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# ORIGINAL: Comparative Study of the Efficacy of Cognitive-Behavioral Therapy and Sertraline in Generalized Anxiety Disorder

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**ABSTRACT**

**Introduction:** Generalized anxiety disorder is one of the most critical issues of global health organizations. The aim of study was comparison of the efficacy of cognitive-behavioral therapy (CBT) and Sertraline with Sertraline alone in general anxiety disorder.

**Material and Methods:** This randomized clinical trial study was performed randomly among patients referring to the specialty psychiatric clinic of Imam Sajjad Hospital, Ramsar. Group 1 received cognitive-behavioral sessions in combination with Sertraline and Group 2, received only drug (starting at a daily dose of 25 mg and after the one-week dose was increased to 50 mg, and then, according to the patient's examination and response, the treatment gradually increased to 150 mg daily). Patients were assessed with Beck Anxiety Questionnaire before and after the end of treatment. Data were analyzed using SPSS version 22.

**Results:** There were no significant differences between the two groups treated with Sertraline + CBT and Sertraline alone in terms of gender, marital status, socio-economic status, educational status, occupational status, and degree of anxiety before and after the study ($P < 0.05$). In Sertraline + CBT group, there was no significant relationship between gender and educational level, job status, socio-economic status and marital status of patients with severity of anxiety after treatment ($P < 0.05$).

**Conclusion:** From the results of this study, it can be concluded that treatment of Sertraline + CBT with Sertraline alone would not result in a further reduction in the anxiety score and degree of anxiety in patients, and this treatment was not related to gender, marital status, socio-economic status, and the degree of patients.

## Introduction

Generalized anxiety disorder (GAD) is one of the most critical issues of concern of the World Health Organization. Numerous studies around the world have shown that GAD comprises major physical and social injuries compared to major depressive disorder (1-3).

One of the main features of GAD is the constant presence of anxiety and nervousness and uncontrollable anxiety, and during the six months, most days are seen. Symptoms of

GAD include restlessness, aggression, muscle contraction, fatigue, sleep disturbances, and difficulty concentrating. Drug therapy is an essential treatment for GAD (4).

GAD is associated with an increased risk of medical illnesses. It has been considered as a risk factor in the etiology of many psychiatric disorders, especially depression and alcohol abuse, and its timely diagnosis and treatment are one of the major concerns of physicians and clinical therapists (5). In general, there are three types of treatment for GAD: drug therapy, relaxation exercises for body muscles, and cognitive-behavioral treatment (6,7). Cognitive-behavioral therapy is a targeted effort to maintain the effects of behavior modification and integrate cognitive activities to make therapeutic changes. In this therapeutic approach, the emphasis is on the role of cognition in the development of behavioral and emotional changes. Cognitive and behavioral therapy is a short-term, problem-focused, organized therapy that aims to modify inaccurate and irrational cognitions (8,9).

Researchers in studies of patients with GAD have shown that cognitive-behavioral therapies are more effective than drug therapies. The researchers concluded that cognitive-behavioral therapies for the treatment of GAD had a beneficial effect on reducing anxiety and worrying thoughts, and their beneficial effects continued after a follow-up period of 6 to 12 months.

Overall, it seems that anxiolytic drugs temporarily alleviate GAD until the medication is discontinued, while cognitive-behavioral practices provide the most lasting improvement. Because cognitive-behavioral therapy is a short-term treatment, it is usually less expensive than other treatment options. The benefits of this treatment have also been shown empirically and have also been shown to help patients recover from maladaptive behaviors effectively.

There are different opinions regarding the results of research on the effectiveness of cognitive-behavioral therapy. Therefore, to clarify the actual value of the effect of cognitive-behavioral interventions on reducing anxiety symptoms, and considering the positive impact of this therapy, the need for drug therapy and consequently the side effects of the drugs used will be diminished, and Most studies appear to have been conducted in large environments with a high socioeconomic level. No reviews have been conducted in small environments with a low socio-economic level that is resistant to CBT acceptance, so this study aimed to compare the effectiveness of Cognitive Behavioral Therapy (CBT) and Sertraline with Sertraline in diffuse anxiety disorder in patients referring to Ramsar Imam Sajjad Psychiatric Clinic.

# Methods

## Study design and setting

In this randomized clinical trial study, patients with generalized anxiety disorder diagnosed by a psychiatrist according to DSM-V criteria were randomly assigned to one treatment group. The patient in group 1 received cognitive-behavioral sessions with Sertraline, and the patient in group 2 received only medication. This study did not contain a placebo. Patients were evaluated before and then at the end of the intervention.

## Cognitive-behavioral therapy:

In the present study, cognitive-behavioral therapy included muscle relaxation training and attentional focusing (focusing on an object, concentrate on pleasant memories and fantasies, sensory awareness of the surroundings, mental exercises, and fun activities) and self-control methods. Also, identifying negative thoughts and familiarity with its behavioral consequences and coming to the belief that these beliefs are changeable and assertive were among the cognitive problem solving and cognitive restructuring methods.

Cognitive-behavioral therapy was performed according to the above model for three months during 12 sessions. During the first two weeks, two days a week, and in the third to twelve weeks, one day, weekly meetings

were performed for 45 minutes. At the beginning of the study, both groups completed the Beck Anxiety Questionnaire. At the same time, like cognitive-behavioral therapy, drug treatment for the first group was started. (the daily dose was 25 mg and increased to 50 mg after one week, then gradually increased to 150 mg depending on the patient's examination and response to treatment, and the second group received only drug treatment. At the end of treatment, the Beck Anxiety Questionnaire was again administered to both groups, and the results were compared. This questionnaire has high validity, and it is a 21-item scale that selects one of four choices for each question that indicates the severity of anxiety. The four options for each question are scored on a four-part Likert scale range from 0 to 3. Each of the test items describes one of the most common symptoms of anxiety (mental, physical, and phobic symptoms). Therefore, the total score of this questionnaire is in the range of 0 to 36. Patients' anxiety scores were categorized according to the scores of 0-7 without anxiety, 15-8 with mild anxiety, 25-6 with moderate anxiety, and 26-63 with severe anxiety.

### Ethical consideration

The authorization to conduct the research was obtained from the Ethics Committee of Mazandaran University of Medical Sciences. This study had no physical, psychological, financial, etc. harm to the study participants. All the information in the patients' medical records was kept confidential by the researchers.

### Statistical analysis

After entering data in SPSS version 22, mean, standard deviation, frequency, and percentage were used to describe the data. Independent t-test was used to compare the mean of the two groups in the normal distribution of data, and for comparison before and after data, the paired t-test was used. Man-Whitney and Wilcoxon nonparametric tests were used if the distribution of data was not normal. A Chi-square test was used to compare the qualitative variables.

## Results

In each group, 55 patients were included in the study. The frequency of gender in the treated groups was not statistically significant (P = 0.105). 80% of the Sertraline + CBT and 90.9% of the treated with Sertraline alone were males. There was no significant difference in marital status between the two groups (P = 0.530), and There was no significant difference in age between the two groups (P = 0.110). There was no statistical difference between the two groups in terms of educational level (P = 0.423).

The mean and standard deviation of the Beck Anxiety Inventory before and after the study and Beck score changes were analyzed separately in the treatment group, with no significant difference between the two groups (***Table 1***).

The frequency of pre-intervention anxiety severity classification in the treated groups was not statistically significant (P = 0.869). 18.2%, 61.8% and 20.0% of Sertraline + CBT patients and 14.5%, 63.6% and 21.8% of Sertraline treated patients had severe, moderate and mild anxiety, respectively. Then the frequency of post-intervention anxiety severity classification in the treated groups was not statistically significant (P = 0.221). 12.7%, 61.8%, and 25.5% of the

**Table 1. The mean and standard deviation of Beck Anxiety questionnaire before and after the study and changes**

| Score | Group | Mean | Standard deviation | P-value* |
|---|---|---|---|---|
| **Before study** | Sertraline+ CBT | 24.3636 | 12.54084 | 0.501 |
| | Sertraline | 22.8545 | 10.86349 | |
| **After study** | Sertraline+ CBT | 13.6545 | 5.21827 | 0.447 |
| | Sertraline | 12.8545 | 5.75557 | |
| **Changes** | Sertraline+ CBT | -11.4727 | 10.53540 | 0.431 |
| | Sertraline | -10.0000 | 8.92769 | |

*Mann-Whitney

Sertraline + CBT patients had moderate, mild, and low or no anxiety, respectively And 1.8%, 25.5%, 47.3%, and 25.5% of Sertraline-treated patients had severe, moderate, mild, and minimal or no anxiety, respectively (***Table 2***).

## Discussion

The efficacy of cognitive-behavioral therapy, combined with drug therapy, has been investigated in various studies. For example, Shahriari et al. (10) Studied the effectiveness of cognitive-behavioral interventions in the treatment of generalized anxiety disorder during a review study. The findings of this meta-analysis showed that the magnitude of the effect of cognitive-behavioral interventions in the treatment of generalized anxiety disorder is high.

However, some studies have emphasized the similarities of cognitive-behavioral therapy with drug therapy alone, and some studies have even emphasized that the speed of drug therapy is more significant (11). Therefore, there are conflicting results in this area that warrant further investigation.

There was no significant difference between the two groups in the treatment of Sertraline + CBT and Sertraline alone in terms of gender, marital status, socio-economic status, educational level, occupational status, and degree of anxiety before and after the study.

The severity of anxiety after the study was 12.7%, 61.8% and 25.5% of the patients in the Sertraline + CBT group, respectively, with moderate, mild and minimal or no anxiety, respectively and 1.8%, 25.5%, 47.3%, and 25.5% of Sertraline-treated patients had severe, moderate, mild, and minimal or no anxiety, respectively. In the Sertraline + CBT group, there was no significant relationship between sex and education, occupational, socioeconomic status, and marital status of patients with severity of anxiety after treatment ($P > 0.05$). In this context, studies have been conducted, for example, in the study of Ansari Zadeh et al. (12) to evaluate the effectiveness of cognitive-behavioral group therapy, drug therapy, and placebo in reducing anxiety in patients with substance abuse. The results of covariance analysis indicated the efficacy of cognitive-behavioral group therapy in reducing stress compared to drug therapy and placebo groups.

The difference between this study and our study was that the study population in the study included patients with substance abuse, but this study excluded patients. In another study by Wang et al. (13), the efficacy of cognitive-behavioral and pharmacotherapy interventions in pediatric anxiety disorder was investigated, and the results showed that CBT reduced the symptoms of primary anxiety; however, this decrease was more significant than that of fluoxetine and Sertraline. Also, the concomitant use of CBT and Sertraline significantly reduced the symptoms of anxiety compared to the use of either alone. The difference between this study and our study was that children were included in the survey, while adults were included in our research, which may justify the difference in results.

In another study, the effect of cognitive-behavioral therapy on reducing anxiety in adolescent girls with a generalized anxiety disorder was investigated by Alirezai Motlaq et al. (14). The results of this study showed that there was no significant difference between the mean scores of anxieties in experimental and control groups before cognitive-behavioral therapy. However, after the cognitive-behavioral therapy, the anxiety scores of the experimental group were lower than the control group. Also, there was a significant difference between the mean

**Table 2. Frequency of pre-intervention and post-intervention anxiety severity classification in the treated groups. N (%)**

| | Groups | Minimal or no | Mild | Moderate | Severe | P-Value |
|---|---|---|---|---|---|---|
| **Pre-intervention** | **Sertraline+ CBT** | 0 | 11 (20) | 34 (61.8) | 10 (18.2) | 0.869 |
| | **Sertraline** | 0 | 12 (21.8) | 35 (63.6) | 8 (14.5) | |
| **Post-intervention** | **Sertraline+ CBT** | 14 (25.5) | 34 (61.8) | 7 (12.7) | 0 | 0.221 |
| | **Sertraline** | 14 (25.5) | 26 (47.3) | 14 (25.5) | 1 (1.8) | |

scores of anxieties in the experimental group before and after the cognitive-behavioral therapy. In one study, the results showed that drug therapy had a rapid effect on reducing anxiety. Combined treatments and placebo have had a similar impact on drug therapy, which confirms our study (10).
In the study of Walkup et al. (15), they investigated the separate efficacy of cognitive-behavioral interventions and Sertraline as well as the combined efficacy of cognitive-behavioral interventions and Sertraline. The results showed that CBT and Sertraline alone reduced anxiety symptoms, but combination therapy led to a greater reduction than either alone. CBT also had less insomnia and fatigue. Evaluations between different studies and comparing their results with those of our study emphasize that Sertraline + CBT treatment probably does not lead to a greater reduction in anxiety score and degree of anxiety than Sertraline alone.
Therefore, given the inconsistency between the results, there is a need for further studies in this field, which seems to be due to the lack of a culture of individuals and patients and the need for new cultivation in this area because patients despite attending classes and they did not follow the recommendations.

## Conclusion

From the results of this study, it can be concluded that treatment of Sertraline + CBT with Sertraline alone would not result in a further reduction in the anxiety score and degree of anxiety in patients, and this treatment was not related to gender, marital status, socioeconomic status, and the degree of patients. Therefore, the use of CBT therapy in addition to drug therapy, in this case, is not effective in smaller environments with a lack of applied culture, and there is a need for further development in their culture.

## Conflicts of interest

The authors declare that there is no conflict of interest regarding the publication of this article.

## Authors' contributions

Study design: AH.SK.
Writing: T.D., AH.SK., and A.A.
Final revision: All authors

## Ethics approval

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# References

1. Essau CA, rer s, Conradt J, Petermann F, Phil. Frequency, Comorbidity, and Psychosocial Impairment of Anxiety Disorders in German Adolescents. Journal of Anxiety Disorders. 2000;14(3):263-79.
2. Hunt C, Slade T, Andrews G. Generalized Anxiety Disorder and major depressive disorder comorbidity in the National Survey of Mental Health and Well-Being. Depression and anxiety. 2004;20(1):23-31.
3. Kessler RC, Berglund P, Demler O, Jin R, Merikangas KR, Walters EE. Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. Archives of general psychiatry. 2005;62(6):593-602.
4. Barlow DH, Rapee RM, Brown TA. Behavioral treatment of generalized anxiety disorder. Behavior Therapy. 1992;23(4):551-70.
5. Dugas MJ, Koerner N. Cognitive-behavioral treatment for generalized anxiety disorder: Current status and future directions. Journal of Cognitive Psychotherapy. 2005;19(1):61.
6. Hofmann SG, Smits JA. Cognitive-behavioral therapy for adult anxiety disorders: a meta-analysis of randomized placebo-controlled trials. The Journal of clinical psychiatry. 2008;69(4):621-32.
7. James AC, James G, Cowdrey FA, Soler A, Choke A. Cognitive behavioural therapy for anxiety disorders in children and adolescents. The Cochrane database of systematic reviews. 2015(2): Cd004690.
8. Hawton KE, Salkovskis PM, Kirk JE, Clark DM. Cognitive behaviour therapy for

psychiatric problems: A practical guide: Oxford University Press; 1989.
9. Purgato M, Gastaldon C, Papola D, van Ommeren M, Barbui C, Tol WA. Psychological therapies for the treatment of mental disorders in low- and middle-income countries affected by humanitarian crises. The Cochrane database of systematic reviews. 2018;7: Cd011849.
10. Shahriari H, Zare H, Aliakbari Dehkordi M, Sarami Foroushani GR. Effectiveness of Cognitive-Behavioral Interventions in the Treatment of Generalized Anxiety Disorder: A Systematic Review and Meta-analysis. Journal of Rafsanjan University of Medical Sciences. 2018;17(5):461-78.
11. van der Heiden C, Muris P, van der Molen HT. Randomized controlled trial on the effectiveness of metacognitive therapy and intolerance-of-uncertainty therapy for generalized anxiety disorder. Behaviour research and therapy. 2012;50(2):100-9.
12. Ansari Zadeh Mehdi JMH, Moeinan Davood. Comparison of the effectiveness of cognitive-behavioral group therapy, drug therapy and placebo in reducing anxiety in substance abusers. Addiction Research. 2017;11(44):59-74.
13. Wang Z, Whiteside SPH, Sim L, Farah W, Morrow AS, Alsawas M, et al. Comparative Effectiveness and Safety of Cognitive Behavioral Therapy and Pharmacotherapy for Childhood Anxiety Disorders: A Systematic Review and Meta-analysis. JAMA pediatrics. 2017;171(11):1049-56.
14. Alirezai Motlaq M, Asadi Z. Cognitive-Behavioral Therapy (CBT) in Ameliorating Adolescent Anxiety in Generalized Anxiety Disorders (GAD). Research on Exceptional Children, 2009;9(1): 25-34
15. Walkup JT, Albano AM, Piacentini J, Birmaher B, Compton SN, Sherrill JT, et al. Cognitive behavioral therapy, Sertraline, or a combination in childhood anxiety. The New England journal of medicine. 2008;359(26):2753-66.