is part of a larger study that was performed in two sections. In the first section, the information needed to design the program was collected in two ways. First, in the theoretical stage, a literature review guided the collection of data related to the re-use of drugs (lapse and relapse), the factors affecting drug re-use, and countermeasures and preventive strategies. For this purpose, the keywords including lapse, substance use disorders, and relapse prevention, along with their Persian equivalents and their combinations, were searched in books and articles indexed and published until March 2019 in Pubmed, Scopus, Science Direct, Google Scholar, ISI, ISC, and SID databases.

Then, qualitative data were collected through face-to-face interviews with 10 clients undergoing methadone maintenance treatment to determine the educational needs of the clients in terms of lapse management. The participants were selected purposively according to the inclusion criteria. Accordingly, individuals who had attempted to quit addiction during the past six months and had at least three positive urine tests (lapse) as reported in their records were asked an open-ended question, "What training do you need to avoid committing lapses?" The duration of each interview was about 45 minutes, and each person was interviewed in one to two sessions.

Subsequently, a five-member focus group was formed with the participation of a psychiatrist, a psychiatric nurse, and three nursing professors to design and develop a preliminary program by combining the results of the previous stage (needs assessment and literature review). The meeting continued for three hours, during which each item (component) of the program was discussed, and the items were prioritized by consensus until the program was finally developed.

In the second section of the study, the opinions of a panel of experts were used to validate the program. The members of this panel comprised 11 experts in the fields of psychology (n = 4), psycho-nursing (n = 3), and psychiatry and addiction therapy (n = 2), as well as two lecturers in the field of addiction, who were selected by purposive sampling. The inclusion criteria were theoretical mastery, practical experience, and willingness to participate in research. After the panel members were selected, the materials (package) and the questionnaire were distributed and collected in two stages, either in person or electronically.

In the first stage, the program and educational content were provided to all members of the panel of experts (11 people) in the form of a booklet, along with a questionnaire that held open-ended questions. They were asked to observe the accuracy and appropriateness of the contents in terms of grammar and vocabulary, simplicity, relevance, and clarity (face and content validity). The participants were also asked to indicate any other considerations.

In the second stage, the modified program was given (in the form of a booklet) to the panel of experts (n = 10; one of the panel members withdrew from cooperation after the first stage), along with another questionnaire. This questionnaire contained questions to evaluate the face and content validity of the program quantitatively.

The quantitative content validity was assessed using the content validity ratio (CVR) and content validity index (CVI). To determine the CVR, experts were first asked to comment on the necessity of each item on a three-point Likert scale: necessary, useful but not necessary, not necessary (Formula 1).

\[ CVR = \frac{nE - \frac{n}{2}}{n} \]  

(1)

In this formula, "nE" is the number of specialists who have selected the necessary option, and "n" is the total number of evaluators. To determine the CVI, the panel members were asked to comment on the relevance, simplicity, and clarity of each item on a four-point Likert scale (Formula 2).

\[ CVI = \frac{\text{No. of agree responses with 3rd and 4th ranks}}{\text{total number of responses to each item}} \]  

(2)

Also, quantitative face validity was determined by calculating an impact score. In this way, experts were asked to
comment on the importance of each item on a five-point Likert scale: from totally important (score 5) to not important at all (score 1):

\[ \text{Impact Score} = \text{Frequency (\%)} \times \text{Importance} \]

The "Frequency" in the formula was the number of people who rated the items 4 and 5, and "Importance" was the mean score of the respondents based on the Likert scale. At the end of this stage, face validity was assessed through face-to-face interviews with the target group. In this way, the finalized program was given to 10 randomly selected methadone maintenance clients to comment on the level of difficulty, the degree of appropriateness, and any ambiguity in the program.

4. Results

In the first stage of the study, the educational needs of the clients concerning post-lapse management were identified. The most important needs were related to controlling craving, controlling anger, improving family relationships, coping with life problems (problem-solving), controlling thoughts, dealing with inappropriate friends (saying no), and considering post-lapse actions.

The lapse management primary content was initially designed using information obtained from client needs assessment and related resources. Then, using the comments from the focus group, the main components and items were determined, and the content was finalized. The main items extracted from the content included lapse, craving, self-awareness, and self-efficacy. It should be noted that no item was eliminated in the validation process.

4.1. Introduction of the Program

The present program is an eight-session training and counseling course for post-treatment lapse prevention and control in substance abusers. The contents of the program were presented in a group-based manner (in person) and individually (by telephone) through short lectures, group discussions, homework using worksheets, and telephone follow-ups. The most important strategies used in these sessions comprised coping skills, including assertive behavior and saying no, anger management skills, and problem-solving skills (according to the needs assessment in the first phase of the study).

4.2. Lapse Calendar Self-assessment Technique

This technique involves preparing a calendar for the whole year. Each day when the client has no lapse, a big checkmark will be placed in the cell of that day, representing a non-lapse day. The client must make every effort not to break the chain so that at the end of the year, he will see the progress toward one year without lapse. It was necessary to follow the implementation of the calendar technique in all telephone sessions.

4.3. Program and Educational Content Validation

In the first stage, after the opinions of the experts were collected, the sections were modified and revised. These comments were mainly concerned with simplifying and editing some of the sentences.

The minimum and maximum CVR values for each item or component of the program were calculated as 0.8 and 1, respectively. Given n = 10 for the panel members and the minimum acceptable amount to verify the content validity of the program components, which was 0.62 (18), the CVR value obtained was appropriate for each component or item of the program. Also, the minimum and maximum CVI rates for each item or component of the program were 0.86 and 1, respectively. This suggests that all components of the program had a score above 0.79 (19) and were appropriate. Finally, the mean content validity index for the entire program was 0.94.

In the quantitative assessment of face validity, an impact score of 1.5 or above for an item was the criterion for maintaining that item (20). Overall, all items had impact scores above 1.5 (4.5 - 5), and thus all the items were maintained. Finally, the results of face-to-face interviews with the clients showed that the program was simple and clear enough and was well designed to fit the purpose of the program (lapse management). Table 1 shows the program and the findings related to face and content validity from the experts’ points of view.

5. Discussion

The present study aimed to develop and psychometrically assess a lapse management program and educational content after quitting in patients with substance use disorders. In this study, first, the educational needs of the clients concerning lapse management were identified. Based on the findings, the most important needs were related to controlling craving, controlling anger, improving family relationships, coping with life problems (problem-solving), controlling thoughts, dealing with inappropriate friends (saying no), and considering post-lapse actions.

The findings also showed that the main items extracted from the content included lapse, craving, self-awareness, and self-efficacy. Actually, the lapse management program provides training and skills related to lapse, craving, self-awareness, and self-efficacy, designed in eight sessions of training and counseling. Then, it was validated using the opinions of 10 experts. The research results showed that this program and its educational content had an appropriate face and content validity. Validation results showed that the minimum and maximum CVR values for each component of the program were calculated as 0.8 and 1, respectively. Also, the minimum and maximum CVI values were 0.86 and 1, respectively. These findings indicate that this
program and its educational content had an appropriate face and content validity.

According to the findings of this study, one of the main causes of lapse and relapse is craving, which, if not controlled properly, leads to the re-use of drugs (21). According to previous studies, one of the important ways for reducing craving in clients is to increase their awareness of the conditions and symptoms that cause craving and teach them how to deal with these symptoms more effectively (22). Exposure to situations associated with consumption causes the urge to consume craving and then recurrence (23). As a result, the person more aware of high-risk and tempting situations, cause to avoid them the better or apply the coping skills learned in the face of them.

In this program, to prevent return, the client is helped to identify and plan to deal with high-risk situations that may occur in the future, and is taught coping strategies and special skills to avoid the craving. Such training improves the sense of efficacy, develops self-control strategies in high-risk situations, and reduces the risk of lapse.

Relapse behaviors and factors affecting it, including craving, are behaviors that are not completely under the control of one's will. Therefore, the client requires an efficient structure that can help control such behaviors,
such as self-awareness. By reinforcing self-efficacy (24), self-awareness interventions can also be conducive to preventing early treatment discontinuation (by preserving treatment motivation) and improving addiction treatment outcomes (13). The feeling of self-efficacy refers to a person’s judgment of his/her ability to cope successfully with high-risk situations. Low levels of this feeling are associated with the recurrence of drug use, and high levels are associated with avoidance of drug use (25). Litt et al. (2008) stated that self-efficacy was the best predictor of continued substance abstinence after one year (26).

The lapse management program helps clients to change their responses to negative emotions by increasing their awareness of their strengths and weaknesses, as well as the thoughts and emotions that accompany cravings, without responding immediately to consumption craving.

One of the items obtained from this content and program was motivation reinforcing through the use of the lapse calendar self-assessment technique. Various studies have shown that enhancing the motivation for abstinence and self-control can reduce the risk of a lapse in substance-dependent individuals (27, 28). It seems that the use of the lapse calendar self-assessment technique can also be effective in controlling lapses by strengthening these factors.

The checkmarks put in the calendar boxes help persons to cling to their goals, which is the continuity of abstinence in the face of factors that motivate lapses. In this way, the person is encouraged to go from one day without a lapse to one year without a lapse. The continuity of the checkmarks on the calendar strengthens one’s motivation to stay on the path of quittance (29, 30).

In general, it can be said that this program, by creating awareness of slippery situations on the one hand and self-awareness and change in thoughts and feelings on the other hand, can make positive changes in addictive behaviors and the desire to re-use. Finally, it is suggested that to operationalize this program in the community and use it for lapse and relapse prevention in clients with substance-related disorders, clinical trials are performed to demonstrate the impact of the lapse management program.

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Footnotes

Authors’ Contribution: Study concept, design, and drafting of the manuscript, HKh and MN.; Study supervision, AE.; Interpretation of data, GhSh and HKh.; Critical revision of the manuscript, MN, SAV, and HKh.

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References

1. Shorey RC, Elmoquist J, Gawrysiak MJ, Strauss C, Haynes E, Anderson S, et al. A randomized controlled trial of a mindfulness and acceptance group therapy for substance use patients. Subst Use Misuse. 2017;52(1):1400–10. doi: 10.1080/10826084.2017.1284232. [PubMed: 28430015]. [PubMed Central: PMC6080615].

2. Jalali A, Seyedfatemi N, Peyrovi H. Relapse model among Iranian drug users: A qualitative study. Int J Community Based Nurs Midwifery. 2015;3(1-2-11). [PubMed: 25553329]. [PubMed Central: PMC4280553].

3. Smyth BP, Barry J, Keenan E, Ducray KJIMJ. Lapse and relapse following inpatient treatment of opiate dependence. Ir Med J. 2000;103(6):376-9. [PubMed: 20669601].

4. Hendershot CS, Witkiewitz K, George WH, Marlatt GA. Relapse prevention for addictive behaviors. Subst Abuse Treat Prev Policy. 2010;5:37. doi: 10.1007/s11747-009-9147-6. [PubMed: 21771341]. [PubMed Central: PMC316190].

5. Law B, Gullo MJ, Daglish M, Kavanagh DJ, Feeney CF, Young RM, et al. Craving mediates stress in predicting lapse during alcohol dependence treatment. Alcohol Clin Exp Res. 2016;40(5):1054-64. doi: 10.1111/acer.13034. [PubMed: 27012658].

6. Kadden RM, Litt MD. The role of self-efficacy in the treatment of substance use disorders. Addict Behav. 2012;36(12):1120–6. doi: 10.1016/j.addbeh.2011.07.032. [PubMed: 21849232]. [PubMed Central: PMC379802].

7. Witkiewitz K, Bowen S. Depression, craving, and substance use following a randomized trial of mindfulness-based relapse prevention. J Consult Clin Psychol. 2010;78(3):362-74. doi: 10.1037/a00199072. [PubMed: 20255211]. [PubMed Central: PMC2880693].

8. McKay Jr, Franklin TR, Patapits N, Lynch KG. Conceptual, methodological, and analytical issues in the study of relapse. Clin Psychol Rev. 2006;26(2):199-27. doi: 10.1016/j.cpr.2005.11.002. [PubMed: 16371242].

9. Agapie E, Avrahami D, Marlow J. Staying the course: System-driven lapse management for supporting behavior change. Conference on Human Factors in Computing Systems. San Jose, California, United States. CHI ’16: Proceedings of the 2016 CHI Conference on Human Factors in Computing Systems; 2016. p. 1072–83.
10. Oraki M, Bayat S, Khodadust S. [Study of effectiveness mindfulness cognitive therapy and marlaat relapse preventive intervention for mental health in male crack addictions]. Health Psychol. 2012;22-30. Persian.
11. Castine BR, Albein-Unios N, Lozano-Rojas O, Martinez-Gonzalez JM, Hohwy J, Verdejo-Garcia A. Self-awareness deficits associated with lower treatment motivation in cocaine addiction. Am J Drug Alcohol Abuse. 2019;45(1):308-14. doi: 10.1080/00952990.2018.1517255. [PubMed: 30883371].
12. Moeller SJ, Goldstein RZ. Impaired self-awareness in human addiction: deficient attribution of personal relevance. Trends Cogn Sci. 2014;18(12):635-41. doi: 10.1016/j.tics.2014.09.003. [PubMed: 25278368]. [PubMed Central: PMC4254155].
13. Sevari K, Mansheshadi S. The efficacy of self-awareness training on reduction of internet addiction and loneliness and increase of self-efficacy. Clinical Psychology Studies. 2016;6(2):163-79.
14. Ahmed HA, Almasri YM. Effect of self awareness education on the self efficacy and sociotropy-autonomy characteristics of nurses in a psychiatry clinic. Life Sci. 2013;8(2):55-63.
15. Koohestani Z, Shoja M, Nabavi SH, Shoja M. [Survey of affecting factors the lapse among the patients referring voluntarily to addiction-abandoning centers in Esfarayen]. Journal of North Khorasan University of Medical Sciences. 2014;5(5):1145-51. Persian. doi: 10.29252/jnkums.5.5.55145.
16. Salehi L, Alizadeh L. Efficacy of a cognitive-behavioral relapse prevention model in the treatment of opioid dependence in Iran: A randomized clinical trial. Shiraz E-Medical Journal. 2018;In Press. doi: 10.5812/emj.14707.
17. Bowen S, Witkiewitz K, Cliftasefi SL, Grow J, Chawla N, Hsu SH, et al. Relative efficacy of mindfulness-based relapse prevention, standard relapse prevention, and treatment as usual for substance use disorders: A randomized clinical trial. JAMA Psychiatry. 2014;71(5):547-56. doi: 10.1001/jamapsychiatry.2013.4546. [PubMed: 24647726]. [PubMed Central: PMC4438971].
18. Lawshe CH. A Quantitative Approach to Content Validity. Pers Psychol. 1975;28(4):563-75. doi: 10.1111/j.1744-6570.1975.tb0193LX.
19. Hyrkas K, Appelqvist-Schmidlechner K, Oksa L. Validating an instrument for clinical supervision using an expert panel. Int J Nurs Stud. 2003;40(6):699-25. doi: 10.1016/s0020-7489(03)00036-4. [PubMed: 12814927].
20. Hajizadeh E, Asghari M. [Statistical methods and analyses in health and biosciences]. Tehran, Iran: ACECR Press: Sazmane Entesharate Jahade Daneshgahi; 2010. Persian.
21. Tajri B, Ahadim H, Jomehrim F. [Evaluating effectiveness of cognitive-behavioral therapy on abstinence, craving, relapse & attitude in methamphetamine abuse]. Clinical Psychology Studies. 2012;27(3):23-29. Persian.
22. Ahmadpanah M, Mizraei Alieejeh M, Allahverdiour H, Alian F, Haghighi M, Afsar A, et al. Effectiveness of coping skills education program to reduce craving beliefs among addicts referred to addiction centers in Hamadan: A randomized controlled trial. Iran J Public Health. 2013;42(10):139-44. [PubMed: 26060622]. [PubMed Central: PMC4436542].
23. McGrawe-Clark AL, Carter RE, Price KI, Baker MI, Thomas S, Saladin ME, et al. Stress- and cue-elicited craving and reactivity in marijuana-dependent individuals. Psychopharmacology. 2011;218(1):49-58. doi: 10.1007/s00213-011-2376-3. [PubMed: 2171070]. [PubMed Central: PMC3209966].
24. Engin E, Cam O. Effect of self-awareness education on the self-efficacy and sociotropy-autonomy characteristics of nurses in a psychiatry clinic. Arch Psychiatr Nurs. 2009;23(2):248-56. doi: 10.1016/j.apnu.2008.05.003. [PubMed: 19327557].
25. Reese ED, Veilleux JC. Relationships between craving beliefs and abstinence self-efficacy are mediated by smoking motives and moderated by nicotine dependence. Nicotine Tob Res. 2016;18(1):48-55. doi: 10.1093/ntr/ntv054. [PubMed: 25744968].
26. Litt MD, Kadden RM, Kabela-Cormier E, Petry NM. Coping skills training and contingency management treatments for marijuana dependence: Exploring mechanisms of behavior change. Addiction. 2008;103(4):638-48. doi: 10.1111/j.1360-0443.2008.02157.x. [PubMed: 18339108]. [PubMed Central: PMC2697818].
27. Muraven M. Practicing self-control lowers the risk of smoking lapse. Psychol Addict Behav. 2010;24(3):446-52. doi: 10.1037/a0018545. [PubMed: 20853930]. [PubMed Central: PMC2944669].
28. Minami H, Yeh VM, Bold KW, Chapman GR, McCarthy DE. Relations among affect, abstinence motivation and confidence, and daily smoking lapse risk. Psychol Addict Behav. 2014;28(2):376-88. doi: 10.1037/a0034445. [PubMed: 24955665]. [PubMed Central: PMC4997809].
29. Dehghan Nayeri N, Yadegary MA, Seylani K, Navab E. Development and psychometric evaluation of coronary artery disease treatment adherence scale. Cardiol Ther. 2011;6(1):163-5. doi: 10.1007/s40199-013-0355-4. [PubMed: 30972558]. [PubMed Central: PMC6525209].
30. Polit DF, Beck CT. Nursing research: Generating and assessing evidence for nursing practice. Philadelphia, Pennsylvania, United States: Lippincott Williams & Wilkins; 2008.