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# The Effect of Group Psychoeducation Program on Medication Adherence in Patients with Bipolar Mood Disorders: a Randomized Controlled Trial

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## ABSTRACT

**Introduction:** Medication nonadherence is highly prevalent in patients with bipolar disorders and often results in worsening disease prognosis. The purpose of this study was to investigate the effect of group psychoeducation on medication adherence in female patients with bipolar mood disorder type I.

**Methods:** This randomized controlled trial was conducted on 76 patients with bipolar mood disorder admitted in female psychiatric wards of Razi teaching hospital, Tabriz, Iran. The participants were selected by convenience sampling method and were randomly assigned to experimental and control groups. Patients in experimental group received 10 continuous 90 minutes sessions of psychoeducation, two times a week. Medication adherence was measured using the medicine check list and medication adherence rating scale (MARS) before and after intervention. Data analysis was performed with SPSS ver.13.

**Results:** There was no significant difference between two groups regarding medication adherence before the intervention. After the study intervention, the mean scores of medication adherence check list and medication adherence rating scale in the experimental group were significantly higher than the control group.

**Conclusion:** Since group psychoeducation was effective in improving patients' medication adherence, it could be recommended for psychiatric nurses to apply this intervention in the clinical setting.

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## Introduction

Bipolar mood disorder (BMD) is a common and severe psychiatric disorder that high rate of readmission, relapse and nonadherence medication are its main complications.<sup>1</sup>

According to WHO report in 2009, BMD is the sixth cause of disability among people aged 14-55.<sup>2</sup> The lifetime prevalence of bipolar mood disorder is 1%. Prognosis of this disorder is not so good and suicide attempts occur in 25-50% of patients.<sup>3</sup>

Although pharmacotherapy is usually the first line treatment in psychiatric disorders,<sup>4,5</sup> nonadherence to medication is prevalent in patients with bipolar mood disorder.<sup>6</sup> Medication adherence is defined as the patient's conformance with the provider's re-

commendation with respect to timing, dosage, and frequency of medication-taking during the prescribed length of time.<sup>7,8</sup>

Adherence in psychiatric disorders often becomes more difficult when patients are required a complex medication regimen to control their illness.<sup>9</sup> Approximately 21 to 50% of patients with BMD do not adhere to their recommended treatment regimen.<sup>10</sup> It has been reported that more than one out of three BMD patients did not continue the treatment twice or more without consulting a physician; Nine out of ten patients think about quitting the treatment and at least one of them considers giving up the treatment throughout his or her life. Moreover, at least one out of three patients with BMD doesn't take more than 70% of their

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prescribed medication<sup>11</sup> which leads to failure in treatment and worsens prognosis.<sup>6</sup> The consequences of nonadherence to medication can be destructive for patients and their families in terms of personal suffering, readmission, prolonged hospital stays, and reduced quality of life, as well as, for society in general, due to loss of income and direct costs of healthcare.<sup>12,13</sup>

The Health Belief Model assumes that a person, when realizes one's health is at risk and benefits of a proposed treatment outweigh the costs of that treatment, is willing to follow up the treatment.<sup>14</sup> The results of some studies demonstrated several factors to be the causes of nonadherence medication such as patients low awareness about their illness, general beliefs and attitudes towards health and medication adherence based on previous experiences, cultural beliefs, socioeconomic status<sup>15</sup> and side effects of medications.<sup>9</sup> In addition, the findings of Lacro *et al.*, showed that good therapeutic relationship between therapists and patients is resulted in higher adherence rate.<sup>16</sup>

Although psychoeducation is a primary component of the collaborative model of treatment that advocates the rights of the patient to make informed about their treatment plan,<sup>17</sup> it has been reported that individual psychoeducational strategies had lowest success in improving adherence to treatment.<sup>18</sup> Considering the role of peer in person's behaviors, it seems that group psychoeducation could lead to improved medication adherence in patients with bipolar disorders.<sup>19</sup> In addition, it seems that group psychoeducation is more effective on reducing relapse rate than individual education.<sup>20</sup>

Psychoeducation could increase patient's responsibility when they faced with the illness. It allows them to actively collaborate with their treatment plan.<sup>21,22</sup> Patient collaboration with treatment plan is a critical factor for medication adherence. Collaborative communication with considering the patient's perspective about treatment decisions plays the main role in medication adherence.<sup>12</sup> Implementation of evidence-based collabor-

ative care in Medicaid and in integrated care programs for individuals could substantially improve medical and mental health outcomes and functioning, as well as reduce health care costs.<sup>23</sup>

By reviewing the aforementioned studies, it can be concluded that, although individual psychoeducation seems to improve patients' knowledge about illness and pharmacotherapy, it is not clear about enhancement of medication adherence. While some studies showed that psychoeducation has increased the treatment adherence,<sup>9,18,19,20-22</sup> others state that there were no increase in the adherence via education.<sup>17,24-27</sup> Therefore, this inconsistency in body of knowledge needs more attention.

As psychiatric nurses are in a close relationship with the patients throughout the treatment plan, they could play a key role in preparing psychoeducation programs for patients to improve adherence to treatment.

Today, duration of hospitalization is decreasing and demand for low-cost interventions is increasing; so group psychoeducation can be considered as an effective intervention. This study aimed to investigate the effect of group psychoeducation program on medication adherence of female patients with bipolar disorder to remedy the current gap.

## Materials and methods

This study was a single-blinded randomized controlled trial. The study population included all patients with bipolar disorder type I, hospitalized in the female psychiatric wards in Razi teaching hospital, Tabriz, Iran, in 2014.

The study was conducted in Razi teaching hospital affiliated to Tabriz University of Medical Sciences in Iran, during the September to November 2014. The pilot study conducted with 12 participants (six participants for each group) who had inclusion criteria for entering the study. By considering an alpha of 0.05, power of 90%, and possibility of 10% loss of sample, the sample size were calculated 38 patients for each group. Thus, a total of 76

patients were selected through convenient sampling method within 3 month period. The eligible participants were randomly assigned to experimental or control group. Consort flow chart of participants is shown in figure 1.

Allocation sequence was determined using computer-generated randomizer program. The person who collected and analyzed the data was unaware of the type of groups (experimental or control).

The inclusion criteria were being diagnosed as bipolar disorder type I based on specialists' diagnostic interviews and SCID-I/CV test results, being in the age range of 18 to 50; being literate, having no comorbidity disorders like personality disorders based on SCID-II test results, first relapse or more, willingness to participate, having no mental retardation, and having the euthymic mood during the study (score less than or equal to 7 for Hamilton scale and score less than or equal to 14 for Young Mania scale). Exclusion criteria included: not having the insight toward illness and having psychotic features.

The study primary outcome was medicine adherence which was measured before the intervention (T1) and immediately after intervention (T2). Data were collected through a six part questionnaire as follows:

1- A demographic questionnaire included age, marital status, education, job and number of hospitalizations.

2- Structured clinical interview for DSM-IV (Diagnostic and statistical manual of mental disorders) Axis I disorders (SCID-I) is a diagnostic tool used to determine DSM-IV Axis I disorders. All of SCID-I usually were administered in a session and take time from 45 to 90 minutes.<sup>28</sup> The Persian translation of SCID-I was used which its reliability and validity was previously confirmed in clinical population.<sup>29</sup>

3- Structured clinical interview for DSM-IV Axis II personality disorders (SCID- II) is a semi-structured diagnostic interview for assessing the 10 DSM-IV axis II personality disorders, depressed personality disorder, and passive-aggressive personality disorder in NOS (not otherwise specified) section of Axis

II. The SCID-II can be used in research and clinical settings. Its implementation takes less than 20 minutes. Reliability and validity of this scale was previously reported as desirable.<sup>29,30</sup>

4- Hamilton Rating Scale for depression is an instrument with a multiple items used to provide an indication of depression, and as a guide to evaluate recovery. Test-retest reliability for the Hamilton depression scale ranged from 0.81 to 0.98.<sup>31</sup> The validity of this scale and its correlation with other instruments ranged 0.60 to 0.84 and also the validity of the internal assessment has been reported as 0.84-0.90.<sup>32</sup>

5- The Young Mania Rating Scale was used to measure the severity of mania. This questionnaire contains 11 questions.<sup>33</sup> The Cronbach's alpha coefficient has been reported as 0.72 and the correlation coefficient between raters was 0.96.<sup>34</sup>

The tests, Young Mania Rating Scale, Hamilton Rating Scale, SCID-I and SCID-II, were used to exclude non-eligible participants.

6- Medicine check list is consisted of 4 items in 5 point Likert. The check list was developed by Ebrahimi et al.,<sup>35</sup> with score range of 0 to 20. Patients' taking the medicine was observed by staff nurse and the acquired score was considered as patient's medicine adherence.

7- The medication adherence rating scale (MARS) which developed by Thompson et al., is an easy-to-use scale that includes 10 questions. It is answered with "yes" or "no" response<sup>36</sup> and measures the adherence to medication in psychiatric patients. The test-retest reliability coefficient was 0.91.<sup>37</sup> Low values (0-7) on the scale show the low adherence and the high values (8-10) show high adherence level.

SCID-I, SCID-II, Young Mania Rating Scale and Hamilton Rating Scale were conducted by psychiatrist. For face and content validity of the MARS, it was presented to 10 faculty members of nursing and psychiatry department at Tabriz University of Medical Sciences. The final questionnaire was developed after collecting comments and making the required corrections. The reliability of the MARS in this study was calculated by

Cronbach's alpha at 0.87. The reliability of medicine check list also was determined by inter-rater reliability. The correlation coefficient between the two observers was determined using the kappa coefficient (0.8).

The study intervention was a psychoeducation program which was implemented in Razi teaching hospital in 10 continuous 90-minute sessions twice a week. The contents of each session were as follows:

Session 1. The introduction of the researcher and participants to each other, explanation of rules of group therapy, roles of participants and the topics of group therapy.

Session 2. An overview of bipolar disorder and its effects on patients' life, and problems associated with being diagnosed as mentally ill.

Session 3. Causes of hospitalizations and readmissions.

Session 4. Treatment modalities, role of medication, types of medication and side effects of medication.

Session 5. Negative consequences of nonadherence to medication.

Session 6. Role of the patient in enhancement of treatment efficacy.

Session 7. Importance of continuing to taking medication in maintaining phase.

Session 8. Education of problem solving strategies.

Session 9. Protective role of medication adherence in prevention of relapse.

Session 10. Review and evaluation.

Protocol of psychoeducation program was developed based on psychoeducation manual for bipolar disorder.<sup>38</sup>

The intervention was performed by a MSc in psychiatric nursing (first author) who had received specialized training in this area. The sessions were managed under the supervision of a PhD in nursing education and a psychiatrist. The sessions were held at Tabriz Razi teaching hospital. After conducting pre-test, the control group continued routine psychiatric care with pharmacotherapy; but the experimental group participated in the group psychoeducation program along with routine treatment. Because of the large number

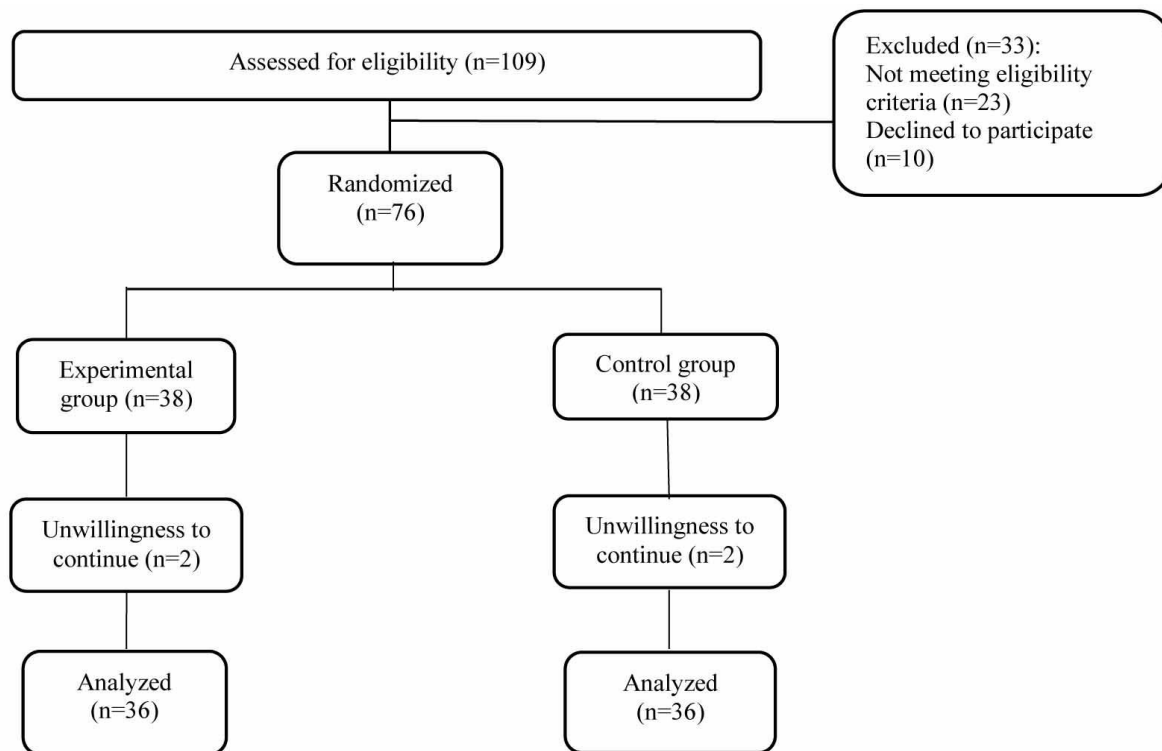
of experimental group, it was divided into 3 groups. Each session was started with an introducing learning objectives and patients' task. Before starting the discussion, the participants' opinions were asked on the subject. Then using interactive teaching methods (role playing, questions and answers, discussion and presentation), the topic of the session was discussed with all of patients. In the end, patients answered to question about the discussed topic. After the assignment of task, the session was over.

After completion of psychoeducation program, the posttest was conducted for both groups. During the study period, two participants in the control group and two participants in the experimental group were unwilling to continue; therefore, final analysis was based on as treated (72 participants) (Figure 1). Data were analyzed using SPSS statistical version 13. The normality of data was confirmed by Kolmogorov-Smirnov test. Chi-Square and Independent-sample's t-test was used for comparison of demographic data and the scores of two groups both before and after the intervention. In addition, paired-t test was used to compare the medicine check list score before and after the intervention within each group.

This study was approved by the ethics committee of Iran- Tabriz University of Medical Sciences (ethical code: 2324) and was submitted in IRCT registration system (IRCT registration number: 201112108359N1). Furthermore, other ethical issues like participants' and their Legal guardians' consent, respecting the principle of personal confidentiality and confidentiality of the data were considered. Furthermore, the participants of the control group were informed that if they were interested, the researcher would hold training sessions for them after conducting post-test for both groups.

## Results

The mean (SD) of the patients' age was 29.3 (5.2) and 30.2 (6.3) years for experimental and



**Figure 1.** Flow chart of the study

control group respectively with no significant difference. The age of all participants ranged from 24 to 45 years. The majorities of them was housewife (61.1%), had diploma education (37.5%), were married (41.6%) and hospitalized for second time (48.6%). As seen in table 1, there were no significant differences between the groups in terms of demographic characteristics. As shown in table 2, there was no significant difference in medicine check list score before intervention between experimental and control groups. The mean (SD) of pretest of all patients was 10.6 (2.5). But, in comparison with the control group, medicine checklist score of posttest was significantly higher in experimental group ( $P < 0.05$ ) (Table 2 & Figure 2).

As seen in table 3, there was no significant difference between the groups in terms of MARS score before intervention. But, in comparison with the control group, MARS score of post-test was significantly higher in experimental group ( $P < 0.05$ ) (Table 3 & Figure

2).

## Discussion

This study aimed to investigate the effect of group psychoeducation on medication adherence among patients with bipolar mood disorders. This study revealed two major results. First, medication adherence rate was poor in all patients before intervention. This result is consistent with the findings of other studies in which nonadherence rates was reported high in patients with bipolar disorder.<sup>9,18,39</sup> The studies reported various rates of nonadherence in the patients. In a study on 71 adolescents with BMD followed up for 1 year after their first hospitalization, results showed that 42% of patients were partially adherent and 23% were nonadherent.<sup>40</sup> Sajatovic et al. found that 54% of 44,637 patients being treated for BMD with lithium or anticonvulsants were completely adherent, 25% were partially adherent, and 21% were nonadherent.<sup>26</sup>

**Table 1.** Comparison of demographic characteristics between two groups (n=36)

Variables	Experimental group N (%)	Control group N (%)	P <sup>†</sup>
<b>Hospitalization</b>			
Second time	25 (69.4)	27 (75.0)	0.26
More than twice	11 (30.6)	9 (25.0)	0.49
<b>Education</b>			
Primary and secondary school	6 (16.7)	7 (19.4)	0.47
High school	15 (41.7)	12 (33.3)	
Diploma	11 (30.5)	12 (33.3)	
University	4 (11.1)	5 (14.0)	
<b>Marital status</b>			
Single	12 (33.3)	11 (30.5)	
Married	19 (52.7)	21 (58.4)	0.39
Widow	3 (8.3)	3 (8.3)	
Divorced	2 (5.5)	1 (2.8)	
<b>Job</b>			
Housewife	23 (63.8)	21 (58.4)	
Employed	13 (36.1)	15 (41.6)	0.27

† Chi square

**Table 2.** Comparison of mean scores for medicine adherence checklist before and after intervention (n=36)

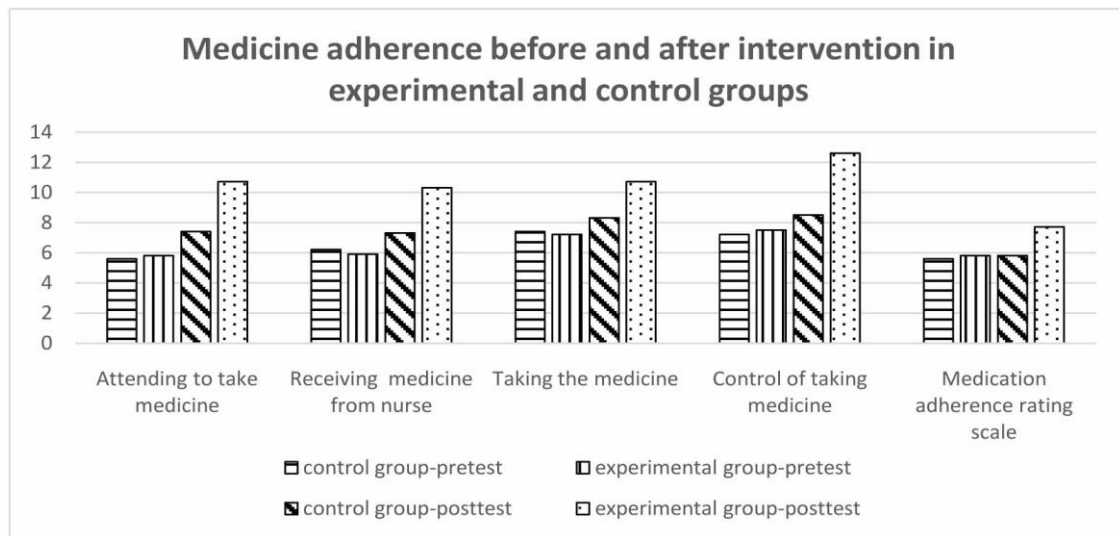
Variables	Experimental group Mean (SD)	Control group Mean (SD)	Mean Difference (95% CI)	P <sup>§</sup>
<b>Attending to take medicine</b>				
Pre	3.8 (1.9)	3.6 (1.4)	0.2 (-1.3, 1.4)	0.70
Post	4.7 (2.4)	3.8 (2.2)	0.9 (1.2, 3.5)	0.02
Dependent t-test result	t= 3.0, df=35, P=0.01	t=-2.4, df=35, P=0.22		
<b>Receiving medicine from nurse</b>				
Pre	3.9 (1.3)	3.2 (2.7)	0.2 (-0.9, 0.5)	0.19
Post	4.3 (2.7)	3.3 (2.2)	2.0 (1.4, 2.8)	<0.001
Dependent t-test result	t= 2.6, df=35, P<0.001	t=-0.4, df=35, P=0.28		
<b>Taking the medicine</b>				
Pre	2.2 (1.6)	2.3 (1.3)	0.1 (-1.0, 0.3)	0.39
Post	3.9 (2.4)	2.4 (2.3)	1.5 (1.6, 2.8)	0.007
Dependent t-test results	t= 2.3, df=35, P=0.003	t=-0.8, df=35, P=0.41		
<b>Control of taking medicine</b>				
Pre	2.5 (1.9)	2.8 (1.7)	0.3 (-0.2, 1.2)	0.26
Post	4.6 (3.6)	3.1 (1.5)	1.5 (1.2, 2.4)	<0.001
Dependent t-test results	t= 4.1, df=35, P=0.02	t=-0.5, df=35, P=0.38		
<b>Total score</b>				
Pre	10.6 (2.5)	9.8 (2.2)	0.8 (-0.1, 1.0)	0.35
Post	17.8 (3.7)	10.1 (2.3)	7.7 (7.2, 9.5)	<0.001
Dependent t-test result	t= 4.2, df=35, P<0.05	t=-3.7, df=35, P=0.42		

§ t-test

**Table 3.** Comparing mean scores for MARS before and after intervention (n=36)

Variable	Experimental group Mean (SD)	Control group Mean (SD)	Mean Difference (95% CI)	P <sup>€</sup>
<b>Medication adherence</b>				
Pre	6.8 (1.9)	6.6 (1.4)	0.2 (-0.28, 1.02)	0.29
Post	9.4 (2.4)	7.1 (2.2)	2.3 (2.21, 2.14)	<0.001
Paired t-test statistics	t=2.0, df=37, P<0.05	t=0.4, df=37, P>0.05		

€ t-test



**Figure 2.** Comparing mean scores for medicine adherence before and after intervention

As mentioned earlier, bipolar mood disorder is a chronic mental illness in which the patients have to take medicine for a long time, sometimes for a lifetime. Furthermore, in most cases, they are not informed about their treatment plan, nature of the disease and the need to continue taking the medicine during recovery. All of these along with side effects of medicine could be result in poor medication adherence.

The second major result of this study was that the mean score of medication adherence in the experimental group were increased as compared with control group. This finding is consistent with the results of previous studies.<sup>8,12,17,18,20-22,37,41</sup>

Some of the positive outcomes of psychoeducational program are improvement of patients' knowledge and attitude toward the disease, about advantages of following the treatment plan and about negative consequences of nonadherence.<sup>9,14,18, 23,24,41,42</sup>

Colom et al., compared the plasma lithium level of the patients who received psychoeducation (n=49) with the patients who did not receive psychoeducation (n=44) for a period of more than two years. They concluded that the mean of plasma lithium levels in the patients of experimental group was higher and more stable than patients of

control group.<sup>22</sup> Moreover, the results of another study showed that a brief group psychoeducation program in patients with bipolar disorder decreased relapse rate and improved medication adherence.<sup>21</sup> It is suggested that patients with a high level of awareness and insight into their illness were more likely to have good adherence to treatment.<sup>15,43,44</sup>

It seems that providing the opportunity for patients to participate in sessions of psychoeducation could improve their insight to disease and, finally decrease nonadherence rates. Furthermore, it seems that meeting other people with bipolar disorder normalized their view toward themselves, provided a feeling of solidarity and helps for de-stigmatizing.

Psychoeducation could be considered as a key element of a good medical practice. In this regard, Poole et al., concluded that group psychoeducation may influence on participants' perceived social support, knowledge and acceptance of bipolar disorder, personal insight, attitude towards medication and access to services. Participants pointed out the importance of informal elements of the group sessions, reporting that they benefited learning from others, and consequently felt less lonely and isolated.<sup>45</sup>

The main limitation of this study was that

the intervention group was divided into 3 groups to conduct the intervention in smaller groups. Despite, all the conditions were same for all groups, it is better to generalize the results with caution.

## Conclusion

The findings revealed that group psychoeducation seems an effective intervention for enhancing of medication adherence in pharmacologically treated patients with bipolar disorders. Due to the low cost and simplicity of this intervention, mental health care providers can apply this intervention for all bipolar disorder patients when the patients are in euthymic phase of disease and discharge from hospital.

Therefore, the use of psychotherapeutic treatment along with pharmacotherapy in bipolar disorder patients is suggesting as prophylactic factor for inhibition of nonadherence and relapse occurrence

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## Ethical issues

None is to be declared.

## Conflict of interest

The authors declare no conflict of interest in this study.

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