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Comparison of the Effectiveness of Pharmacotherapy and Cognitive-Behavioral Stress Management and Their Combination on Distress Tolerance and Headache Reduction in Patients with Tension Headache

S. A. Amiri Argmand (MA)[1], B. Mirzaeian (PhD)[*2], S. M. Baghbanian (MD)[3]

1.PhD Student in General Psychology, Faculty of Human Sciences, Sari Branch, Islamic Azad University, Sari, I.R.Iran.
2.Department of Psychology, Faculty of Human Sciences, Sari Branch, Islamic Azad University, Sari, I.R.Iran.
3.Department of Neurology, School of Medicine, Mazandaran University of Medical Sciences, Sari, I.R.Iran.

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ABSTRACT

Background and Objective: Tension headaches are the most common type of headache which lead to functional decline in patients with this problem. Considering the fact that pharmacotherapy alone cannot be a complete treatment for this problem, the present study was conducted to evaluate the effectiveness of cognitive-behavioral stress management alone and along with pharmacotherapy on the treatment of tension headaches.

Methods: In this cross-sectional study, 40 patients with tension headache were selected by convenience sampling method and were divided into four groups of ten. The first group received stress management program, the second group underwent pharmacotherapy, the third group was under pharmacotherapy and stress management, and the fourth group received no treatment. Subjects were treated for eight weeks and they completed Distress Tolerance Scale (DTS) and Tension Headache Questionnaire before and after the intervention and the results were compared.

Findings: Mean distress tolerance scores in the first group changed from 41.50±8.38 to 46.50±9.05, the second group from 42.43±7.18 to 42.00±7.46, the third group from 37.00±9.73 to 45.75±9.25 and the fourth group changed from 40.86±9.61 to 38.43±9.67 (p=0.000). Headache severity in the first group changed from 7.50±2.07 to 4.75±1.48, the second group from 7.14±1.95 to 4.57±1.90, the third group from 6.75±2.81 to 2.25±1.66 and the fourth group changed from 6.86±1.95 to 7.71±2.13 (p=0.00). Pairwise comparison of the groups demonstrated that the third group (combination therapy) showed a significant difference in both variables compared to other groups (p=0.04).

Conclusion: The results of the study demonstrated that combination therapy (cognitive-behavioral stress management and pharmacotherapy) showed the greatest effect on distress tolerance and headache reduction. Therefore, stress management can be a suitable complement to medication.

Keywords: *Distress Tolerance, Tension Headache, Cognitive-Behavioral Stress Management.*

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***Corresponding Author: B. Mirzaeian (PhD)**
Address: Department of Psychology, Faculty of Human Sciences, Sari Branch, Islamic Azad University, Sari, I.R.Iran.
Tel: +98 (11) 33379022. **E-mail:** bahrammirzaian@gmail.com

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Introduction

Headache is one of the most common studied complaints in neurology clinics. The most common types of headaches are tension headache and migraine headache. The number of people suffering from tension headaches is much higher than migraine headaches; 25% of the total population of the world suffer from tension headaches and 14% suffer from migraine headaches (1). According to the definition of Headache Classification Committee of the International Headache Society in 2018, tension headache is a compression and non-throbbing headache that lasts from 30 minutes to 7 days and is the result of contractions in the muscles of pelvic floor, head, neck, shoulders and face and the most important causes include nervous excitement, stress and emotional pressures. This type of headache is not dangerous but occurs frequently and most adults experience this type of headache (2).

Tension headaches lead to loss of efficiency and productivity and more frequent use of health services and impose a great deal of cost on the person and society and is considered a big health problem and therefore the treatment of this problem is highly important (1). In their study, Oliveira et al. found that headache disorders are one of the leading causes of absenteeism, with an economic burden of up to $ 33.5 billion per year in a country like Brazil (3).

Pharmacotherapy is one of the first choices for treating tension headaches. However, pharmacotherapy is not a complete treatment for people with tension headaches in Iran (4). Medications are generally quick-acting, but their persistence is low because they do not solve the main problem of tension headaches (5). To treat headaches, it is necessary to manage stress. However, it should not necessarily be eliminated. The existence of eustress is one of the basic conditions for adaptation, survival, growth and development. Nevertheless, too much stress leads to physical and mental problems (6, 7).

Stress management can be effective on tension headaches when it increases the body's tolerance threshold for stress, which is called anxiety tolerance (8). Higher stress tolerance means that the body mentally and physically reaches a level of endurance that does not react to any stress, is able to tolerate it and the person's health is not endangered (9-13).

One of the methods of stress management is Cognitive-Behavioral Stress Management (CBSM), which was designed by a group of psychologists and psychiatrists from the University of Miami, USA, led by Antoni (14). Research shows that cognitive-behavioral stress management is effective in reducing anxiety, depression, and headache, and increases mental health and anxiety tolerance (15-22). Therefore, the present study was conducted to investigate the effectiveness of cognitive-behavioral stress management alone and in combination with pharmacotherapy on the treatment of tension headaches.

Methods

After registration in IRCT system with the code IRCT20200413047057N1 and obtaining permission from the ethics committee of Islamic Azad University, Sari branch, with the code IR.IAU.SARI.REC.1398.127, this clinical trial was conducted on 40 patients with tension headache referred to the Neurology Clinic of Dr. Baghbanian and Tooba clinic in Sari based on convenience sampling. The samples were divided into four groups of ten. There were three experimental groups: the first group underwent only cognitive-behavioral stress management method and the second group only received pharmacotherapy and the third group received both treatments and the fourth group or control group did not

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receive any treatment. In the course of treatment, a number of subjects withdrew from the study, and finally 8 people remained in the first group, 7 people in the second group, 8 people in the third group and 7 people in the fourth group.

Individuals with full symptoms of tension headaches according to the diagnostic criteria of the International Headache Society (ICHD III) (2) whose problem was diagnosed by a neurologist, had a history of at least three months of headache complaints, were willing to participate in all training sessions, had a degree of at least middle school diploma and at least 18 years of age were included in the study. In case of being absent for more than three sessions, the presence of a known complication or malignant disease, the presence of cognitive disorders due to psychosis such as schizophrenia, major depression, alcoholism, substance abuse or other psychedelic drugs, subjects were excluded from the study.

Tension headache questionnaire: This scale is prepared according to the ICHD III standard and has ten questions, nine of which examine the indices of tension headache and the tenth question examines the severity of headache, which is scored from zero to ten; zero indicates the lowest severity and ten indicates the highest severity of headache (23).

Distress Tolerance Scale (Simons & Gaher 2005): This is a self-assessment indicator of distress tolerance developed by Simons & Gaher. The questionnaire has 15 questions based on a five-point Likert scale from strongly disagree to strongly agree. The minimum score of the subject in each question is 1 and the maximum is 5, and in total, the minimum score is 15 and the maximum is 75. The alpha coefficient of this scale is 0.82 and the validity coefficient is reported to be 0.61 (24). Descriptive and inferential statistics were used in this research and analysis of covariance (ANCOVA) was used for analysis of scores based on SPSS software.

In this study, after dividing the subjects into four groups, they were asked to complete questionnaires on tension headache and distress tolerance. Then, the first group (stress management group) and the third group (combination therapy with stress management and pharmacotherapy) were trained in 8 two-hour sessions of cognitive-behavioral stress management based on Antoni's book (14). The second group (pharmacotherapy group) received medication based solely on medications prescribed by a neurologist, including simple and caffeinated sedatives, nonsteroidal anti-inflammatory drugs, and tricyclic antidepressants. The third group (combination therapy with stress management and pharmacotherapy) took medication and at the same time, attended stress management sessions. Due to the fact that the sessions were held once a week, it took two months for the sessions to end, and one week after the sessions, all groups were again tested for distress tolerance and tension headaches. In stress management sessions, meditation and muscle relaxation techniques were performed at the beginning and end of each session. During each session, the following cognitive topics were taught: knowledge of stress and the correct way to deal with stress, learning cognitive errors, automatic thoughts and negative beliefs and how to challenge them, learning problem solving skills, courageous behavior, and anger management, all of which lead to a reduction in stress levels.

One-way analysis of covariance (ANCOVA) was used to compare the average post-test scores (with respect to the pre-test scores). The most important conditions for ANCOVA implementation are homogeneity of variances and regression slope, which were tested by Levene's test and homogeneity of regression slopes test, respectively. After ANCOVA, the groups were compared pairwise through the Bonferroni test to determine the significance of the difference between them, and $p<0.05$ was considered significant.

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Results

Mean distress tolerance scores in the first group changed from 41.50±8.38 to 46.50±9.05, the second group from 42.43±7.18 to 42.00±7.46, the third group from 37.00±9.73 to 45.75±9.25 and the fourth group changed from 40.86±9.61 to 38.43±9.67 (p=0.000). Headache severity in the first group changed from 7.50±2.07 to 4.75±1.48, the second group from 7.14±1.95 to 4.57±1.90, the third group from 6.75±2.81 to 2.25±1.66 and the fourth group changed from 6.86±1.95 to 7.71±2.13 (p=0.00).

In Levene's test (distress tolerance scores), p value was equal to 0.24 which is greater than 0.05 and therefore the variances are homogeneous and according to the regression slope test, p value was equal to 0.40 which is greater than 0.05 and therefore the regression slope is homogeneous. Table 1 shows the adjusted mean scores (i.e., mean post-test scores with respect to pre-test scores) of distress tolerance, according to which the third group (combination therapy) with an adjusted mean score of 48.98 had the highest mean score. ANCOVA test of adjusted mean scores showed p=0, which is less than 0.01, indicating that the difference between the mean scores (at least between two groups) was significant.

Table 1. Adjusted mean scores of groups (distress tolerance)

Groups	Raw mean score	Adjusted mean score
The first group (cognitive-behavioral stress management)	46.50	45.41
The second group **(**pharmacotherapy)	42.00	40.02
The third group (cognitive-behavioral management of stress and pharmacotherapy)	45.75	48.98
The fourth group (no intervention)	38.43	37.96

The groups were compared pairwise in the Bonferroni test, which showed that there was a significant difference between the third group (combination therapy) and other groups (p=0.04) (Table 2).

Table 2. Bonferroni test of distress tolerance (test for pairwise comparison of adjusted means)

Group comparison		p-value
Stress management group	Pharmacotherapy group	0.01
Stress management group	Combination therapy group	0.04
Stress management group	Control group	0.00
Pharmacotherapy group	Combination therapy group	0.00
Pharmacotherapy group	Control group	1.00
Combination therapy group	Control group	0.00

The mean scores of tension headache in the subjects before and after the intervention in the combination therapy group (cognitive-behavioral intervention and medication) showed the greatest difference (p<0.05) (Table 3).

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Table 3. Mean scores of tension headache in pre-test and post-test stages

Separation of groups based on the type of intervention	Before intervention Mean±SD	After intervention Mean±SD
Group one (cognitive-behavioral stress management)	7.50±2.07	4.75±1.7548
Group two (pharmacotherapy)	7.14±1.95	4.57±1.90
Group three (cognitive-behavioral management and pharmacotherapy)	6.75±2.81	2.25±1.66
Group four (without intervention)	6.86±1.95	7.71±2.13

For the scores of headache variable according to Levene's test, p value was equal to 0.14 which is greater than 0.05, so the variances are homogeneous and according to the regression slope test, p value was equal to 0.71 which is greater than 0.05 and therefore the regression slope is also homogeneous. The lowest adjusted mean score of headache variable belonged to the third group (combination therapy), which was ranked first with an adjusted mean score of 2.41. In ANCOVA test, the mean scores were compared and p value was equal to 0 which is less than 0.01, so the difference between the mean scores (at least between two groups) was significant (Table 4).

Table 4. Adjusted mean scores of study groups (tension headache)

Groups	Raw mean score	Adjusted mean score
Group One (cognitive-behavioral stress management)	4.75	4.53
Group two (pharmacotherapy)	4.57	4.53
Group three (cognitive-behavioral management and pharmacotherapy)	2.25	2.41
Group four (without intervention)	7.71	7.82

Based on Bonferroni test, the adjusted mean scores of headaches were compared pairwise, which showed that there was a significant difference between the third group (combination therapy) and other groups ($p<0.05$) (Table 5).

Table 5. Bonferroni test of tension headache (test for pairwise comparison of adjusted means)

Group comparison		p-value
Stress management group	Pharmacotherapy group	1
Stress management group	Combination therapy group	0.04
Stress management group	Control group	0.00
Pharmacotherapy group	Combination therapy group	0.04
Pharmacotherapy group	Control group	0.00
Combination therapy group	Control group	0.00

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Discussion

The findings of this study showed that the combination method of pharmacotherapy and stress management is significantly more effective in reducing tension headache compared to pharmacotherapy and stress management methods (alone). This result is explained by the fact that medication causes hormonal and biological changes in the central nervous system and somehow upgrades the hardware of the brain system (25) and stress management upgrades the software of the brain system by entering data about stress-coping strategies and increases the long-term effects of pharmacotherapy (26). In addition, stress management with its relaxation mechanisms can probably cause the muscles involved in headache to expand and reduce headaches. Another explanation is the formation of conditioning process. In other words, the relief caused by the drug due to its simultaneity with stress management makes the patient think that it is because of stress management that his/her headache is reduced and therefore he/she has an active condition and feels more control over his/her headache. The stronger this conditioning process and sense of control, the more likely it is to reduce headaches. However, more research needs to be done to determine whether stress management has the same effect after gradual elimination of the drug.

Several studies confirm the effect of the combination method of pharmacotherapy and stress management on headache (27-33). Lee et al. confirmed the above result in their review of more than 12,000 articles (34). On the other hand, some studies reject the above results (35). In their research on 44 studies, Verhagen et al. concluded that there was no indication of the above result. However, out of 44 articles, they found only 5 articles without bias and they drew these conclusions based on 5 articles (36).

The combination method of pharmacotherapy and stress management has been significantly more effective on distress tolerance compared to other mentioned methods (alone). In explaining the above result, it should be stated that two factors are needed to increase distress tolerance. First, the biological preparation of the brain and parasympathetic nervous system in the controlled release of stress hormones such as adrenaline and cortisol. This is where medications play a major role. Second, the preparation of the cognitive system of the brain in order to gain the necessary knowledge about stress and acquire the necessary skills to deal with it, which is the responsibility of the cognitive part of stress management (37). This is probably when these two conditions together cause a significant increase in distress tolerance.

Based on the results of the study by Antoni et al., among the available treatments using distress reduction methods such as muscle relaxation, cognitive restructuring, effective coping training, emotional expressiveness training and anger management, cognitive behavioral stress management has been more successful in dealing with emotional problems such as tension headache (14). Many studies have been conducted regarding the effect of stress management and cognitive behavioral therapy on increasing distress tolerance (38-42), all of which confirm the effect of cognitive behavioral therapy on distress tolerance. But not much research has been done on the combination of pharmacotherapy and stress management on distress tolerance.

The limitations of the research include the small size of the samples, short time interval between the post-test assessment and the treatment, lack of sufficient background to investigate the effectiveness of pharmacotherapy and stress management on distress tolerance, not doing repeated assessment once every few sessions, and the use of convenience sampling.

Previous studies indicate the effect of distress tolerance on headache reduction (8), and in this research, distress tolerance increased and headache decreased. It is likely that the therapeutic intervention increased

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distress tolerance and distress tolerance decreased headache. Whether this simultaneity is a causal relationship or not can be determined in future researches.

The results showed that the effect of combination therapy (stress management and pharmacotherapy) on increasing distress tolerance and reducing headache is much higher than their effect individually.

Conflict of interest: In this research, there is no conflict between the research results and the interests of individuals or organizations that are somehow related to this study.

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