Jundishapur Journal of Chronic Disease Care
Volume 12 · Issue 4 · e136243

OPEN PEER REVIEW

Comparison of Effectiveness of Transdiagnostic Treatment and Schema Therapy in Sleep Quality and Clinical Symptoms in Women with Migraine

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SUBMITTED	REVISED	ACCEPTED	DOI
10 Mar 2023	26 Jun 2023	11 Aug 2023	10.5812/jjcdc-136243

About this report

This open peer review (OPR) report shows the public comments made on this article during peer review, by the reviewers, the associate editor and the editor-in-chief, for every revision round, together with the authors' replies. Comments appear only with the consent of the people who wrote them. Reviewers who chose to sign their report are named; the others are shown as "Referee". Comments are edited for language only, and confidential remarks to the editors are not included.

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1 Original submission

4 comments · 27 Mar 2023 – 8 May 2023

Referee 1 Reviewer

MAJOR REVISION 27 Mar 2023

Hello, and thank you for the opportunity to review this project. Overall, the study examines an important and practical topic. However, the following points need to be considered to improve the content of the article.
Abstract:
The sampling method is convenience sampling, not purposive sampling. References do not need to be included in the abstract. It would be better to report exact P values rather than merely stating that the P value is less than or greater than 0.05.
Introduction:
References should be formatted according to the journal's requirements. The problem statement suggests that the study will be conducted among nurses, but no such population is mentioned in the methods.
The introduction is too long. First, discuss migraine, its prevalence, and its complications (its symptoms and effects on sleep quality) in about two paragraphs. Then briefly explain the two treatment methods and explain why they need to be compared as the rationale for conducting the study.
The problem statement does not discuss women, although the title states that the study is conducted among women.
The article includes a section titled Background that discusses similar studies. According to the journal's format, this section is not needed.
Methods:
The sampling method is convenience sampling (not purposive sampling), after which the participants were randomly assigned to three groups.
The randomization method is not specified.
On what basis was the sample size determined?
For items assessed using scores, specify in the inclusion and exclusion criteria the exact scores required for study entry.
Specify in the inclusion criteria that only female patients are selected.
What is meant by drug treatment in the inclusion and exclusion criteria? You cannot discontinue drug treatment for the disease. Your interventions are complementary therapies. The two groups should be matched in some way for the medications they receive; randomization may achieve this.
Include a subsection titled Intervention in the methods, and describe how the intervention was implemented, its location, duration, and content.
Results:
Why do the inclusion criteria specify an age range of ۲۰ to ۴۰ years, whereas the results and Table ۳ report an age range of ۴۰ to ۷۰ years?
Why are the scores measured in the fourth week not reported in Table ۴ or in the graphs?
In this table, the scores at each stage could have been compared using one-way analysis of variance.
The way the results of the repeated-measures test are reported needs to be revised. Usually, when reporting the results of this test, the first table shows the overall effect of time, and the second table compares the overall effect of the experimental group.
The control group is missing from the graphs!
The labels on the horizontal and vertical axes of the graphs should be corrected to reflect the variable names.
Discussion:
The discussion is well written.

Referee 2 Reviewer

MINOR REVISION 1 May 2023

The total volume of the text is very large. Be sure to reduce the number of words, especially in the introduction and background.
Please delete table number 3. Alternatively, explain why you have chosen the age variable among all the demographic variables. What statistical test have you used for it to show the similarity of the groups? Currently, this table has no statistical value.

Discussion:
In the discussion, you should compare the results of your study with those of other similar studies and argue why these results are similar or different.
Rewrite the discussion section completely.

Associate Editor

MAJOR REVISION 8 May 2023

Dear Author,
Based on our reviewer's comments, your manuscript needs some revision in all sections. Please revise and resubmit as soon as possible.
Thank you very much indeed.

Editor-in-Chief

MAJOR REVISION 8 May 2023

Dear Author,
Based on the reviewers' comments, your manuscript needs some revisions. Please revise and resubmit.
Thank you

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Revision 1

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

With greetings, courtesy and respect to the respected reviewers
With appreciation and thanks for reviewing this article and providing your valuable comments, the requested corrections are submitted to you in the table below, in order and corresponding to the comments; also, all corrections requested by the respected reviewers were applied in the article file.

Respectfully
Jamshidi

Corrections made	Comments of the respected reviewers	No.
This was a semi-experimental research with a pre-test, mid-test, post-test and follow-up with a control group. The statistical population included all women aged 20 to 40 diagnosed with migraine in Shahrekord in 2022. A total of 45 people were selected as sample from among the women referring to specialized clinics in Shahrekord, using the available sampling method and taking into account the inclusion criteria of the subjects, and they were randomly assigned into two experimental groups and one control group (each group 15 people). The research tools included the Ahvaz Migraine Questionnaire, the Sleep Quality Scale, the Transdiagnostic Treatment Protocol and the Schema Therapy Protocol. To analyze the data, multivariate and univariate analysis of covariance was used using SPSS-27. **Results**: The results showed that there was a significant difference between the overall mean scores of migraine clinical symptoms and sleep quality in the two groups of transdiagnostic treatment and schema therapy (p=0.001). In general, it can be concluded that the transdiagnostic treatment method had a greater effect on the clinical syndrome scores of migraine and sleep quality than the schema therapy method (p=0.001).	The points mentioned regarding the abstract were corrected. (The sampling method, as well as the method of calculation and the p value, were corrected)	1
Migraine is characterized by recurrent moderate to severe debilitating headaches. Migraine Research Foundation declares that migraine	The way of citing references was corrected in accordance with the journal format The problem statement was	2

headaches are the third most common disease in the world. Despite such a high prevalence, there is little understanding of its symptoms, causes, and treatment Error: Reference source not foundError: Reference source not found, and brain and neurological disorders are among the most common reasons people refer to outpatient clinics. It appears due to the dilation of the vessels enclosing the brain and is pulsating on one side of the head, accompanied by nausea and vomiting, which may be aggravated by daily activities. Women suffer from migraine three times more often than men. Also, women experience longer attacks that are more debilitating Error: Reference source not found. It is known that headache in patients with migraine plays an important role in their quality of life. So that greater pain intensity leads to a decrease in performance in most components of the mental health scale, including general health, vitality, mental health, and social functioning, and in general, decreased quality of life in these patients Error: Reference source not found. Results of studies show that insomnia is a common symptom in patients with chronic headache and sleep complaints are very common among people with migraine. Also, sleeplessness and oversleeping may also be considered migraine triggers, so that sometimes migraine attacks can be predicted by the length of sleep the night before Error: Reference source not found. Sleep is one of the necessities of life, its deprivation can endanger everyone’s health. It will not be possible to have a good and productive awakening without enough or quality sleep. In order to achieve this goal, it is very important to correctly understand sleep, which occupies about 1.3 of a person’s life Error: Reference source not found. At least over one-third of the adult population suffers from intermittent insomnia, while 10-15% suffer from chronic and persistent sleep problems.	corrected in line with the method. The introduction was summarised and the points intended by the respected reviewer were applied. Also, the article background section was deleted.	

Deprivation of sleep or its poor quality causes dysfunctions in the central nervous system. These functions range from the most basic functions such as appetite regulation and body temperature regulation to higher level functions such as memory and hearing Error: Reference source not found. Sleep quality is a complex phenomenon that is difficult to define and it is subjectively measured Error: Reference source not found. Due to the debilitating nature of migraine, it is very important to treat it and reduce the severity of its symptoms. Drug treatments and different types of psychotherapy are used in this regard. Extensive research shows the effectiveness of psychological treatments on reducing the symptoms of migraine and chronic headaches Error: Reference source not found. One of the treatments that has recently received attention is transdiagnostic treatment. This treatment is designed to compensate for the shortcomings of previous treatments and has been relatively successful. Transdiagnostic treatment was developed by Barlow et al. Error: Reference source not found. Another treatment that is examined in this research is schema therapy. Schemas are among the basic variables that benefit from high explanatory power, because many cognitive processes, coping strategies and lifestyle of patients are influenced by these basic structures. Schema therapy is a fundamental development in cognitive therapy Error: Reference source not found. Generally speaking, transdiagnostic treatments and schema therapy are considered new and effective treatments for psychological problems and disorders. These two types of third generation treatments, whose effectiveness has been confirmed on emotional regulation, reducing anxiety, depression and increasing physical health, can be more economical and effective than traditional cognitive behavioral treatments, while		

being more effective in comorbidity psychological disorders which are also common in migraine Error: Reference source not found, than usual treatments and this makes the use of non-pharmacological methods in the form of therapeutic supplements more obvious. On the other hand, the use of such strategies enables patients to play an active role in their care and treatment and to effectively control the disease. Due to the importance of recognizing psychological factors as related and effective factors of physical condition and symptoms of migraine and limitations in generalizing the results abroad due to cultural differences, the importance of the current research is felt more than ever. According to the materials and studies, this research aims to compare the effectiveness of transdiagnostic treatment and schema therapy on sleep quality and clinical symptoms of migraine in women with migraine in 2022.		
This study is one of the semi-experimental designs with pre-test, mid-test, post-test and follow-up with a control group. Its statistical population include all women aged 20 to 50 with migraine diagnosis in Shahrekord in 2022. From among the women referring to specialized clinics in Shahrekord, using the available sampling method and taking into account the inclusion criteria, a total of 45 women were selected as a sample and randomly assigned by lottery in two experimental groups and a control group was placed (15 people per group). Inclusion criteria are: 1) consent to participate in the research and permission to withdraw at any stage of the research, 2) obtaining a higher than average score in the migraine clinical symptoms questionnaire and sleep quality , 3) minimum diploma literacy to understand the items of the questionnaires, 4) age between 20 and 50 years, 5) at least 6 months being passed since the diagnosis of migraine, 6) not	The sampling method, as well as the randomization method, were stated correctly. The basis for determining the sample size, as well as the exact score intended for entry into and exit from the study, were stated Also In the inclusion criteria it was stated that only female patients were selected. What is meant by drug treatment in the inclusion and exclusion criteria was explained In the method, a heading entitled Intervention was stated, and the explanations regarding how the intervention was implemented, and the place, duration and content of the intervention, were stated in it	3

being in any medical and psychological treatment at the same time, and 7) suffering from physical and mental disease that lead to interference with the research variables, and the exclusion criteria are: 1) Dissatisfaction with continuing to cooperate in the research, 2) Failure to answer all the research questions. and 3) absence of more than two sessions in treatment sessions. After obtaining the code of ethics with the number IR.IAU.AHVAZ.REC.2022.103 and approval of the proposal in the research council of the faculty and after coordination with the clinics of Shahrekord and upon obtaining the sample group and assigning them in 3 groups randomly, the pre-test phase is carried out on all three experimental and control groups before starting the treatment courses. Then two experimental groups are subjected to specified treatments and the control group do not receive any treatment. Then, at the end of the treatment periods, the post-test phase is performed on all three groups. Two months after the follow-up phase, all three groups are tested again. In order not to violate the rights of the people in the control group, after the follow-up phase, intensive treatment courses are implemented for them. Then the data are collected and prepared for final analysis in SPSS-26. Some of the ethical considerations considered in this research are: 1) The researcher will explain all the steps of the research honestly and clearly and get the opinion of the candidates to participate in the test. 2) All people participating in this research before answering the questions of the tests will sign the consent form to participate in the research and they can withdraw at any stage. 3) The researcher is committed to keep all the information of the candidates confidential. 5) The researcher morally respect each person involved in the research process and avoid discrimination between ethnicities,		

genders, social and economic status. **Intervention** In order to carry out the research, the necessary coordination was done with the specialized clinic of Imam Ali. The implementation method was such that after coordinating with the clinic officials and providing information about the desired sample (including age, etc.), the sample group was provided to the researcher. After selecting the sample subjects, the subject, treatment courses and their goals were explained to the subjects and they were told that participation in the treatment courses is voluntary and with the consent of the individual and there was no compulsion to participate in the courses. The content of the interventions is as follows:		
In Table 5, the results of the analysis of variance with repeated measurements are presented to investigate the intra-test and inter-test effects. According to the results of the F test, the group effect and the time effect were significant for sleep quality variables and migraine clinical symptoms ($p<0.001$). There was a difference between the three stages of pre-test, post-test and follow-up in these variables in the experimental and control groups ($p<0.001$). Also, the results of Table 5 indicated that there is an interaction between the effect of group and time in sleep quality variables and Clinical symptoms of migraine ($p<0.001$). which shows the stability of Transdiagnostic treatment and schema therapy on sleep quality variables and Clinical symptoms of migraine	The tables related to the inclusion criteria (age, etc.) were corrected. Because the study was conducted in three stages (pre-test, post-test and follow-up), Table 4 was deleted entirely. The way of reporting the results of the repeated measures test was corrected. In the charts, the control group was stated, and the names along the length and width of the charts were corrected based on the names of the variables	4
Bolis et al. (2021) in their research titled the effectiveness of transdiagnostic treatment on disorders affected by emotion, conducted on 50 patients with psychosomatic disorders, examined and confirmed the effectiveness of transdiagnostic treatment on reducing the symptoms of emotional disorders.Warkowitzki, Sherrill and	In the Discussion section, the results obtained from comparing this study with similar studies were corrected in accordance with the respected reviewer's opinion.	5

Roger (2021) in their research titled evaluation of the effectiveness of treatment based on transdiagnostic approach in improving emotional disorders in trauma patients, conducted on 30 patients, showed that transdiagnostic treatment improved the emotional disorders of people with PTSD.De Orleans Maya et al. (2020) in their research titled the effectiveness of transdiagnostic treatment on reducing emotional and psychological problems of patients with migraine, on 40 adult migraine patients, showed that transdiagnostic treatment was effective in reducing emotional and psychological problems of patients with migraineIn explaining this finding, it should be said that the transdiagnostic approach, emphasizing the cognitive and behavioral processes of migraine patients, tries to reanalyze the patient's anxiety control and the response to pain anxiety from a cognitive and emotional point of view and help to resolve the patient's cognitive and behavioral errors Error: Reference source not found Taluksi et al. (2017) in their research titled the effectiveness of transdiagnostic treatment on anxiety, depression and positive and negative emotions and emotional problems in patients with anxiety disorders showed that 12 sessions of transdiagnostic treatment resulted in a significant reduction of symptoms of anxiety, depression, and negative emotions, behavioral inhibition and emotional regulation problems in patients with anxiety disorders.Saro-Zaula et al. (2016) in their research titled the effectiveness of transdiagnostic treatment on reducing anxiety and improving emotion dysregulation in migraine patients showed that transdiagnostic treatment reduced anxiety in migraine patients and improved their emotion regulation.Sariaho (2016) in his research titled the effectiveness of schema therapy on reducing pain intensity and increasing pain acceptance in migraine patients on		

33 female migraine patients showed that the adjustment of most schemas had a significant effect on reducing pain intensity and pain acceptance.Carter et al. (2016) in their research entitled investigating the effect of schemas on pain intensity in people with migraines showed that there was a relationship between initial maladaptive schemas and pain intensity and among schemas, emotional deprivation schema had significant scores compared to others. . Johnson et al. (2021) in their research entitled the effectiveness of schema therapy on reducing depression caused by illness in patients with chronic pain in 33 patients with chronic pain showed that schema therapy was effective in treating depression and this treatment was known as antidepressant.Flieger et al. (2020) in their research entitled the effect of schema therapy on comorbidity anxiety and depression disorders in primary care and psychiatry showed that this treatment significantly reduced the symptoms of depression even with comorbidity anxiety disorders.Goldin et al. (2020) in their research entitled the effectiveness of schema therapy on improving social anxiety disorder in 40 patients with social anxiety disorder showed that schema therapy improved social anxiety disorder through its effect on brain reactions related to re-evaluation of social criticism.Askey-Jones, David, Silber, Shaw and Chalder (2020) in their research entitled the effectiveness of schema therapy on reducing depression and anxiety in patients with MS, concluded on 30 female adult patients with MS concluded that schema therapy could significantly reduce anxiety and depression in MS patients. Siegel et al. (2019) in their research entitled the effectiveness of schema therapy on reducing depressive symptoms in patients with chronic psychosomatic pain in 40 female patients, showed that schema therapy was		

effective in reducing depressive symptoms in patients with psychosomatic pain.The results of the meta-analytical research of Amsberg et al. (2019) in their research titled the effectiveness of schema therapy on anxiety disorders of adolescents with fibromyalgia disorder, conducted to 30 patients, showed the high effectiveness of schema therapy in the treatment of anxiety disorders.Hunt et al. (2019) in their research titled the effectiveness of cognitive behavioral schema therapy reported the effect of this method in reducing anxiety and depression in patients with migraine, on 19 female patients with effective coping skills and reducing the catastrophizing of pain and symptoms, and symptoms of the disease.Wells et al. (2018) in their research titled the effectiveness of schema therapy on reducing pain on 30 patients with chronic pain showed that schema therapy can reduce the intensity of pain and increase the ability to perform activities and self-efficacy of patients suffering from chronic pain. Emotional schema therapy techniques with the help of controllability management, empowerment methods based on the psychology of validation and decision-making techniques based on the psychology of distress intolerance are effective in improving		

2 Revision 1

2 comments · 11 Aug 2023 – 11 Aug 2023

Associate Editor

ACCEPT 11 Aug 2023

Dear Author,
All comments have been made, and it is acceptable.
THANK YOU

Editor-in-Chief

ACCEPT 11 Aug 2023

Dear Author,
This manuscript in its current version is acceptable for publication.
Thank you