

Original Article



Effects of Reflexology on the Pain Intensity among Patients with Depression after Receiving Electroconvulsive Therapy: A Randomized Clinical Trial

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Abstract

Introduction: High prevalence of psychiatric disorders and the high effectiveness of electroconvulsive therapy (ECT) have made this treatment a useful intervention. Memory impairment, headache, and muscle pain are the most important complications after ECT. This research aimed to determine the effect of reflexology on the headache and muscle pain intensity of patients after receiving ECT.

Methods: This randomized controlled trial was conducted in Razi teaching hospital of Urmia, Iran. A total of 56 patients with depression receiving ECT were randomly assigned into two equal groups of control (n=28) and intervention (n=28). In the intervention group, reflexology was performed for 20 minutes at reflex points and, in the control group, only the conventional measures were taken. Pain intensity was measured with visual analogue scale (VAS) before and 1, 6, and 24 hours after the intervention. Data were analyzed using the SPSS software version 13. Furthermore, chi-square, Mann-Whitney, Wilcoxon, and repeated-measures tests were performed.

Results: The mean difference in the severity of headache and muscle pain in the intervention group was significantly reduced compared to the control group. Moreover, the results demonstrated a significant difference between the mean headache and muscle pain in the two groups after the intervention.

Conclusion: The results of this study showed the positive effect of reflexology on reducing the intensity of pain in patients receiving ECT. Thus, it is recommended that nurses, health care providers, and caregivers use reflexology to reduce pain in patients with depression receiving ECT.

Introduction

Depressive disorders are characterized by sadness, loss of interest or pleasure, feelings of guilt or low self-worth, disturbed sleep or appetite, feelings of tiredness, and poor concentration. Depression can be long-lasting or recurrent, substantially impairing an individual's ability to function at work or school or cope with daily life. At its most severe, depression can lead to suicide. The total number of people living with depression in the world is 322 million. Nearly half of these people live in the South-East Asia Region and Western Pacific Region.¹ The results of meta-analysis showed that the prevalence of accumulated point, one-year prevalence and lifelong depression for 1994 to 2014 were 12.9%, 7.2% and 10.8%, respectively, and the heterogeneity was high in prevalence.² According to a systematic review in 2013, the prevalence of depression in

various Iranian populations was 5.69%-73%.³

Depression is among the most treatable of mental disorders.⁴ Although pharmacotherapies has widely replaced other physical treatments, they have many complications and several weeks must be passed before they could show their therapeutic effects. Furthermore, electroconvulsive therapy (ECT) is one of the important therapeutic methods for the treatment of patients with severe mental disorders.⁵ In this method, electrical stimulation at the voltage of 70-150 V enters the brain for 0.1 to 1 second, which causes a complete convulsion and is associated with therapeutic effects.⁶

The introduction of ECT in treating serious psychiatric illnesses such as depression and bipolar disorder has been a revolution in psychiatry.⁷ Thus, the clinical response of depressed patients has been reported to be between 80% to

100% as the fastest and most effective treatment for major depression.⁸ ECT is the most effective and rapid treatment available for elderly patients with depression, bipolar disorder and psychosis.⁹ Nearly 100 000 people in the United States and more than 1 million people worldwide receive ECT per year.¹⁰ This treatment method, similar to most of the medical treatments, is associated with several complications.¹¹

Headache, muscle pain, nausea, dizziness, and delirium are ECT complications.⁵ Although the most effective tool available for reducing the pain of patients is pharmacotherapy, due to the complications of analgesics and difference in response to them, it is important that non-medicinal methods must be used to reduce pain in addition to these medicines.¹² Today, the non-steroidal anti-inflammatory drugs and narcotics are used routinely to relieve this pain, each of which has its complications.¹³ One of the interventions for pain relief is the use of (alternative) complementary care methods. Most of these interventions are inexpensive and easy, with few complications and risks, and can be used alone or combined with other methods.¹⁴ Complementary therapies are a part of comprehensive care in nursing and, nowadays, nursing has been focused on comprehensive care,¹⁵ which represents the art of nursing profession.¹⁶ Once the science and art are combined, the level of care quality is maximized.¹⁷

Reflexology is one of the six widely used complementary and alternative therapies in Norway, Denmark, the United Kingdom, and the United States.¹⁸ Accordingly, the energy flows through the vertical areas throughout the body of the foot to the head and applying pressure to a reflex point in the hand or foot can affect all organs, including the glands, bones, and muscles.¹⁹ Touching soft tissues that occur in reflexology reduces pain and increases the comfort and relaxation of the patient; thereby, it increases the patient's adaptation to the condition.²⁰ This method has been used for the treatment of a variety of physiological problems such as nausea and vomiting, increased quality of life, and reduced depression, fatigue, and anxiety, stress, tension, increased blood flow in the body and increased homeostasis.^{21,22}

According to a systematic review, reflexology is focused on physical illnesses, including diabetes as well as cardiovascular, pulmonary, orthopedic, and cancer patients.²³ The problems of patients with mental disorders who have a high percentage of illnesses, disabilities, and deaths are not considered.³ Doubts on the effectiveness of complementary medicine in the medical community are one of the main challenges for introducing these measures into the set of caring performance, which necessitates the need for rich research support for the faster entry of this therapy into the interventions.²⁴ Given the increasing trend of patients with depression in different social groups, especially among high-risk and productive groups,²⁵ and the need for faster treatment using early efficacy

treatments such as ECT, the complications including pain after ECT should be reduced. Thus, this study is aimed to determine the effect of reflexology on the pain severity after ECT in patients with depression.

Materials and Methods

This research is a clinical trial with the pre- and post-test design with a control group. The research population was all (outpatient or hospitalized) patients with depression receiving ECT at Razi psychiatric teaching hospital, Urmia. The inclusion criteria were the age of 18-65 years old, having one type of depression requiring ECT, lack of obvious anomalies in the organs (due to difficulty in accessing the reflex points), lack of underlying diseases such as diabetes and neuromuscular diseases (for the possibility of reduced sensitivity), and no use of analgesics at least 4 hours before the intervention. The exclusion criteria were patients who were in the acute phase of psychosis, mild pain score (less than 3), patients who refused to continue the study for any reason, and lack of ability to tolerate the massage in the desired area. According to the study by Sadeghi Shermeh et al., the mean and standard deviation of pain intensity after the intervention was 5 (1.9) in the control group and 3.34 (1.5) in the intervention group.²⁰ To determine the sample size at 95% confidence level and 0.9 test power, the sample size for each group was at least 18.3. According to the effect of the sampling design, the resulting number was multiplied by 1.5 and the sample size for each group was estimated at 28 people.

The data collection tools included a socio-demographic questionnaire (age, sex, educational level, history of ECT, and history of hospitalization,...). The second part was the visual analogue scale (VAS), combines pictures and numbers for pain ratings. Given that the pain intensity after ECT in this study was considered as acute pain and acute pain is a one-dimensional pain, the VAS scale was used to evaluate the pain intensity before and after the intervention (foot and hand reflexology). The numerical scale of pain is a horizontal ruler from 0-10 and the participants should select a number that describes the pain intensity in the best possible way. In this ruler, 0 indicates a lack of pain, 1-3 indicates mild pain, 4-6 is moderate pain, and 7-10 is severe pain. On this scale, a 30-50% reduction in the pain score indicates the adequacy of treatment.²⁶ Based on Jin et al., study, The ICCs for paired VAS scores at admission, 30 minutes after admission, and 1 hour after treatment were 0.988 (95% CI=0.98 to 0.99), 0.968 (95% CI=0.95 to 0.98), and 0.989 (95% CI=0.98 to 0.99), respectively.²⁷ Based on Rezvani Amin et al., study, that correlation of Visual Pain Scale (VAS) with McGill Shortened Pain Questionnaire was evaluated, shows an excellent correlation between these two tools ($r = 0.86$ was obtained).²⁶

The first researcher attended the ECT unit of Razi teaching hospital, Urmia, and gave some information to the patients receiving ECT who were eligible, had the

inclusion criteria and willingness to participate in the study. They were informed about voluntary participation in the study. Then, informed consent was acquired from them and the participants filled out the socio-demographic questionnaire. After selecting the individuals based on the inclusion criteria, they were assigned to the intervention and control groups based on sex in a stratified random manner. For this purpose, in two separate and distinct bags per sex (male or female), 14 numbers of 1 and 14 numbers of 2 that were written on the cardboard pieces were thrown. Each of the patients who chose number 1 was placed in the intervention group and each of the patients who got 2 out of the bag was placed in the control group. At the end of the drawing, 14 female patients were placed in the intervention group and 14 female patients were placed in the control group. Also, 14 male patients were placed in the intervention group and 14 male patients were placed in the control group (Figure 1).

Before receiving ECT, the use of VAS was taught to the patients. ECT was carried out weekly on the odd days from 8:30 AM until the last patient based on the list sent from admission and outpatient wards by the order of the doctor. The admitted patients were delivered to the ward after complete consciousness and the outpatient subjects were monitored in the recovery until the discharge permission by the doctor. It should be noted that the type of electroconvulsive shock that was given to patients in the ECT unit of Razi psychiatric teaching hospital was generally bilateral.

Patients were transferred to the recovery after receiving the ECT. The researcher was present in the recovery room.

After patient consciousness in both intervention and control groups, the location of the pain was determined using the human figure image prepared for this purpose. The pain intensity was specified by one of the numbers in the VAS.

For the patients in the intervention group, the reflexology was carried out by the first researcher who acquired the required theoretical, practical, and supplementary skills by participating in the reflexology training class for 30 hours. The reflexology was performed using odorless olive oil and without the use of gloves in a relaxed environment. The researcher wore a clean uniform and the intervention was performed by removing the ring and the watch with clean and disinfected hands and placing the pillow under the organ receiving massage prepared for this purpose and by warming up the hands. Meanwhile, before the intervention, the hands and feet of the patient were disinfected using an antibacterial gel. Warming of the target limb was done with the gentlest rotating movements (8-10 movements) at the site of the wrist and joint of the fingers. Also with gentle movements of hands from the wrist or ankle of the patient towards the fingers, toes, and vice versa, the reflexology points were pressured using the reflexology stick with gentle pressure and without causing pain. Finally, the solar network located at the border between the upper and middle one-third of the sole where the foot folds were formed when the foot was bent was massaged directly for 2 minutes using the thumb. Afterward, the rotational massage was continued. The massage was done by rotational clockwise and continuous movement of the thumb or other fingers

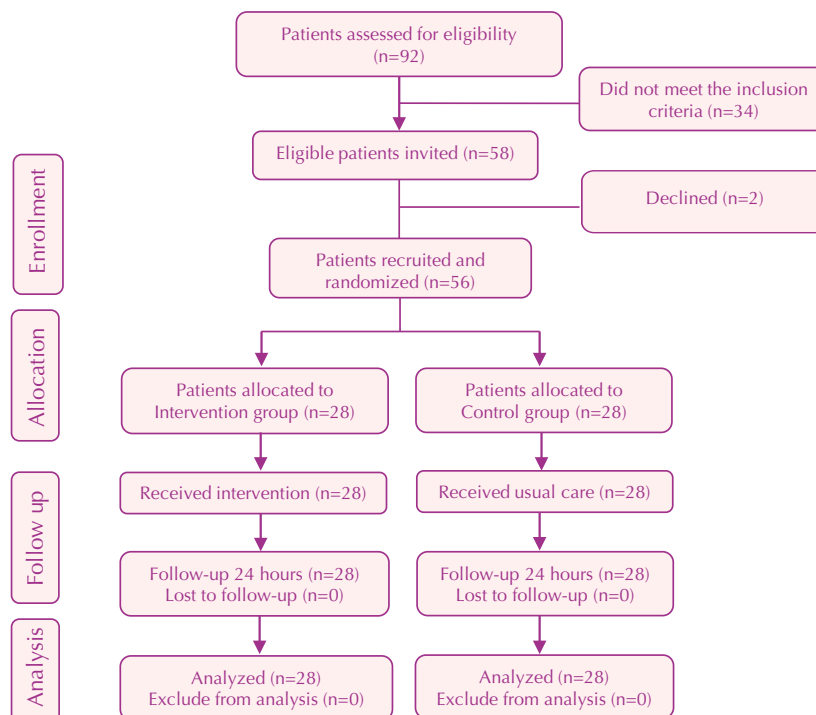


Figure 1. Flow diagram of the study

to the reflex points without interruption in contact with skin. The pressure was to the extent that the upper one-third of the researcher's finger paled and the patient also felt this pressure but did not feel pain. At the stage that the reflexology caused pain in the patient, the pressure did not continue in the relevant area. All the above stages were performed in 20 minutes; then, the patient's organ under massage was dried with a clean towel and was kept warm. Both participants and researcher were blind to participant allocation; however, due to noticeable differences in massage, it was not possible to blind the researcher who performed the massage intervention and participants.

Ten minutes after the end of the reflexology, 6, and 24 after ECT in the intervention group, the post-test was performed by re-examining the location and intensity of pain by the first researcher. In the case of ineffective intervention and continued pain in the patients in the intervention group, the analgesics were given according to the doctor's order. The control group received routine care during this period in the ward (acetaminophen pill if necessary). Pain intensity was measured after patient consciousness, 1, 6, and 24 hours after receiving ECT in the control group. Given that headache and muscle pain caused by ECT are acute pain, usually occur within half an hour after receiving the electroconvulsive and disappear or reduced after 24 hours, the intervention was performed only once. But due to the possibility of pain return for patients within 24 hours after ECT, patients were taught reflexology massage at the relevant reflection points to perform their reflexology before requesting analgesics. To observe the research ethics, after the intervention and post-test, the reflexology training was also given to the control group at the reflex points. After data collection, their analysis was performed using SPSS software (version 13.0, Chicago, IL, USA).

The descriptive statistics including number, percentage, mean, and standard deviation were used to describe the characteristics of the participants and their pain intensity. Given that using the Shapiro-Wilk test, the assumption of data normality was rejected in both the control and intervention groups, therefore, the non-parametric tests were used. So that the Mann-Whitney test was employed to compare the two independent groups and the Wilcoxon test was used to compare the mean before and after the intervention. To compare the pain intensity at different times, the repeated-measures test was used. Finally, using chi-square and Fisher's test, the underlying variables of the two groups were compared. The significance level was considered less than 0.05.

After selecting the samples, the researcher introduced himself to the patient (and if present to the family of selected patients) and filled out the consent and demographic questionnaires by stating the aims of the study and answering the possible questions. At the request of the participants, they could withdraw from the study.

Results

The results of the chi-square test showed that both groups were homogeneous in terms of socio-demographic characteristics such as sex, age range, economic status, marital status, education, history of hospitalization, and history of ECT ($P > 0.05$). The mean (SD) age was 41(13.38) in the intervention group and 39.39(10.74) in the control group (Table 1).

According to the results, the Wilcoxon test showed a significant difference between the mean score of headache in the intervention group before and after the intervention ($P < 0.001$). While this test showed no significant difference between the mean score of headache in the control group before and after the intervention ($P = 0.10$). Also, the results

Table 1. Socio-demographic characteristics of patients receiving ECT in the intervention and control groups

Characteristics	Intervention group (n = 28) No. (%)	Control group (n = 28) No. (%)	P value
Age (years)[€]	41 (13.38)	39.39 (10.74)	
Age range			0.80 [€]
18 -27	5 (17.86)	5 (17.86)	
28 -42	9 (32.14)	12 (42.86)	
43 -65	14 (50)	11 (39.28)	
Gender			1.00 [€]
Male	14 (50)	14 (50)	
Female	14 (50)	14 (50)	
Marital status			0.10 [¥]
Married	13 (46.43)	13 (46.43)	
Unmarried	13 (46.43)	8 (28.57)	
Divorced	0 (0)	5 (17.86)	
Widow	2 (7.14)	2 (7.14)	
Education (years)			0.24 [¥]
Illiterate	10 (35.72)	4 (14.29)	
Under the diploma (≤11)	7 (25)	8 (28.57)	
Diploma (=12)	3 (10.71)	8 (28.57)	
University (≥13)	8 (28.57)	8 (28.57)	
Economic status			0.14 [¥]
Less than enough	12 (42.86)	5 (17.86)	
Enough and more	2 (7.14)	3 (10.71)	
Income is equal to expenses	14 (50)	20 (71.43)	
Having a history of hospitalization	21 (75)	16 (57.14)	0.15 [€]
History of ECT	12 (42.86)	11 (39.28)	0.78 [€]
Inpatient or outpatient status			0.29 [¥]
Inpatient	25 (89.29)	21 (75)	
outpatient	3 (10.71)	7 (25)	

[€]Data are presented as mean (SD); [€]Chi-square test; [¥]Fisher's test.

of the Mann-Whitney test demonstrated no significant difference in the mean score of headache between the intervention and control groups before the intervention ($P=0.44$). This test showed a significant difference in the mean score of headache between the intervention and control groups after the intervention ($P<0.001$), which indicated the effect of providing reflexology on reducing pain in the intervention group.

The results of the Wilcoxon test for muscle pain score also showed a significant difference in the intervention group before and after the intervention ($P=0.02$). While this test represented no significant difference between the mean score of muscle pain in the control group before and after the intervention ($P=0.65$). Mann-Whitney test indicated no significant difference in the mean score of muscle pain between the intervention and control groups before the intervention ($P=0.44$). This test suggested a significant difference in the mean score of muscle pain between the intervention and control groups after the intervention ($P=0.008$). This indicated the effect of providing reflexology intervention on reducing muscle pain in the intervention group (Table 2).

The results of the repeated-measures test showed a significant difference between the mean score of pain in the intervention group before and 1, 6, and 24 hours after the intervention ($P<0.001$). Moreover, this test showed a significant difference between the mean score of pain in the control group before and 1, 6, and 24 hours after the intervention ($P=0.02$). However, according to Table 3, the total pain relief in the intervention group was higher than the control group, which indicated the effect of providing reflexology for total pain relief in the intervention group.

Discussion

Comparing the mean scores of headache and muscle pain in the two groups showed there was no difference between the mean score in the control group on the pre- and post-tests. This difference was significant in the intervention group. Also, a significant difference was found between

the mean score of headache and muscle pain in the two groups after the intervention. Therefore, the results of this study showed that reflexology was effective for pain relief in the patients.

In the interventions associated with reduced pain, numerous studies have been conducted on the patients who are experiencing other painful conditions. In the study by Shahriari et al., in determining the effect of foot reflexology on reducing pain in 50 patients undergoing lower extremity amputation, it was shown that foot reflexology led to pain relief.²⁸ Also, the results of the study by Han et al., on the effect of foot reflexology on postoperative pain in the patients undergoing gastrectomy²⁹ and the results of Rahimi Zarchi et al., who evaluated the effect of foot reflexology on pain in 90 patients undergoing abdominal surgery,³⁰ showed that the foot reflexology has been effective for the patients' pain and the patients receiving the postoperative foot reflexology have better pain relief, which is consistent with the results of the present study.

In the present report, the effect of reflexology by the trained nurse on pain relief and the unwanted pain associated with this treatment was investigated, which showed a decrease in the pain scale after the intervention. The results of the current study are also in line with those of Stephenson et al., who demonstrated that reflexology in all the patients in the intervention group (except one person) reduced pain in the patients with metastatic cancer.³¹ The importance of reflexology on pain relief has been also shown in the study by Quinn et al.,³² and Nazemzadeh et al.³³ In these studies, the effect of reflexology on lower back pain has been investigated and the results have shown that reflexology is more important in reducing lower back pain in patients. This is consistent with the results of the current study, in which reflexology was particularly important as a dimension of care leading to pain relief.

The results of the study by Bauer et al., evaluating the effect of reflexology on the patients after cardiac surgery showed the important role of reflexology in reducing pain,

Table 2. Comparison of mean score of patients' headache and muscular pain in intervention and control groups before and after the intervention

Variable	Headache			Muscular pain		
	Baseline	post-intervention	<i>P</i> value [‡]	Baseline	post-intervention	<i>P</i> value [‡]
Intervention [‡]	6.50 (2.16)	2.53 (1.5)	<0.001*	1.53 (3.09)	0.50 (1.07)	0.02*
Control [‡]	5.92 (2.76)	6.64 (1.7)	0.10	3.50 (4.03)	3.42 (3.93)	0.65
<i>P</i> value [‡]	0.44	0.001*		0.44	0.008*	

[‡] Data are presented as mean (SD); [‡] Wilcoxon test; [‡] Mann-Whitney test; * Statistically Significant.

Table 3. Comparison of mean score of patients' pain in intervention and control groups in baseline, 1 hour, 6 hours and 24 hours after the intervention

	Baseline	1-hour post-intervention	6-hour post-intervention	24-hour post-intervention	<i>P</i> value [‡]
Intervention [‡]	6.67 (1.78)	2.53 (1.50)	1.14 (0.97)	0.21 (0.41)	<0.001*
Control [‡]	6.50 (1.79)	6.64 (1.74)	5.96 (2.53)	0.92 (0.97)	0.02*

[‡] Data are presented as Mean (SD); [‡] Repeated measures test; * Statistically Significant.

anxiety, and stress,³⁴ which is consistent with the results of the current study in terms of the effect of reflexology. Rigi et al., evaluated the effect of reflexology on the pain of 52 patients undergoing coronary artery bypass graft surgery. The results of their study represented that it was significantly effective for pain relief,³⁵ which is consistent with the present study conducted on the patients receiving ECT.

Mohammad Aliha et al., conducted a study to determine the effect of reflexology on the pain of the surgery site of 90 patients undergoing abdominal and chest surgery in the intensive care unit. The results of their study showed that, immediately after the intervention, no significant difference was found in the pain intensity of three groups, but 10 min and 24 hours after the intervention, there was a significant difference between the two groups.³⁶ In our trial, the pain intensity of the patients was evaluated 1, 6, and 24 hours after the reflexology, and results showed that the intervention was effective for pain relief.

Lalehgani et al., evaluated the effect of reflexology on the pain intensity of 60 patients undergoing lumbar discectomy surgery. The results of their study showed that reflexology was associated with significant pain relief in the second, third, and fourth days after the intervention.³⁷ Moreover, in the study by Sahbaee et al., on the effect of reflexology on the pain scale of 56 patients with scoliosis undergoing spinal surgery, revealed a significant difference between the control and intervention groups in terms of the post-test scores.¹⁹ These studies are also consistent with the present study, which performed reflexology to reduce pain in patients.

Among the limitations of this research, the anxiety of patients before receiving ECT can be mentioned. This might affect the response of the research participants. Also, there was a problem in communicating with some of the patients with major depression that had been partly controlled using the techniques of therapeutic communication. For greater effectiveness of reflexology, a quiet place is essential with specific colors and decoration, the use of aromas compatible with individual problems, mild music, and salt rock in the room to absorb negative energies. Providing these conditions in the hospital environment was not possible due to the principles of the University's Research Committee and each of the above cases was considered as a separate intervention. Therefore, all the factors were excluded from the study, so that the study was an intervention to examine the pure effect of reflexology. Thus, it is suggested to perform reflexology on patients by preserving all conditions and it is recommended to evaluate the multi-lateral therapeutic effects of reflexology.

Conclusion

The findings showed that reflexology is effective for reduced headache and muscle pain in the patients receiving ECT. Given that pain and its consequences are prevalent

Research Highlights

What is the current knowledge?

Complementary therapies are a part of comprehensive care in nursing and, Once the science and art of nursing profession are combined, the level of care quality is maximized.

What is new here?

Reflexology is effective in reducing headache and muscle pain in the patients receiving ECT.

in this group of patients, providing interventions to reduce pain is necessary and health care providers can play an important role for interaction and further communication with the patients using proper reflexology. These non-medicinal interventions are easy and within the scope of the duties of the nurses. Therefore, based on the results, it is suggested that nurses spend a longer time with patients to reduce complications, especially pain after ECT. Moreover, the officials and nursing planners can also prepare the personnel for reflexology by holding training sessions specialized for ECT. Therefore, it is possible to improve the pain in these patients and provide comfort and increase the quality of life and comfortable treatment for them by using low-cost and safe methods that can be taught to nurses, families and even patients.

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Ethical Issues

This research was performed in 2018 after registering at the Iranian Registry of Clinical Trials (identifier: IRCT20161116030926N1; <https://www.irct.ir/trial/31748>) as well as acquiring the permission of the ethics committee from Vice-Chancellor for Research and Technology (IR.UMSU.REC.1397.171), Urmia University of Medical Sciences.

Conflict of Interest

The authors declare no conflict of interest in this study.

Authors' Contributions

LA and MAJ designed the study; MAJ and RGHA analyzed data; MAJ, LA, SAR and RGHA reviewed manuscript critically; drafted the article; and finally approved the manuscript.

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