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Original Research



The Effect of Foot Reflexology on Amnesia in Patients Undergoing Electroconvulsive Therapy: A Randomized Clinical Trial

Saeed Alinejad Machiani¹⁰, Hossein Namdar Areshtanab^{1*0}, Hossein Ebrahimi¹⁰, Parvin Sarbakhsh²⁰, Seyyed Gholamreza Noorazar³⁰, Sakineh Goljarian⁴⁰

¹Department of Psychiatric Nursing, Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences, Tabriz, Iran ²Department of Statistics and Epidemiology, Faculty of Public Health, Tabriz University of Medical Sciences, Tabriz, Iran ³Department of Psychiatry, Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran ⁴Department of Physiotherapy, Faculty of Rehabilitation, Tabriz University of Medical Sciences, Tabriz, Iran

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Corresponding Author: Hossein Namdar Areshtanab, Email: namdarh@tbzmed.ac.ir

Abstract

Introduction: Electroconvulsive therapy (ECT) is the oldest procedure among the early biological treatments introduced in psychiatry. However, the most debated and treatment-limiting adverse effect of ECT is amnesia. Therefore, due to the restriction of the use of drugs to manage amnesia in patients undergoing ECT, the present study investigated the effect of reflexology on amnesia. **Methods:** In this randomized controlled trial, 68 patients who met the inclusion criteria were randomly allocated to intervention and control groups. The intervention group received foot reflexology with olive oil 20 minutes a day for 3 days, while the control group was given a gentle foot rub with olive oil 20 minutes a day for 3 days. The amnesia rate of all patients was measured by the Galveston Orientation and Amnesia Test (GOAT) 30 minutes after the end of ECT. The data were analyzed using SPSS software version 11.5 and t-test, chi-squared test, and repeated measures ANOVA.

Results: The results showed that reflexology significantly increased recalling scores in the intervention group compared to the control group. Foot reflexology seems to be effective in managing amnesia in patients after ECT.

Conclusion: Foot reflexology, as a relatively simple, inexpensive, and non-invasive technique with few side effects, can be used to manage amnesia in patients after ECT.

Introduction

Today, electroconvulsive therapy (ECT) is globally used as an effective and useful treatment for many mental disorders.¹ Approximately 100000 people in the United States and more than 1 million people around the world currently receive this treatment.2 Despite decades of widespread use in the treatment of depression, catatonic schizophrenia, and other psychotic disorders, and in people with suicidal thoughts, ECT has not yet found its rightful place in the field of psychiatry because of its invasive nature and complications.^{3,4} Also, despite numerous technical modifications to its use, cognitive complications still regularly occur during ECT.⁵ Prolonged return to the level of consciousness, confusion, and retrograde and anterograde amnesia are common complications of ECT among which retrograde amnesia has been reported as the most common side effect.⁶ Memory loss may include certain events, details of events, or thoughts and emotions experienced during periods of amnesia.7 A meta-analysis showed that retrograde memory in adult patients is typically recovered over 15 days. Retrograde amnesia for

autobiographical events after the ECT may be sustainable for those life events near the time of treatment. It is also possible for retrograde amnesia for public events to be persistent for two months in some patients.8 Recovery time can vary based on age, placement of electrodes, lateralization, and electrical dose associated with seizure threshold.6 on the other hand, some the psychiatric drugs cause cognitive dysfunction.9 Moreover, severe and prolonged stress can have a devastating effect on longterm and short-term memory.¹⁰ However, in recent years, the use of non-drug methods in the field of psychiatry such as anxiety and stress management is a relatively simple, inexpensive, and non-invasive method with fewer side effects compared with pharmaceutical methods.¹¹⁻¹³ One of the common non-pharmaceutical, non-invasive methods in complementary medicine is foot reflexology. It is applying pressure at specific points on the body. It works via the nervous system with pressure applied to reflexes on the feet that send a signal to the peripheral nervous system and then the central nervous system where the brain can process the information. The brain relays messages to

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internal organs and glands to make adjustments.14

Having an impact on physiological responses, its positive effects lie in the management of various diseases such as anxiety and physiological parameters in patients undergoing coronary artery bypass graft surgery and agitation in elders with cognitive impairment.^{15,16} Studies have shown that psychosocial stress and anxiety can cause memory loss by increasing cortisol and causing sleep deprivation.^{10,17} On the other hand, stress and anxiety relief is one of the indicators of reflexology in psychiatric patients.¹⁸

Today, reflexology can be used as a caring intervention along with medical treatments.¹⁹ Considering the important role of complementary medicine in helping patients, the use of ECT, and lack of studies in this field, the present study aimed to investigate the effect of reflexology on amnesia in patients undergoing ECT.

Materials and Methods

The present single-blind clinical trial was conducted to determine the effect of foot reflexology on amnesia.

Participants included 68 patients undergoing ECT hospitalized in Razi psychiatric teaching hospital affiliated to the Tabriz University of Medical Sciences, Iran. The inclusion criteria were male and female patients aged 18 years and above; hospitalization and candidacy for bilateral ECT by a psychiatrist; having a willingness to participate in the study having no ulceration or scarring on the foot, no substance dependency or use of hypnotic drugs during the night before ECT, lack of perceptional disorders, impaired reality (delusions and hallucinations), or anxiety disorder, and getting consent to intervene from the protector of the patient. The exclusion criteria were the unwillingness of the patients to participate in or continue the study and absence of more than one session in the intervention process. The sample size was calculated on 20 patients (10 patients per group) after doing a pilot study. Based on the memory score of the first session after the intervention, the comparison of it between two groups 73.41 (9.30) in intervention and 65.01(11.80) in control group. Then the number of participants using a formula of sample size with the confidence interval of 95%, power of 0.9 was calculated 34 for each group.

Written consents were obtained from eligible participants and their families who were then randomly divided into a foot reflexology group and a control group. The random sequence generation was used to randomize the assignment of participants to groups.

The researcher, according to the criteria for entering the study, received informed consent from patients, using the randomized allocation of patients into two groups (intervention and control). Random assignment by random sequence generation was performed by random number table in excel software. After identifying the subjects in two groups, the intervention and control groups were used to cover the allocation to the two groups of nontransparent and closed packets, then the envelopes were given by an individual other than the researcher to locate the subjects in the control and intervention groups. It should be noted that patients were not aware of their allocation to the intervention and control groups. The reflexology intervention and the questionnaire were completed by the researcher and the assistant researcher who were aware of the allocation of patients to the two intervention-control groups (single-blind). The intervention was supervised by the reflexology specialist and research team.

In the intervention group, reflexology using olive oil without gloves was performed every other day in a private room during the morning shift, while the control group was given every other day a gentle foot rub (no pressure) with the olive oil on the heels and reflexology for each foot 20 minutes a day for three days (10 minutes of general massage on the foot and 10 min of massage and relaxing the areas related to anxiety). There were not reflexology points and areas on the heels which were selected in group control. The intervention was conducted by the reflexology specialist (SG), researcher (SAM), and a trained female assistant. According to the reflexologists' claim, the points on the sole of the foot which may be associated with the reduction of anxiety were selected. On the other hand, studies have shown that psychosocial stress and anxiety can cause memory loss.17

Control group received general heel massage (superficial touch, and without any pressure). There were not reflexology points and areas on the heels which were selected in group intervention. In both groups, the patients were in the supine position on the bed and the massage was applied first to the right foot and then the left one. Selected points on the right foot included solar plexus (It is called the relaxation point. Perhaps it helps calm, balance, relaxation, panic reaction, and reducing anxiety and stress.), hypothalamus gland (Perhaps links the pituitary gland point to secrete hormones and balances the autonomic nervous system.), pituitary gland (Probably stimulating this point causes control of other endocrine glands, secretion of the hormone, creating balance in the secretion of hormones, creating emotional and physical balance.), lung (Maybe stimulation of the lung area regulates breathing and oxygen level.), and adrenal glands (Perhaps stimulating this point causes the secretion of adrenaline and hydrocortisone, creating balance, combating with stress and calming stress response.). Selected points on the left foot included solar plexus, hypothalamus gland, pituitary gland, lung, heart (Probably stimulating this point regulates blood circulation.), and adrenal glands.

First, initial movements of relaxation included three techniques, namely, rotate the foot, stretch the Achilles, and open and stretch the chest were administered respectively, each for one minute before giving reflex point massage on each foot. The first, the heel was held with the opposite hand from the below, the metatarsal arch was gripped with the hand of the same side, and rotated clockwise and counterclockwise several times. The second, the heel was pulled and released with the opposite hand in the same position. The third, fingers of both hands are placed on top of the foot in a way that the fingertips are located towards the base of toes in zone 3 (a longitudinal area that begins from above the head, passes through the eyes and reaches the middle fingers and toes), and both thumbs are placed under the metatarsal arch in this area. Stimulation of solar plexus was done through placing pressure and releasing and applying rotational pressure with the thumb. Stimulation of the hypothalamus gland, pituitary gland, heart, and the adrenal area was performed through applying rotational pressure with the thumb. Stimulation of lung area was done by pulling back the toes and executing biting movements with the thumb from above the diaphragm area on the sole towards the toes. 20

Data were collected using a demographic information form (age, sex, marital status, degree of education, and smoking) and the Galveston Orientation and Amnesia Test (GOAT). The latter is a measure of attention and orientation and comprises 16 items with scores of 76-100 suggesting normal, 66-75 indicating borderline, and below 66 showing an impaired level of consciousness. After the return of consciousness in patients undergoing ECT, the test was completed with the help of a trained person who was unaware of the allocation of subjects to intervention or control groups. None of the participants refused or withdrew from the study. Amnesia is defined as the patient's inability to remember past experiences.

In some cases, patients were not aware of some questions related to the events before the accident, such as failure to maintain the exact date. In these cases, explanations were given to patients on problematic questions. The total score of the test was calculated as 100-N (N=sum of scores of questions related to the events before the accident that the patient was not aware of).

The Persian version of GOAT (based on the level of consciousness and amnesia Galveston test) includes five factors. The first factor comprises 6 questions related to place orientation and patient's memory of the events before the accident. The second factor, which includes two questions, is associated with the events taking place after the accident. The third factor, with two questions, is related to personal information. The fourth factor asks about the present time in terms of year and month and consists of two questions. The fifth factor which is assessed by three questions is also related to time but in terms of hours, and also asks how the patient has been transferred to the hospital. This questionnaire had been standardized for use in Iran with the Cronbach's alpha (95% confidence interval) of 0.84 (0.76-0.91). Moreover, Pearson correlation between the total scores of two raters was 0.98, and kappa coefficient (95% CI) between

outcome rankings of raters was 0.73 (0.61-0.85) for the Persian version of GOAT. $^{\rm 21}$

After the normality of the data was established by a histogram and the Kolmogorov-Smirnov test, basic quantitative (demographic) variables were compared between the two groups using an independent t-test. Qualitative variables were compared with the chi-square test. For normal data, repeated-measures ANOVA was employed to determine the effect of group therapy on time and amnesia of the participants. The assumption of sphericity was controlled by Mauchly's sphericity test (P=0.04). Due to the violation of this assumption, Greenhouse-Geisser was used for investigating the effects of time and interaction with the group. The data were analyzed in SPSS version 11.5 by descriptive and inferential statistics. The study diagram is shown in Figure 1.

The study was conducted after the approval of the Medical Research Ethics Committee of Tabriz University of Medical Sciences (TBZMED.REC.1394.842), receiving an ethical code, and obtaining informed consent from all the participants and their families.

Results

The mean (SD) age of the patients was 36.05 (10.7) years and most of them were married. The intervention and control groups did not show any significant difference in their demographic features (Table 1).

Comparing mean recalling scores between intervention and control groups before therapy sessions were not significant (Table 2).

According to the repeated measures ANOVA, the effect of time in therapy sessions (regardless of the treatment group) on recalling score was not significant (P=0.39). The interaction of time and group was not significant either. In other words, the impact of the intervention on

Table 1. Demographic	characteristics of con	trol and intervention groups

Variable		Control group (n=34) No. (%)	Intervention group (n=34) No. (%)	Р
Sex	Female	14 (41.2)	16 (47.1)	0.62
	Male	20 (58.8)	18 (52.9)	
Marital status	Single	14 (41.2)	11 (32.4)	0.58
	Married	18 (52.9)	19 (55.9)	
	Divorced	2 (5.9)	4 (11.8)	
Education level	Illiterate	11 (32.4)	10 (29.4)	0.94
	Under diploma	10 (29.4)	10 (29.4)	
	Diploma	8 (23.5)	10 (29.4)	
	University	5 (14.7)	4 (11.7)	
Smoking	Yes	19 (55.9)	20 (58.8)	0.80
	No	15 (44.1)	14 (41.2)	
Age ^a (years)		34.6 (9.93)	37.5(11.47)	0.27



Figure 1. Flow chart of the study.

amnesia score did not change over time or during various sessions (P=0.16). The effect of the group on the amnesia score was significant. This means that all the participants who had received the intervention had significantly higher recalling score (P=0.03) than the control group (Table 3).

Considering the lack of interaction between time and group, the effect of the group regardless of the time of the study and in three points of time was also examined. The results revealed that the estimated mean of the linear model related to repeated measures ANOVA was higher in the intervention group (Table 4).

Moreover, according to the model, the mean recalling score at three points in time did not show any significant difference between the three points (Figure 2).

Discussion

The current study investigated the effect of reflexology on amnesia in patients undergoing ECT. The results revealed that the effect of time in therapy sessions (regardless of the treatment group) on recalling scores was not statistically significant. The interaction of time and group was not significant either. In other words, the impact of the intervention on amnesia score did not change over time or during various sessions. Nevertheless, the effect of the group on the amnesia score was significant. This means that all the participants who had received the intervention had significantly higher recalling scores than the control group.

In line with the study, Moyle et al., carried out to

determine the effect of foot reflexology on agitated behaviors in 17 men and 5 women with a history of dementia and agitated behavior. The intervention was performed for 10 minutes for 14 days.²² The study findings

 Table 2. Comparing mean recalling scores between intervention and control groups before therapy sessions

Group	Mean (SD)	Р	
Intervention	67.13 (8.05)	0.08	
Control	66.01 (7.08)	0.08	

 Table 3. Comparing mean recalling scores between intervention and control groups in three sessions

Variable		Control	Intervention	Effect of time
Recalling	Session 1	68.14 (17.61)	73.55 (9.79)	P=0.39
score	Session 2	68.97 (15.81)	75.47 (10.14)	
	Session 3	66.17 (13.17)	75.29 (10.22)	
Effect of the treatment group $P=0.03$				
Interaction between time and group				P=0.16

Table 4. Estimated mean for recalling score in intervention and control groups

Group	Mean Standard e	Standard orror	95 %	5% CI	
		Stanuaru error	Lower bound	Upper bound	
Control	67.76	2.10	63.56	71.96	
Intervention	74.77	2.10	70.57	78.97	



Figure 2. Comparison of mean amnesia scores before and after the intervention in the two groups.

revealed that the intervention could decrease behavioral and memory problems in the patients.

In a study that Williamson et al., carried out to determine the effect of foot reflexology on menopausal symptoms in 76 women with menopausal symptoms, the intervention for 45 minutes per session during nine sessions (6 weekly sessions and 3 monthly sessions) was conducted.²³ The study findings revealed that foot reflexology is not more effective than a massage to reduce hot flashes and other symptoms of menopause such as memory and focusing on the problem. Using four reflexologists and gender of subjects (only female) in the study could be possible causes of this difference. It seems the effectiveness of reflexology based on the amount of pressure, status, area, and duration of the massage is different.

Based on a search in different scientific databases, no similar study could be found to directly compare the results. Studies have been conducted on the effect of reflexology on the management of anxiety.²⁴⁻²⁷ and pain in patients with scoliosis undergoing spine surgery,²⁸ as well as fatigue,^{29,30} hypertension,³¹ and restless behavior in elderly patients with dementia.^{32,33} Review studies in Iran and other countries also revealed that reflexology has a positive impact on patients' anxiety and health status.³⁴⁻³⁸

Concerning the effect of reflexology in the management of pain and anxiety, it can reduce cortisol levels and the stress related to it,^{39,40} leading to increased levels of dopamine and serotonin.⁴¹ Given that severe and prolonged stress can have a devastating effect on long-term and short-term memory,¹⁰ and taking into consideration the damaging effect of stress on memory, reflexology will likely have a positive impact on the score of amnesia by reducing the level of cortisol and stress.

According to Andrade, possible mechanisms affecting amnesia disorder induced by ECT are high blood pressure and brain neurotransmitters. According to this study, when a person is under the impact of increased levels of glucocorticoid hormones, the function of the hippocampi and the amygdala gland is impaired with negative impacts on cognitive processes.⁴²

ECT reduces brain anticholinergic activity in the

central nervous system that can explain the causes of memory impairment in patients undergoing ECT.^{43,44} The neurotransmitter acetylcholine has a positive effect on information retrieval,⁴⁵ and improving memory performance.⁴⁶ Moreover, reflexology has a positive role in regulating the function of the autonomic nervous system,⁴⁷ and activating the parasympathetic nervous system.^{48,49} It is widely accepted that norepinephrine is effective in memory and learning regulation.⁵⁰ Therefore, it can be concluded that reflexology can be effective in improving memory function.

The sample of the current study was selected from a treatment center, and may not be generalizable to other patients. Also, a research assistant helped in completing the questionnaires which may have impacted the participants' answers. By holding workshops about the study, we attempted to create more coordination between study agents. Other limitations of the study were the different electrical doses received by the patients which may have affected the time of gaining consciousness and amnesia time. On the other hand, there is no finding to be reflecting recent study results.

Conclusion

It is recommended that the results of the study were used with caution. Also, further investigation is recommended in this regard. It seems that foot reflexology, which is a relatively simple, inexpensive, and non-invasive technique with low side effects and can be used by nurses in patients undergoing ECT to manage their amnesia.

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Ethical Issues

This trial study has been approved by the ethics committee of Tabriz University of Medical Sciences (code of ethics: TBZMED.REC.1394.842). Additionally, the study was registered in the Iranian Registry of Clinical Trials (identifier: IRCT2015080623525N2; https://www.irct.ir/trial/20041).

Conflict of Interest

The authors declare no conflict of interest in this study.

Research Highlights

What is the current knowledge?

Stress and anxiety relief is one of the indicators of reflexology in psychiatric patients.

What is new here?

Foot reflexology seems to be effective to manage amnesia in patients after ECT.

Author's Contributions

All author were in the conception and design, acquisition of data, analysis and interpretation of data, drafting the article, review of article and find approval.

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