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# Effect of Rosa damascena Oil Aromatherapy on Fatigue Severity in Patients Receiving Hemodialysis: A **Randomized Controlled Trial**



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**Original Article** 

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### Abstract

Objectives: The prevalence of fatigue in patients receiving hemodialysis is high. This study aimed to investigate the effect of Rosa damascena oil on fatigue severity in patients receiving hemodialysis.

Materials and Methods: This randomized controlled trial was performed on 74 patients receiving hemodialysis in Tabriz, Iran from January 21 to February 21, 2019. The patients were conveniently recruited and assigned into two groups of intervention and control using a block randomization method with block sizes of four and six and a sequence of 1:1. Patients in the intervention group were trained to inhale three drops of R. damascena oil each night for one month. We used the Fatigue Severity Scale (FSS) for data collection and analyzed the data using the independent samples and paired *t* tests.

Results: No significant difference was found between the two groups respecting the mean baseline fatigue scores (P=0.12). However, at the end of the study, the mean fatigue score was significantly lower in the intervention group compared to the control group (*P*=0.001).

**Conclusions:** We witnessed that *R. damascena* oil aromatherapy significantly reduced the severity of fatigue in patients receiving hemodialysis. This useful and inexpensive technique can be utilized as a complementary method to relieve fatigue in patients receiving hemodialysis.

Keywords: Renal dialysis, Aromatherapy, Fatigue

## Introduction

Chronic kidney disease jeopardizes various aspects of a patient's health (1). In end-stage renal disease, alternative treatment methods such as hemodialysis should be used to replace the kidney functions and keep the patient alive (2). Patients undergoing hemodialysis experience many symptoms such as nausea, vomiting, decreased appetite, hypotension, muscle contractions, chest pain, headache, and fatigue, all of which adversely affect their daily functioning and quality of life (3). Fatigue is a prevalent and frustrating symptom among these patients (3-5). About one-third of patients experience fatigue an hour after starting a hemodialysis session and one-fourth of them feel tired at the end of each session (6). The chronic and debilitating nature of fatigue can restrict the patients' ability to perform their roles and daily activities and may even lead to job loss and increased dependence on health care. Given the high prevalence of fatigue in patients receiving hemodialysis (3-5) and the related adverse effects (7), special efforts should be made to reduce fatigue in these patients.

the complications in hemodialysis patients (8). Despite the benefits of medicines, they are often prescribed and used for long periods and may cause several side effects (9). Therefore, some non-pharmacological complementary therapies have been tested to reduce these side effects (10). Aromatherapy is a holistic treatment approach used as a complementary therapy (11). In aromatherapy, volatile oils derived from some plants are used for the improvement of health. These herbal oils can be used through inhalation, aromatic compresses, baths, and massages (12).

Damask rose (Rosa damascena), is one of the most widely used aromatic, therapeutic, and decorative plants. It is the main variety of Rosa planted to make rose water and rose oil, and is mainly used in the perfume and food industries (13). R. damascena, known as "Gol-e Mohammadi" in Iran (14), grows in a variety of climatic conditions (15). There are a variety of carotenoids, flavonoids, and vitamins in R. damascena (16), and its oil has sedative, hypnotic, calming, and antispasmodic effects (16-18). It also has beneficial effects on sleep quality, blood pressure, and even in relieving mild to moderate postoperative pain (19-21).

Pharmacotherapy is often used as the first step to reduce

Inhalation of some essential oils has been reported to

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#### Key Messages

- Rosa damascene oil aromatherapy reduces the severity of fatigue in patients receiving hemodialysis.
- Rosa damascene oil aromatherapy can be utilized as a complementary method to relieve fatigue in patients receiving hemodialysis.

reduce anxiety, depression, and fatigue (22,23). Yet, there are contradictory findings concerning the outcomes of different aromas, and the precise mechanism by which aromatherapy works is still unknown (24).

Despite the widespread use of *R. damascena* in Iran, no study has investigated its effects on fatigue in patients receiving hemodialysis.

## Objective

The present study aimed to investigate the effect of *R. damascena* oil on the severity of fatigue in patients receiving hemodialysis.

## Methods

## Study Design, Setting, and Participants

This randomized controlled trial included 74 patients admitted to the hemodialysis units of Imam Reza Hospital in Tabriz, Iran from January 21 to February 21, 2019. The inclusion criteria were patients in the age range of 18-65 years, with no allergy to *R. damascena*, no chronic disease, no olfactory disorders, and no history of cancer, acquired immunodeficiency syndrome (AIDS), and psychiatric and sleep disorders needing medication. Exclusion criteria included voluntary withdrawal and non-compliance with aromatherapy practice at least three times a week.

The sample size was calculated using the results of a previous study by Muz and Taşcı, in which sweet orange and lavender oil aromas were used to relieve fatigue in people undergoing hemodialysis. The study showed that the mean fatigue scores at the first follow-up were 6.40 ± 1.28 and 7.32 ± 1.14 in the aromatherapy and control groups, respectively (25). Therefore, using the formula  $(n = ((z_{1-\alpha/2} + z_{1-\beta/2})^2 \times (\sigma_1^2 + \sigma_2^2))/(\mu_1 - \mu_2)^2)$  and considering a type I error of 0.05, a power of 0.90, a  $S_1$  of 1.28, a  $S_2$  of 1.14, a  $\mu_1$  of 6.40, and a  $\mu_2$  of 7.32, the sample size was estimated to be 37 subjects in each group.

# Sampling and Random Allocation

The participants who met the inclusion criteria were initially enrolled conveniently and randomly assigned into two groups of intervention and control. We used a block randomization technique to assign the participants into two equal groups (n=37 in each). In this way, 74 hypothetical patients were randomly assigned to 14 blocks of 4 or 6, with a 1:1 sequence for the intervention and control groups. To conceal the allocation process, we wrote the group names (i.e., aromatherapy or control) on small cards and put them in sequentially numbered, opaque,

and sealed envelopes. The envelopes were unlocked in the order in which the participants entered the study to determine their group. Those who collected and analyzed the data were unaware of the study intervention.

All patients completed the Fatigue Severity Scale (FSS) on admission. As most patients were illiterate or lowliterate, face-to-face interviews were conducted to gather the data. The first investigator read the scale items to each patient and documented the responses on the scale.

R. damascena 1.5% essential oil was steam distilled from fresh flowers by Barij Essence Pharmaceutical Co. in Kashan, Iran (Quality Certificate: 11114129). Patients in the intervention group were trained to instill three drops of R. damascena oil on a piece of cotton and attach it to their collar with a pin before going to sleep and remove it after waking up for one month. The patients were also called every night at a specific time to remind them of the practice and then the next morning for follow-up. Patients in the control group received no intervention other than the routine instructions to avoid fatigue such as the need for a balance between activity and rest. All participants filled the questionnaires once again at the end of the study. Patients who did not perform aromatherapy for three times were excluded from the study. Finally, 31 subjects in the intervention group and 37 subjects in the control group completed the study (Figure 1).

## Data Collection Instruments

We used a two-part instrument for data collection. The first part included a demographic questionnaire and the second part included filling the FSS tool. The demographic questionnaire included such information as participants' gender, age, education level, marital status, occupation, financial status, illness duration, having other co-morbidities, smoking history, substance abuse, and history of renal transplantation.

The FSS is a 9-item scale developed by Krupp et al in 1989 (26). All items are rated using a 7-point Likert scale from "1: strongly disagree" to "7: strongly agree". The total score ranges from 9 to 63, where a greater score indicates more fatigue.

Shahvaroughi et al examined the validity and reliability of the Persian translation of FSS and the internal consistency coefficient of the scale was confirmed by a Cronbach's alpha of 0.96 (27). At the beginning of this study, 20 patients who did not participate in the main study were asked to answer the questionnaire twice at a two-week interval. The correlation coefficient of the two scores was 0.83.

#### Data Analysis

Data analysis was performed using the SPSS software version 13 (SPSS Inc., Chicago, Illinois, USA). The Kolmogorov–Smirnov test revealed that the quantitative variables were normally distributed. The chi-square and t tests were used to compare groups for their personal



Figure 1. The Study Flow Diagram.

characteristics. The independent samples *t* test was used to compare the mean fatigue scores between the two groups. Furthermore, the paired *t* test was utilized to compare the mean fatigue scores at the beginning and end of the study in each group.

## Results

Out of a total of 298 patients who were assessed for eligibility, 74 eligible ones were equally assigned into the study groups. Six patients from the intervention group failed to complete the study (five due to an allergic response or getting a headache after receiving aromatherapy, and one due to lack of regular use of aromatherapy). Therefore, 37 patients in the control group and 31 ones in the intervention group completed the study (Figure 1).

The age of participants in the control and aromatherapy groups was  $49.13 \pm 14.72$  and  $50.47 \pm 11.43$  years, respectively (*P*=0.66). Most of the participants were male and married. The groups were homogenous in terms of the baseline characteristics (Table 1).

No significant difference was found between the mean fatigue scores of the two groups at the beginning of the study (P=0.12). However, after the intervention, the mean fatigue score in the aromatherapy group was significantly lower than the control group (P=0.001). Within-group comparisons showed that the mean fatigue scores did not change significantly in the control group (P=0.05), but the mean fatigue scores significantly decreased in the aromatherapy group (P=0.001) (Table 2).

#### Discussion

According to the results of this study, a one-month

aromatherapy program using R. damascena oil during sleep effectively reduced fatigue severity in patients receiving hemodialysis. Previous studies have used a variety of aromas to relieve fatigue in hemodialysis patients and reported controversial results. For instance, two studies in Iran (4) and Turkey (25) reported that lavender and orange oils could successfully reduce tiredness in patients receiving hemodialysis. Another study reported that lavender aromatherapy was superior to the relaxation technique in relieving fatigue in those undergoing hemodialysis (5). However, Balouchi et al compared the effectiveness of lavender and orange oils in patients undergoing hemodialysis and reported that lavender was not effective, but orange oil could reduce fatigue after one week of intervention (8). Discrepancies between studies might be attributed to differences in methodology and the aromas used.

Due to the popularity of production, availability, and the reported relaxant effects of the *R. damascena* oil (28), we examined its effect on fatigue in hemodialysis patients. *R. damascena* oil has anti-inflammatory, anti-diabetic, antioxidant, anticonvulsant, neuroprotective, hypnotic, antimicrobial, and anticancer properties (14). It is also a rich source of vitamins and flavonoids (29). In addition, the adaptogenic/anti-stress and analgesic properties of this herb (14,30) might be influential in its anti-fatigue effect.

Several other studies also reported the beneficial impacts of *R. damascena* oil on the quality of sleep (19), blood pressure (20), and depression, anxiety, and stress (31). A study reported that *R. damascena* oil aromatherapy could relieve fatigue in nurses working at emergency departments

Table 1.	Demographic ar	d Clinical	Characteristics	of the	Participants

Variables		(	0)/alaa		
		Control (n = 37), No. (%)	Intervention (n = 31), No. (%)	- P Value	
Gender	Female	12 (32.4)	10 (32.2)	V2-0.22 P-0.4	
Gender	Male	25 (67.6)	21 (67.8)	X <sup>2</sup> =0.23, P=0.4	
	Illiterate	21 (56.7)	18 (58.2)		
Education level	Primary school	6 (16.2)	10 (32.2)		
	High school	4 (10.8)	1 (3.2)	X <sup>2</sup> =7.20, P=0.12	
	Diploma	3 (8.1)	2 (6.4)		
	Academic	3 (8.1)	0 (0.0)		
	Single	7 (18.9)	6 (19.4)	X <sup>2</sup> =1.07, <i>P</i> =0.5	
Marital status	Married	30 (81.1)	24 (77.4)		
	Divorced	0 (0.0)	1 (3.2)		
	Unemployed	7 (18.9)	5 (16.1)	X <sup>2</sup> =7.22, <i>P</i> =0.4	
	Housekeeper	11 (29.7)	7 (22.6)		
	Faculty member	3 (8.1)	1 (3.2)		
	Clerk	0 (0.0)	2 (6.4)		
lob	Military	0 (0.0)	1 (3.2)		
	Farmer	2 (5.4)	1 (3.2)		
	Manual worker	9 (24.3)	12 (38.7)		
	Self-employed	5 (13.5)	2 (6.4)		
	Income <cost< td=""><td>16 (43.2)</td><td>12 (38.7)</td><td></td></cost<>	16 (43.2)	12 (38.7)		
Financial status	Income = cost	15 (40.5)	15 (48.4)	X <sup>2</sup> =0.62, P=0.7	
	Income >cost	6 (16.3)	4 (12.9)		
	Diabetes	25 (67.6)	23 (74.5)		
	Cardiac	2 (5.4)	2 (6.4)		
Other co-morbidities	Chronic obstructive pulmonary disease	2 (5.4)	2 (6.4)	X <sup>2</sup> =7.27, P=0.1	
	Hypertension	8 (21.6)	3 (9.5)		
	Mental	0 (0.0)	1 (3.2)		
	Yes	4 (10.8)	2 (6.4)	X <sup>2</sup> =1.59, <i>P</i> =0.20	
Smoking	No	33 (89.2)	29 (93.6)		
	Yes	0 (0.0)	1 (3.2)		
Substance abuse	No	37 (100)	30 (96.8)	X <sup>2</sup> =2.05, P=0.1	
History of kidney	Yes	2 (5.4)	2 (6.4)	X <sup>2</sup> =4.16, <i>P</i> =0.04	
transplantation	No	35 (94.6)	29 (93.6)		
Age (Mean ± SD, years)		49.13 ± 14.72	50.47 ± 11.43	t=-0.43, P=0.60	
Illness duration (Mean ±	SD, month)	17.52 ± 24.48	$22.87 \pm 20.88$	t=-0.95, P=0.34	

Table 2. Total Fatigue Scores of Hemodialysis Patients Before and After the Intervention

Variable -		Before	After	P Value <sup>a</sup>
		Mean ± SD	Mean ± SD	
Fatigue	Control	5.31 ± 1.97	5.68 ± 1.64	0.05
	Intervention	$5.93 \pm 1.35$	$3.56 \pm 1.11$	<.001
P value <sup>b</sup>		0.12	<.001	
Mean difference*		-0.62	2.12	
95% Cl for mean difference		(-1.40, 0.16)	(1.43, 2.81)	

\*Mean difference: mean group control minus intervention.

<sup>a</sup> Paired *t* test, <sup>b</sup>*t* test.

(29). Another study carried out on 40 healthy volunteers concluded that rose oil considerably decreased autonomic arousal and made people feel more relaxed; however, the exact relaxant mechanism was not mentioned (28). It has been suggested that *R. damascena* oil aromatherapy may stimulate the olfactory nerves and the limbic system, which consequently triggers the hypothalamus and

pituitary gland, evokes pleasant memories and affective responses, and relieve psychosomatic stresses (21,32) that might consequently relieve fatigue.

Fatigue is a multifactorial problem (33) and a variety of interventions can be used to reduce it. Several studies used other non-pharmacological therapies such as reflexology (34), exercise (35), and nutrition-based educational

programs (3) to reduce fatigue in patients receiving hemodialysis. Patients' individual characteristics may also affect the effectiveness of some treatments. Although we witnessed that *R. damascena* oil aromatherapy significantly reduced fatigue in patients receiving hemodialysis, additional studies are needed to elaborate the mechanism by which *R. damascena* oil affects fatigue.

Since no previous study has examined the effect of *R*. *damascena* oil on fatigue in patients receiving hemodialysis, further studies are needed in this area. Furthermore, multicenter trials with larger sample sizes are suggested to examine the magnitude of the effect. It is also advisable to investigate how *R*. *damascena* aromatherapy affects fatigue in patients receiving hemodialysis. The dropout of the samples might have affected the power of our study. Also, there was no follow-up in the current study. So, the duration of the effects of the intervention is unclear. Therefore, it is advisable to conduct a study to assess the longevity of the effect of the intervention.

## Conclusions

This study confirmed the effectiveness of *R. damascena* oil aromatherapy on fatigue in patients receiving hemodialysis. Therefore, as an alternative and cost-effective therapeutic method, it is recommended to use *R. damascena* oil aromatherapy to alleviate fatigue in patients receiving hemodialysis. However, as some of our participants experienced allergic reactions or headaches after aromatherapy, patients must be carefully assessed for possible allergies to *R. damascena* and its products before starting aromatherapy and after the intervention.

#### **Authors' Contribution**

BE: data collection and drafting the manuscript; KP: study design and conducting the study; FJT: revising the manuscript content; PS: statistical analysis; AG: supervised the pharmacological process; FR: critical review of the manuscript and revising the manuscript content.

#### **Conflict of Interests**

Authors have no conflict of interest.

#### **Ethical Issues**

The Research Ethics Committee of Tabriz University of Medical Sciences, Iran approved the study protocol (code: Tbzmed. Rec.1397.354). We also registered the study protocol at the Iranian Registry of Clinical Trials (identifier: IRCT20110629006918N28). All participating patients were briefed on the study objectives, all were assured that their personal information would be kept confidential, participation in the study was voluntary, and they could leave the study at any time. Also, all patients signed an informed consent form to participate in the study. All participants' rights were respected in accordance with the Helsinki Declaration.

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