

A randomized clinical trial: Comparison of group acceptance and commitment therapy with drug on quality of life and depression in patients with obsessive–compulsive disorder

Amrollah Ebrahimi¹, Elham Nasre Esfahan², Shahla Akuchekian³, Razieh Izadi⁴, Elham Shaneh², Behzad Mahaki⁵

¹Department of Health Psychology, Behavioural Sciences Research Centre, Medicine School, Isfahan University of Medical Science, Isfahan, Iran, ²Behavioural Sciences Research Center, Student Research Committee, Isfahan University of Medical Science, Isfahan, Iran, ³Behavioural Sciences Research Centre, Isfahan University of Medical Science, Isfahan, Iran, ⁴Department of Psychology, Isfahan University, Isfahan, Iran, ⁵Department of Biostatistics, Kermanshah University of Medical Science, Kermanshah, Iran

Background: Acceptance and commitment therapy (ACT) is one of the newest treatment strategies that has been developed rapidly to improve the treatment of patients with obsessive–compulsive disorder (OCD). The aim of this study was to evaluate and compare the effect of ACT and selective serotonin reuptake inhibitors (SSRIs) drugs on the severity of depression symptoms and quality of life (QOL) in obsessive–compulsive patients. **Materials and Methods:** A randomized clinical trial with a control group was conducted including 27 patients with OCD. Based on the Diagnostic and Statistical Manual of Mental Disorders-5 criteria for OCD diagnosis, participants were recruited from Tamasha Counseling Center and obsessive–compulsive clinic in the Psychosomatic Research Center in Isfahan, Iran. Selected patients were allocated to two groups (14 in ACT the group and 13 in the drug group with SSRI with a simple random sampling method. ACT group was treated by an ACT therapist in eight 1-h sessions. Data were collected by the World Health Organization QOL Questionnaire (WHOQOL-BREF) and Depression subscale of DASS-42 at admission, after the intervention, and 3 months thereafter. Therapists and evaluators were blind to each other's work. Data were analyzed using analysis of variance with repeated measures method using IBM SPSS Statistics software (V 23, IBM Corporation, Armonk, NY, USA). **Results:** Results revealed that both treatments (ACT and SSRIs drug therapy) had significant impacts on reducing depression subscales scores and increasing WHOQOL-BREF scores at posttreatment ($P < 0.05$). There were no significant differences in QOL scores between the two groups after the intervention and follow-up ($P > 0.05$). Nevertheless, drug therapy presented a significantly greater improvement in depression scores of patients than those resulting from ACT ($P = 0.005$). The persistence of treatment effects continued after 3 months (follow-up) in both groups. **Conclusion:** ACT is equal to SSRIs drug therapy in terms of improving QOL in patients with OCD. However, SSRIs are more effective in treating depression in obsessive–compulsive patients. It may be presumed that ACT without any chemical side effect is equal to drug and is preferred for patients who either cannot use drugs or prefer not to have a drug treatment.

Key words: Acceptance and commitment therapy, obsessive–compulsive disorder, selective serotonin reuptake inhibitors

How to cite this article: Ebrahimi A, Nasr Esfahani E, Akuchekian S, Izadi R, Shaneh E, Mahaki B. A randomized clinical trial: Comparison of group acceptance and commitment therapy with drug on quality of life and depression in patients with obsessive–compulsive disorder. *J Res Med Sci* 2022;27:9.

INTRODUCTION

While drugs, such as selective serotonin reuptake inhibitors (SSRIs), are being used as the main treatment

plan in obsessive–compulsive disorder (OCD), a large number of patients have clinically significant OCD symptoms after these treatments.^[1-4] The acceptance and commitment therapy (ACT) is one of the newest

Access this article online	
Quick Response Code:	Website: www.jmsjournal.net
	DOI: 10.4103/jrms.jrms_449_21

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Address for correspondence: Dr. Amrollah Ebrahimi, Department of Health Psychology, Isfahan University of Medical Sciences, Hezarjerib Aven., Isfahan, Iran.

E-mail: a_ebrahimi@med.mui.ac.ir

Submitted: 27-May-2021; **Revised:** 23-Jul-2021; **Accepted:** 28-Jul-2021; **Published:** 18-Feb-2022

treatment strategies that has recently been rapidly developed to improve the treatment for patients with OCD.^[5,6] As a third-wave behavior therapy, ACT focuses on reducing experiential avoidance, increasing activity in the chosen valued life direction, and increasing psychological flexibility.^[7] According to the ACT theory, patients with OCD attempt to decrease unwanted obsessional thoughts, which often paradoxically increase the frequency or severity of these amiss obsessional thoughts, and thus result in the inability to act in accordance with a patient's valued direction.^[8] ACT teaches patients to create a good and acceptable relationship with obsessive thoughts and emotions. Moreover, it helps patients to spend more time on their valued life goals, as well as to accept their obsessional thoughts and negative feelings and commit to act on the way of their valued life directions whether or not obsessions were occurring. Thus, ACT will exacerbate psychological flexibility, which is the ability to act compatible with a patient's valued life directions regardless of amiss inner experiences.^[8-11] ACT has indicated significant effects on improving OCD symptoms in adults and adolescents.^[8-12] Although OCD and depression are two independent disorders, some researches have revealed that patients with OCD often suffer from depression, a comorbidity accompanied with greater symptom severity and suicide risk.^[13] A review study with 36 RCTs revealed that ACT seems to be more effective than the waitlist group and those who received other treatment, with largely equivalent effects relative to traditional cognitive-behavioral therapy. Findings demonstrate that ACT treatment outcomes are mediated by a decrease in psychological inflexibility, its theorized process of change.^[14] Although cognitive-behavioral therapies were compared with SSRIs in previous studies for the treatment of patients with OCD, there are few studies evaluating the effectiveness of ACT on QOL and the severity of depression symptoms in OCD patients compared with SSRIs. Therefore, this study was designed to investigate the possible effects of ACT on the severity of depression symptoms and QOL in obsessive-compulsive patients.

MATERIALS AND METHODS

Procedure

This randomized controlled trial (RCT) study was performed to compare QOL and the severity of depression symptoms in patients with OCD who underwent the ACT intervention (experimental group) and the routine strategy (SSRIs) for OCD (control group). The statistical society included all patients who were referred to an obsessive-compulsive clinic in Isfahan, Iran. Inclusion criteria were diagnosis of OCD according to the Diagnostic and Statistical Manual of Mental Disorders (DSM)-5 criteria, ages between 18 and 65 years, lack of specific diseases such

as bipolar disorder, psychotic disorders or symptoms, mental retardation, and consenting to participate in the research, without receiving any treatment in 30 days before participating in the study. Exclusion criteria were dissatisfaction with participation in the research at any phase and being absent for more than two sessions. The inclusion and exclusion criteria were carefully controlled by a psychiatrist. Experimental groups were treated with ACT by a clinical psychologist who was a specialist in ACT and a resident in psychiatry as a co-therapist.

Acceptance and commitment therapy sessions

The ACT was conducted in eight 1-h sessions during 1 month (4 weeks with two sessions per week). Treatment sessions were under the supervision of the ACT specialist to monitor the content of sessions to be based on the ACT protocol developed by Twohig.^[15]

Prescribed drugs and their doses

The control group was under the routine drug treatment (SSRIs) prescribed by a psychiatrist. Depending on the needs of each patient, the control group was prescribed fluoxetine at a dose of up to 80 mg per day, as well as fluvoxamine and sertraline at a maximum dose of 300 mg per day.^[1] Quality of life (QOL) and the severity of depression symptoms were measured at admission, 1 month, and 3 months later. This study has been registered in the Iranian Registry of Clinical Trial under the code IRCT20110815007339N3.

Participants

Participants were recruited from Tamasha Counseling Center and an obsessive-compulsive clinic in the Psychosomatic Research Center in Isfahan, Iran, between August and December 2017. All OCD patients who were diagnosed according to the DSM-5 criteria by a psychiatrist during this time were eligible for participation. Considering the inclusion and exclusion criteria, 65 patients were recognized as eligible by the psychiatrist, 35 of whom were excluded and finally, 30 cases were allocated to a restricted randomization method (permuted block randomization) in two groups of ACT and drug intervention (15 cases in each group). To balance the number of participants in each arm, block randomization was performed using a web-based randomization software-random allocation software, Version 1.0.^[16,17] The process of patient allocation and randomization based on CONSORT 2010 Explanation and Elaboration: Updated guidelines for reporting parallel group randomized trials^[18] were performed as follows. After introducing eligible patients to the admission system, the research coordinator at the psychosomatic center randomly assigned eligible patients using a clinical interview checklist. Following eligibility screening by the research coordinator, the system generated a unique number. The

research coordinator then reported the number. In turn, a trained staff referred to a manual of unique numbers generated by an independent statistician prior to study activation to determine the study intervention allocated to the randomized patient. The randomization schedule was stratified by the site in variable blocks of 1 and 2. Randomized patients received therapy according to the intervention they were allocated. Study investigators, research coordinators, and psychological assessors were blinded to treatment allocation. The process of selection and allocation of participants to arm1 and 2 is shown in consort Figure 1. At first, 65 patients were assessed for eligibility. Thirty-five of them, including 23, did not meet the inclusion criteria, 7 persons declined to participate, and 5 due to personal and family problems were excluded. Finally, 30 participants, including 15 in the drug group and 15 people in the ACT, were randomly assigned. Two participants from the ACT group and one person from the drug group did not continue treatment until the end. The data of 13 patients in the ACT group and 14 patients in the drug group were analyzed after the intervention and in the follow-up stage. Prior to the start of drug treatment and before the start of ACT sessions, an initial assessment was performed by the World Health Organization QOL Questionnaire-BREF (WHOQOL-BREF) and the Depression, Anxiety, and Stress Scale (DASS-42). Then, the groups were evaluated by the mentioned scales after the end of the treatment and again 3 months later. This research was approved with No.IR.MUI.REC.1394.3.103 code by the

Ethics Committee of Isfahan University of Medical Sciences and all participants gave written informed consent.

Instruments

Depression, Anxiety, and Stress Scale

This is a 42-item self-report inventory designed to measure the presence of symptoms of depression, anxiety, and stress.^[19,20] This screening measure reflects the experience of depression over the previous 7 days. The depression subscale consists of 14 items that are scored in 4-point Likert (0 none to 3 too much) and scores range from 0 to 42 that high scores indicate more depression. A higher score indicates the severity of depression. Psychometric properties of DASS-42 were reported in several studies. According to the literature, gamma coefficients representing the loading of each subscale on the total score are 0.71, 0.86, and 0.88 for depression, anxiety, and stress, respectively. Internal consistency reliability of the DASS-42 demonstrated excellent Cronbach's alpha values of 0.94, 0.90, and 0.87 for depression, anxiety, and stress domains, respectively. Criterion-related/convergence validity based on the correlation of DASS-42 and HADS were strongly appropriate for both anxiety ($r = 0.87, P < 0.001$) and depression ($r = 0.68, P < 0.001$) domains.^[19]

The World Health Organization Quality of Life Questionnaire-BREF

This questionnaire included 26 items on a Likert scale of 1–5 examining different aspects of a person's

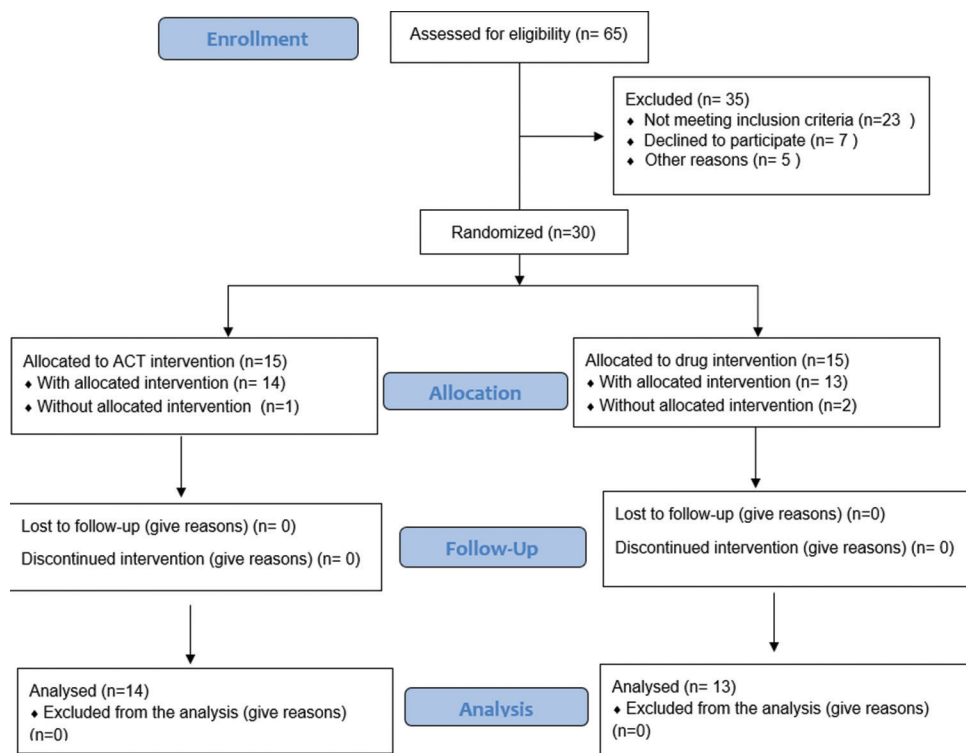


Figure 1: CONSORT diagram for a clinical trial of acceptance and commitment therapy and selective serotonin reuptake inhibitor treatment among patients with obsessive-compulsive disorder

QOL. Two items measure global QOL and general health. Furthermore, 24 items cover four domains including field (1) physical health with seven items, field (2) psychological health with six items, field (3) social relationships with three items, and field (4) environmental health with eight items. This questionnaire is scored quantitatively on a continuous scale and a higher score indicates a better QOL. The psychometric properties of these instruments have been confirmed as acceptable in most of these populations.^[21-24] interclass correlation and Cronbach's alpha values of the Persian version was reported more than 0.7 in all areas. In the sphere of social relations, however, the value was 0.55. The questionnaire has the ability to discriminate different groups after adjustment for confounding factors in a regression analysis that indicated discriminant validity.^[25]

Data analysis

Data were analyzed with repeated measures analysis of variance method using Statistical Package for the Social Sciences-23.^[26] The demographic characteristics of the participants, QOL scores, and the severity of depression were determined and reported using descriptive statistical methods such as mean and standard deviation and for qualitative variables, Chi-square test. The effects of intervention and the interaction of time and intervention variables (comparison of scores before, after, and follow-up phases) were determined using the repeated measure analysis. Pretest scores and age of participants were adjusted. To perform parametric tests, two-sample Kolmogorov-Smirnov, Levene's, and Box's M tests were used to determine the normal distribution of data, equality of variances, and the homogeneity of covariance matrices. The findings revealed that the pre assumptions for performing parametric tests are established.

RESULTS

Demographic characteristics of groups

The mean age of the patients in ACT intervention group (4 males, 10 females) was 32.71 ± 8.27 years and in drug control group (4 males, 9 females) was 31 ± 7.43 years. Age, sex, and marital and education status were not significantly different between the two groups [Table 1].

Changes in World Health Organization Quality of Life Questionnaire scores

The mean of WHOQOL score significantly increased after the intervention and follow-up stage in both groups ($P < 0.001$) [Table 2 and Figure 2].

Changes in depression score

The mean of depression scores significantly decreased during the investigation time in both groups ($P < 0.001$).

Table 1: Characteristics of the study sample

Groups	Mean \pm SD		P
	Control	Intervention	
Age (years)	31 (7.43, 13)	32.71 (8.27, 14)	0.576
Marital status, n (%)			
Single	4 (30.76)	5 (35.71)	>0.999
Married	9 (69.23)	9 (64.28)	
Sex, n (%)			
Male	4 (30.76)	4 (28.57)	>0.999
Female	9 (69.23)	10 (71.42)	
Education, n (%)			
Illiterate	0	1 (100)	0.362
Elementary	1 (50)	1 (50)	
High school	1 (100)	0	
Diploma	7 (70)	3 (30)	
Bachelor	3 (27.3)	8 (72.7)	
Masters and more	1 (50)	1 (50)	

SD=Standard deviation

However, the decrease in the depression score of drug group was more remarkable [Table 2 and Figure 3].

Follow-up outcomes

In both groups, the scores of QOL and severity of depression in the follow-up stage were significantly different from the pretreatment stage ($P < 0.05$). Based on WHOQOL and DASS-42 scores at the follow-up assessment, treatment effects continued after 3 months (follow-up) in both groups.

Comparison of two groups

Analysis of variance with repeated measures method was performed to control the effect of pretest while comparing the groups. Having controlled the effect of pretest, the comparison between groups indicated that there were significant differences between the depression posttest scores in the two groups. Moreover, the SSRI treatment had a greater effect on the severity of depressive symptoms than the ACT treatment did ($P < 0.05$) [Table 2].

DISCUSSION

The findings of this study revealed that the two treatments (ACT and SSRIs drug therapy) were effective interventions in reducing depression symptom severity and increasing perceived QOL based on the WHOQOL-BREF total score at posttreatment and follow-up assessments. This finding, which was based on the effectiveness of acceptance and commitment-based therapy, is similar to those of previous studies that revealed the effectiveness of ACT in reducing the symptoms of patients with OCD.^[8-12] The findings of this study are consistent with those of Dehlin *et al.*, which confirmed the adequacy of ACT treatment in improving depressive symptoms, QOL, and obsessive-compulsive symptoms in OCD patients.^[27] The finding is also consistent with that of Michael *et al.* (2017), who

Table 2: Changes in World Health Organization Quality of Life Questionnaire and depression score before and over 3 months follow-up after intervention

Group	Mean±SD			P*	P*	P**	P**	Effect size***
	Baseline	Posttreatment	Follow up					
WHOQOL								
Medication	73.53±11.96	80.38±14.13	88.23±10.6	<0.001	<0.001	0.802	0.581	0.012
ACT	72.07±9.21	79.14±11.12	84.57±11.86	<0.001				
Depression								
Medication	24.69±9.47	14.07±6.71	8.92±6.48	<0.001	<0.001	0.002	0.070	0.126
ACT	14.71±8.72	10.78±6.17	9±5.14	0.001				

*P=For trend in each group; *P=For time effect; **P=Or time-group interaction; **P=For group effect; ***Effect size=For group effect. ACT=Acceptance and commitment therapy; WHOQOL=World Health Organization Quality of Life Questionnaire; SD=Standard deviation

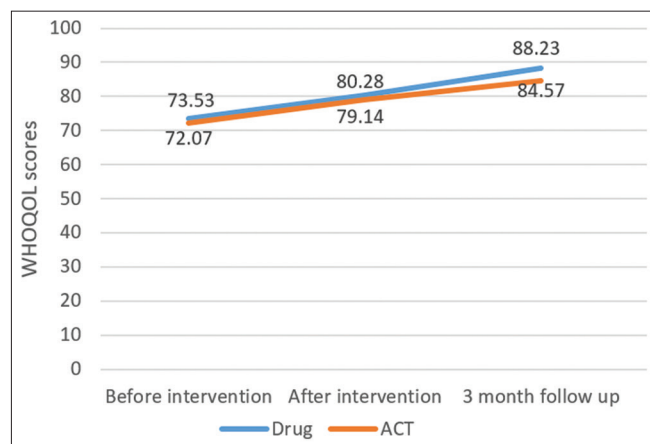


Figure 2: Changes in World Health Organization Quality of Life Questionnaire-Brief scores before, after, and over 3 months of follow-up in two groups

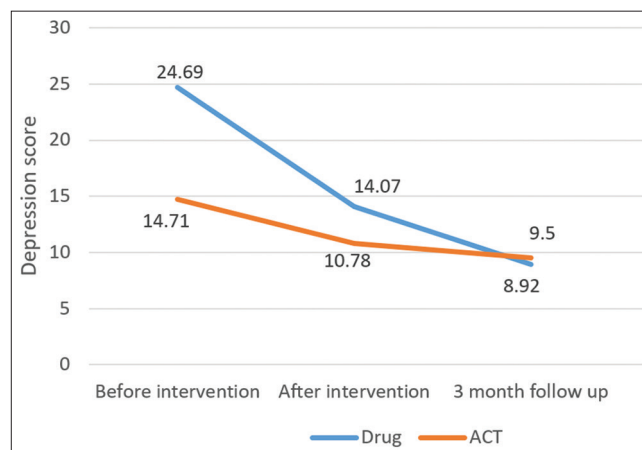


Figure 3: Changes in depression scores before, after, and over 3 months of follow-up in two groups

provided a systematic review of RCTs assessing ACT for depression and anxiety disorders. Their findings revealed that ACT appeared to be more efficacious than waitlist conditions. They showed that ACT therapy outcomes were mediated through increases in psychological flexibility and health behavior.^[14] A possible explanation for the effectiveness of ACT could be due to producing greater psychological flexibility by creating a good and acceptable relationship with obsessive thoughts and emotions in OCD patients. Thus, ACT will exacerbate psychological flexibility, which is the ability to act compatible with patient's valued life directions regardless of amiss inner experiences.^[8-9] To support this perspective, evidences^[9-12] show that reductions in OCD symptoms are due to the specific processes used in ACT (i.e., acceptance and cognitive diffusion).

Our findings also demonstrated that SSRIs, including prescribed fluoxetine, fluvoxamine, and sertraline, were effective in reducing the symptoms of depression and improving the QOL in patients with OCD. These results support the findings of meta-analysis on early onset of response to SSRIs in OCD by Issari *et al.*^[2] This meta-analysis has 17 trials of SSRIs with 3276 OCD patients. Compared to placebo, a statistically significant benefit of SSRIs was

observed within 2 weeks after the start of the treatment and a significantly greater response was associated with using higher doses of SSRIs.

Nevertheless, treatment with SSRIs presented a significantly greater improvement in depression symptoms than those resulting from ACT intervention. This finding is inconsistent with that of a study by Vakili *et al.*,^[28] who showed that SSRIs alone were not more effective than ACT in reducing the symptoms of obsessive-compulsive patients. The reason for this difference may be the tools for measuring variables or the treatment quality. In our study, SSRI treatment was prescribed with caution and in high doses, and ACT therapy was held in compressed sessions (i.e., twice a week instead of once a week), which might have not provided the patients with the opportunity to have sufficient practice.

The results also revealed that SSRIs were effective in improving the QOL consistent with previous studies by Sousa *et al.*,^[29] Foa *et al.*,^[30] Abramowitz *et al.*,^[31] and Shareh *et al.*^[32] In contrast, Giasuddin *et al.*^[33] observed that psychotherapy had better results than pharmacotherapy.

In the present study, however, the SSRI treatment was more effective in reducing depression scores than ACT

intervention. This might be due to biological effects of the drug on the brain emotional system, and therefore, SSRI treatment led to a faster effect than psychological treatments. These results support those of two studies,^[34,35] in which investigators did not find the advantages of combining psychotherapy and pharmacotherapy as compared to pharmacotherapy alone in treating patients with OCD. In the present study, depression scores decreased in two treatment groups, which corresponds to those of Sousa *et al.*^[25] and Twohig *et al.*^[8,9] The striking finding of this study was that the emerging treatment (ACT) had the same effect on QOL in obsessive-compulsive patients as the standard drug therapy. As a result, ACT treatment can be recommended for those who have medicinal restrictions or prefer to use psychotherapy instead of medication. Since the participants in this study were 18–65 years old, the generalizability of these results is limited to this age range, and judging the effectiveness of ACT in OCD in children and the elderly requires a separate research. According to the results of the present study, it is suggested that therapists consider ACT treatment as a suitable alternative for patients who for any reason cannot take medication, or prefer to use nondrug therapies. Nondrug treatments are recommended to help patients' flexibility due to the fact that the drug cannot eliminate all the symptoms and complaints of patients with OCD and has side effects that are intolerable for some patients.^[1-4]

Limitations

Since the patients were from medical centers affiliated with the university and the sessions were intensive, caution should be exercised in generalizing the results to other patients who are from private centers. Other limitations of this study were related to self-report questionnaires to assessment of treatment effects; therefore, other evaluation methods are needed to determine clinically significant effectiveness. Finally, we recommend clinicians to use psychotherapy, including ACT, to augment medication efficacy in obsessive-compulsive treatment.

CONCLUSION

The results of the present study demonstrate that both interventions (ACT and drug) are effective treatments for OCD patients. However, the patients treated with SSRIs experienced a further improvement in the severity of depression symptoms at posttreatment.

Acknowledgments

The authors would like to thank the managers and staff of the Behavioral Sciences Research Center and Psychosomatic Research Center affiliated to Isfahan University of Medical Sciences, as well as the manager of Tamasha Psychological Services Center and the patients who contributed.

Financial support and sponsorship

This study was supported by the Isfahan University of Medical Science.

Conflicts of interest

There are no conflicts of interest.

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