## Comparison of the Effect of Reflexology and Swedish Massage on Restless Legs Syndrome and Sleep Quality in Patients Undergoing Hemodialysis: a Randomized Clinical Trial

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Background: Patients undergoing hemodialysis experience painful complications such as restless leg syndrome and poor sleep quality, which negatively affect their quality of life.

*Purpose:* This study aimed to compare the effect of reflexology and Swedish massage on restless leg syndrome and sleep quality in patients undergoing hemodialysis.

*Method:* This is a randomized clinical trial conducted on 90 patients undergoing hemodialysis. The two intervention groups received either foot reflexology (n = 30) or Swedish massage (n = 30) for four weeks. In the sham group (n = 30), a simple touch of the knee down was performed with the same conditions as the intervention groups. Each sample completed the International Restless Leg Syndrome and Pittsburgh Sleep Quality Index Questionnaires before, immediately after, and one month after the intervention.

Result: The results showed that immediately after the intervention, restless leg syndrome and sleep quality were significantly better in the foot reflexology massage group than the Swedish massage and sham groups ( $P_{RLS} < 0.001$ ,  $P_{PSQI} < 0.001$ ); also, changes in restless leg syndrome and sleep quality, respectively, before and one-month follow-up after the intervention were not significant in all three groups ( $P_{RLS} = 0.47$ ,  $P_{PSQI} = 0.95$ ), ( $P_{RLS} = 0.91$ ,  $P_{PSQI} = 0.87$ ). *Conclusion:* Reflexology and Swedish

*Conclusion:* Reflexology and Swedish massage, as complementary methods, can improve the restless leg syndrome and sleep quality of patients undergoing

# hemodialysis. However, foot reflexology massage had been more effective.

KEYWORDS: reflexology massage; restless legs syndrome; sleep quality; hemodialysis

#### INTRODUCTION

Due to the annual growth of 5%–6% of patients with chronic kidney failure in the world, this disease is one of the most important therapeutic problems.<sup>(1)</sup> Many of these patients need hemodialysis to survive.<sup>(2)</sup> Most of these patients suffer from complications such as restless leg syndrome and sleep disorders<sup>(3)</sup> and various physiological changes associated with psychological distress.<sup>(4)</sup>

Restless Leg Syndrome (RLS) or Willis-Ekbom disease (WED) refers to an excessive pressure to move the leg, which is usually accompanied by unpleasant feelings. During 2020, a 40.7% prevalence of RLS was reported among hemodialysis patients.<sup>(5)</sup>

RLS affects the sleep quality and emotions of hemodialysis patients, and can lead to depression, anxiety, and an increased risk of cardiovascular disease among hemodialysis patients.<sup>(5)</sup>

Sleep disorders are common problems that most patients undergoing hemodialysis face.<sup>(3)</sup> It is estimated that these patients suffer from a prevalence of sleep disorders of 18%–69% in various forms (e.g., patients having restless leg syndrome from insomnia as a result of obstructive sleep apnea).<sup>(6)</sup> Sleep quality is defined as an individual's satisfaction with the sleep experience, integrating aspects of sleep onset, sleep maintenance, amount of sleep, and feeling fresh after waking up.<sup>(7)</sup> Since sleep deprivation causes complications, such as chronic fatigue, dysfunction, changes in the nervous system, and reduced motivation to take care of oneself, it is important to pay attention to the quality of sleep and sleep deprivation treatment in patients undergoing hemodialysis.<sup>(8)</sup>

Despite the encouraging effects of drug treatment, chemical drugs are expensive and have side effects.<sup>(9)</sup> Meanwhile, people with ESRD usually take several medications, and renal failure can lead to an increased risk of side effects, drug interactions, or other drug-related problems.<sup>(10)</sup> Hence, health care providers are actively seeking alternative therapies with fewer side effects to reduce the burden of symptoms on patients.<sup>(11)</sup> Today, the use of complementary and alternative medicine (CAM) has increased widely around the world.<sup>(12)</sup>

CAM is defined as the diagnosis, treatment, or prevention of the disease, which, due to its holism, satisfies the unmet needs of the patient accessing conventional medicine and is a complement treatment.<sup>(13)</sup> Massage therapy is a type of CAM that is used to relax and reduce the pain of patients.<sup>(14)</sup> Massage therapy is the most widely used type of treatment in CAM and one of the most common CAMs in nursing which is easy, safe, non-invasive, and relatively inexpensive to perform.<sup>(15)</sup>

Massage comes in a variety of forms; the most common types of massage are Swedish, reflexology, and shiatsu (massage that works on pressure points).<sup>(16)</sup> Reflexology is a systematic modality based on pressure on parts of the hands, feet, or ears. <sup>(17)</sup> It has an effect on the nervous system, and the pressure on a specific area of the skin stimulates the nerves and transmits impulses to the brain. On the other hand, foot reflexology stimulates the chemical system of the nerve, balances the enzymes, and regulates the function of the endocrine glands in the body.<sup>(18)</sup> Swedish massage, or classical massage, is the most widely used type of massage; it includes strokes, kneading, rubbing, tapotement or tapping, and vibrating that systematically manipulates the soft tissues of the body, reduces stress and anxiety, relieves muscle cramps, strengthens the immune system, relieves fatigue caused by disease, improves blood circulation, and reduces insomnia.<sup>(19)</sup>

Patients undergoing hemodialysis in Iran have the same problems as other patients around the world. They suffer from complications such as restless leg syndrome, sleep disorders, and psychological disorders.<sup>(3,4,20)</sup> In Iran at the end of 2016, the number of patients undergoing dialysis was estimated to be 30,800, of whom 29,200, or about 95%, were receiving hemodialysis.<sup>(21)</sup>

A study entitled *Lifestyle of Hemodialysis* Patients in Comparison with Outpatients in Iran showed a history of high blood pressure, blood sugar, high cholesterol, and smoking in patients undergoing hemodialysis. High salt and protein intake has been observed in hemodialysis patients, and other studies have shown that high protein and salt intake can increase the progression of kidney disease. These patients did not have good coping styles with stress, and the majority sought help from others to solve the problem. Outpatients also had more physical activity than hemodialysis patients and devoted more time to exercise per day.<sup>(22)</sup>

According to another study, more than half of Iranians use at least one of the methods of CAM.<sup>(23)</sup> Based on the results of a different study, 88.4% of Iranian participants had used CAM, of which 84.9% used medicinal plants, 18% cupping, 13.3% prayer, 9.3% vows, 2.7% massage, 1.4% leech therapy, and 0.3% acupuncture.<sup>(24)</sup>

There are a limited number of studies on the effects of Swedish and reflexology massage on restless leg syndrome and sleep quality in patients undergoing hemodialysis, and the available data suggest conflicting results. It seems that further studies in this regard are necessary.

## METHODS

## Study Design & Setting

This is a randomized clinical trial study conducted on all hemodialysis patients undergoing hemodialysis referred to hemodialysis center of Abu Ali Sina Hospital, affiliated to Shiraz University of Medical Sciences, southeastern Iran. The total number of patients in this hemodialysis center was 105, of whom 95 were eligible for the study. This study was conducted from September to December 2020.

#### Sample Size & Sampling

Based on previous clinical trial study,<sup>(25)</sup> the sample size calculation formula showed that, with a power of 80% and a confidence level of 95%, 25 patients were needed for each of the three study groups (i.e., 75 in total). By calculating the attrition of samples, 30 patients were selected. Finally, a total of 90 patients were included in the final analysis.

B = 0.2, z1- β = 0.84, α = 0.05, z1- α = 1.96,  $\mu_1$ = 17.06,  $\mu_2$  = 20.54, σ1 = 5.179, and σ2 = 3.071

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^{2} (\sigma_{1}^{2} + \sigma_{1}^{2})}{(\mu_{1} - \mu_{2})^{2}}$$

Inclusion criteria included being 18 to 65 years old,<sup>(26)</sup> three months or more since the first dialysis,<sup>(27)</sup> having at least three hemodialysis treatments per week lasting 4 hours each time,<sup>(28)</sup> having no medical prohibition for the intervention such as foot ulcers, amputation, and orthopedic problems,<sup>(29)</sup> having no debilitating and chronic diseases such as cancer, chronic respiratory failure, heart failure, rheumatoid arthritis, and lupus erythematosus,<sup>(29)</sup> having no psychological disorders known as depression and bipolar disorder according to the patient's self-declaration, and diagnosis of RLS based on completing a diagnosis questionnaire.

Exclusion criteria included no cooperation in more than two sessions of the interventions, use of sleeping pills or sedatives (Figure 1).

The Ethics Committee of Kerman University of Medical Sciences approved this study. The necessary permissions were obtained from the hospital management. After obtaining informed written consent from the patients, interview method was used to collect the data for before, immediately after, and one month after the intervention in both intervention and sham groups.

#### Measurement

In this study, three instruments were used: a demographic characteristics form, RLS diagnosis and intensity questionnaire, and the Pittsburgh Sleep Quality Index.

#### Demographic characteristics form

This form consisted of questions on age, duration of onset of hemodialysis, gender, job status, level of education, history of addiction, antihypertensive drug, cause of kidney failure, history of disease and surgery, dialysis adequacy (URR and Kt/V), and routine laboratory tests (e.g., Alb, BUN, Na, Cr, K).

#### RLS diagnosis and intensity questionnaire

The first part of the above-mentioned questionnaire is related to the diagnosis of RLS, which includes four questions to confirm that people have such a disease. In the second part of the questionnaire, the RLS intensity is measured, which includes 10 five-choice questions, each having 0–4 points. The scores obtained from the questionnaire vary between 0 and 40, in which the highest value indicates the severity of this disorder.<sup>(30,31,32)</sup>

Content validity and Cronbach's alpha (0.90) coefficient were used to determine the validity and reliability of RLS diagnosis questionnaire, respectively.<sup>(30)</sup> In addition, Cronbach's alpha (0.97) coefficient was utilized for the RLS intensity questionnaire.<sup>(30)</sup>

#### Pittsburgh sleep quality index (PSQI)

PSQI has 18 items in seven subscales: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. Items are scored in a 4-point Likert scale from 0 to 3. The maximum and minimum possible scores are 21 and 0. The higher the score, the worse the quality of sleep.<sup>(33,34)</sup>

Buysse et al. developed PSQI in 1989. They reported the internal consistency using Cronbach's alpha coefficient as 0.83. In their study, this index had a diagnostic sensitivity of 89.6% and a specificity of 86.5% in poor sleep detection.<sup>(34)</sup>

## **Data Collection & Intervention**

The researcher referred to the research environment and obtained the necessary permission from the hospital management and hemodialysis department to conduct the study. After obtaining informed written consent from the patients at the beginning, we collected the data with relevant form through interviews in both intervention and sham groups. The samples were divided into two intervention groups and one sham group using the block randomization method. The block

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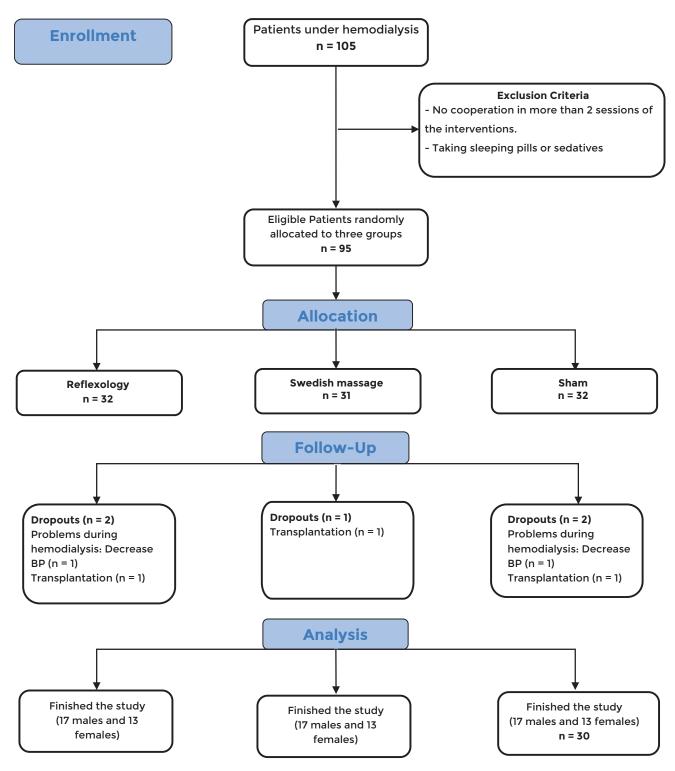


FIGURE 1. Flowchart of patients.

randomization was performed using online software (https://www.sealedenvelope.com/ simple-randomiser/v1/lists). The blocks size was considered 6. Using the lottery, each group was assigned a label of A, B, and C. After that, based on the random block list, the samples were assigned to each group. In the intervention groups, foot reflexology and Swedish massage were performed as the intervention. Data were collected before, immediately after, and one month (for follow-up) after the intervention.

#### **Intervention Protocol**

In both groups, before the intervention, all the necessary measures that kept the patient calm in the massage environment, such as the patient's privacy and verbal communication, were maintained. The patient was placed in a quiet environment with adequate lighting in a completely calm position. The masseur sat on a chair at the bottom of the patient's bed and performed the massage. In each group, the patient's foot was first cleaned using a cotton ball soaked in lukewarm water. The researcher then warmed his/her hands and used 2 to 3 cc of baby oil to soften the skin and ease the massage so as not to irritate the patient. This intervention was performed during hemodialysis.

#### **Reflexology Group**

In the foot reflexology group, general sole reflexology was used, which is performed on 21 points of reflexology in the sole of the foot.<sup>(35)</sup> Before the main massage, the first 1 minute in each session was devoted to the relaxation techniques. These techniques included back and forth movements of the palm of the hand on the outer edge of the foot from the lateral ankle to the little toe, which is used to relieve tension and muscle spasm in the body. First, the masseur supported the toes with one hand and massaged the soles of the feet from the connection point of the toes to the heel (from top to bottom) with the phalanx of the second finger of the other hand. Then, with the edge of the hand, he massaged the inner edge of the foot from the big toe to the inner ankle with a little pressure. The masseur took the heel of one foot in the left hand and massaged it with the thumb of the right hand on the relevant reflex points in the form of alternating pressures in a reciprocating manner. He moved the outer edge of the patient's foot back and forth with the palm of his hand. He massaged all the relevant reflex points on the outside of the big toe with gentle fast-paced movements with a tolerable pressure. Finally, a general massage was performed for 1 minute to relax and cool the muscles. This protocol was performed for 20 minutes on both feet (10 minutes for each foot) and for four consecutive weeks (three times

per week). It is noteworthy that the total time of reflexology massage (with warmup and cool-down steps, 2 to 3 min) on 21 points according to the main reference of reflexology massage was performed approximately in 10 minutes. Because the movements were in a wavy form from one point to another, 1 minute of the protocol time was spent on these movements.

#### Swedish Group

In the Swedish foot massage group, the patient was first placed in a supine position and a pillow was placed under the knees, so that the leg was slightly bent and the head was placed at an angle of 30° to 45°. Massage techniques included stroke or effleurage movements, petrissage, friction, tapotement, and vibration.<sup>(36,19)</sup> First, the masseur started with the effleurage movements for 1 minute to relax and warm the muscles, and then the petrissage, friction, tapotement, and vibration movements were performed each for 2 minutes. Finally, for relaxing and cooling the muscles, effleurage and criss-cross movements were performed for 1 minute. The aforementioned movements were performed for 20 minutes (10 minutes per foot). After the massage, the patient's feet were wiped with a towel to clean the remaining oil. Thus, this protocol was performed for 20 minutes (10 minutes per foot) three times a week for four weeks.

## Sham Group

In the sham group, a simple touch of the knee down to the sole of the foot without pressing the reflexology standard was performed with the same conditions and time as the experimental groups.

## Data Analysis

IBM SPSS statistics software version 22 was used for data analysis (IBM SPSS Statistics, Armonk, NY). The data are presented as mean ± standard deviation (SD); Mann-Whitney U test, ANOVA, Chi-square test, or Fisher's exact test were used to determine the similarity of the three groups (experimental: (reflexology group and Swedish group) and sham group) in terms of demographic characteristic variables at the beginning of the study.

Due to the non-normality of the data, Friedman and Kruskal-Wallis non-parametric tests were used. To determine the mean difference of restless leg syndrome and sleep quality between the two groups, we used Mann-Whitney U test or Friedman test.

#### RESULTS

The majority of the samples in three groups were male subjects with diploma.

There were no statistically significant differences in terms of age, duration of dialysis, gender, level of education, job, history of dialysis, history of addiction, antihypertensive drug, cause of kidney failure, and history of disease and surgery. All three groups were identical in terms of these variables (Table 1).

The mean and SD of laboratory tests before the intervention were not significantly

TABLE 1. Determining and	d Comparison o	f Demographic and	Clinical	Information in Patients
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		Reflex	ology	Swedish i	massage	e Sho	am	<b>-</b> .	
	Group ariable	Mean	SD	Mean	SD	Mean	SD	- Test Statistics	p value
Age (yrs)		51.66	5.42	51.56	5.24	51.56	5.50	f=-0.06	.99
Duration of onset of hemodialysis (yrs)		2.55	0.80	2.59	0.78	2.75	0.75	Z=-0.32	.61
		Freq	Pct.	Freq	Pct.	Freq	Pct.		
Gender	Male	17	56.7	17	56.7	17	56.7		
	Female	13	43.3	13	43.3	13	43.3		
Job	Employed	16	53.4	17	56.7	17	56.7		
	Unemployed	9	30	8	26.7	8	26.7	0.12ª	>.99
	Retired	5	16.6	5	16.6	5	16.6		
Level of Education	Illiterate	0	0	2	6.7	2	6.7		
	High school	9	30	7	23.3	9	30		
	Diploma	18	60	18	60	16	53.3	2.47 <sup>b</sup>	.87
	University	3	10	3	10	3	10		
Addiction	Yes	2	6.7	2	6.7	2	6.7		
	No	28	93.3	28	93.3	28	93.3		
Anti-hypertensive	Yes	10	33.3	10	33.3	11	36.7	0.10ª	.95
drug	No	20	66.7	20	66.7	19	63.3		
Cause of kidney	Diabetes	7	23.4	5	16.7	5	16.7		
failure	Blood pressure	10	33.3	11	36.7	11	36.7		
	Nephrotic syndrome	10	33.3	9	30	9	30	3.10 <sup>b</sup>	.92
	Lupus	0	0	1	3.3	0	0		
	Heart problem	3	10	4	13.3	5	16.7		
History of disease	CABG	1	3.3	2	6.7	2	6.7		
and surgery	Angiography	5	16.7	7	23.3	7	23.3		
	Diabetes	7	23.3	6	20	6	20		
	Kidney stone	7	23.3	7	23.3	7	23.3	2.11 <sup>b</sup>	.99
	Gravel	3	10	2	6.7	2	6.7		
	Bile harvest	1	3.4	1	3.4	2	6.7		
	No history	6	20	5	16.7	4	13.3		

<sup>a</sup>Chi-square test

<sup>b</sup>Fishers exact test

SD = standard deviation; Freq = frequency, Pct. = percentage, f = ANOVA, Z = Kruskal-Wallis test.

different in the three groups, and all three groups were identical in terms of these variables (Table 2).

The mean scores of RLS in the reflexology group before and one month after the intervention were increased, but decreased during the intervention. Also, the mean scores of RLS in the Swedish massage group before and one month after the intervention were increased, but decreased to during the intervention. In the sham group, the mean score of RLS was increased before the intervention, immediately after, and one month after the intervention.

The RLS score decreased significantly in the two intervention groups immediately after the intervention, compared to before and one month after the intervention. Based on the results of Kruskal-Wallis test, no significant difference was observed in the mean score of RLS among the three groups before and one month after the intervention. However, a significant difference was reported among the three groups immediately after the RLS intervention (p < .001) (Table 3). Based on the results of Mann-Whitney U test, RLS difference immediately after the intervention was significantly better in the reflexology group than the Swedish massage (p < .001) and sham groups (p < .001). In addition, immediately after the intervention was significantly better in the Swedish massage group than the sham group (p = .003) (Table 4).

The mean scores of sleep quality in the reflexology group before and one month after the intervention were increased, but they had decreased during the intervention. Also, the mean scores of sleep quality in the Swedish massage group before and one month after the intervention were increased, but had decreased during the intervention. In the sham group, the mean score of sleep quality was increased before the intervention, immediately, and one month after the intervention.

The sleep quality score decreased significantly in the two intervention groups immediately after the intervention compared to before and one month after the intervention. Based on the results of

Groups	Reflex	cology	Swedish	Massage	Sho	m	Independent	p
Variables	Mean	SD	Mean	SD	Mean	SD	t Test	value
Kt.V(L/L)	1.49	0.21	1.46	0.20	1.54	0.29	f=-0.03	.76
Alb(g/dl)	3.74	0.47	3.65	0.39	3.75	0.47	Z=1.78	.74
BUN (mg/dl)	74.86	7.56	76.16	9.00	74.00	7.93	f=0.86	.65
Cr (mg/dl)	6.91	1.69	6.38	1.14	6.47	1.18	t=0.69	.47
FBS (mg/dl)	94.9	20.15	90.93	17.61	94.96	20.27	Z=0.52	.64
K (meq/L)	5.04	0.69	4.68	0.76	4.63	0.48	Z=-0.45	.06
Na (meq/L)	139.56	4.26	138.86	3.83	139.03	3.37	Z=-0.79	.65
Ca (mg/dl)	9.06	0.68	9.1	0.81	9.02	0.79	Z=-0.64	.92
P (mg/dl)	5.22	0.79	5.14	0.83	5.1	1.04	f=-0.21	.77
URR(%)	0.67	0.07	0.68	0.05	0.66	0.07	Z=-0.35	.48
WBC(10*3/UL)	6.36	1.82	6.49	1.81	6.53	1.17	f=-0.66	.42
HCT (%)	36.86	6.17	36.08	7.98	36.85	4.73	Z=-0.43	.93
RBC(10*3/UL)	4.23	0.64	4.23	1.22	4.17	1.23	Z=-0.53	.46
PLT(10*3/UL)	145.36	47.38	149.86	47.00	149.50	44.97	f=0.12	.80
HB(g/dl)	12.24	1.32	12.07	1.34	12.37	1.34	Z=-0.27	.66
Fe (mcg/dl)	385.13	130.69	374.82	117.89	368.65	125.41	Z=-0.91	.82
Ferritin(mg/dl)	304.66	219.77	300.80	196.04	265.23	142.25	Z=0.73	.80
PTH (mg/ml)	363.02	144.09	373.10	104.25	369.38	135.45	Z=0.88	.78

TABLE 2. Comparison of Laboratory Tests Before Intervention in Patients Under Hemodialysis

SD = standard deviation, f = ANOVA, Z = Kruskal-Wallis test.

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Kruskal-Wallis test, no significant difference was observed in the mean score of sleep quality among the three groups before and one month after the intervention. However, a significant difference was reported among the three groups immediately after the sleep quality intervention (p < .001) (Table 5). The results showed that immediately after the intervention, sleep quality was significantly better in the foot reflexology group than the Swedish foot massage and sham groups (p < .001). Sleep quality decreased in one-month follow-up after the intervention in all three groups, which

#### TABLE 3. Determining and Comparing the Intergroup Mean Scores of Restless Leg Syndrome

Group	Reflexology		Swedish Massage		Sham		Kruskal-Wallis	р
Variable	Mean	SD	Mean	SD	Mean	SD	Test	value
Before the intervention	19.90	0.92	20.03	0.96	20.13	0.97	1.53	.47
Immediately after the intervention	6.80	5.95	14.60	5.92	19.46	0.89	49.35	<.001
One month after the intervention	19.53	1.07	19.63	1.27	19.80	1.95	0.19	.91
Friedman test	56.	.18	44.	87	25.	74		
<i>p</i> value	<.0	01	<.0	01	.05	52		

SD = standard deviation.

TABLE 4. Comparing Intervention Group Mean Score Changes of Restless Leg Syndrome Before, Immediately After the Intervention, and One Month After the Intervention

Difference	Group (I)	Group (J)	Mean Changes (I-J)	Mann-Whitney Test Statistics	p value <sup>a</sup>
Before the intervention	Reflexology	Swedish massage	-0.13	402.0	.44
	Reflexology	sham	-0.23	373.0	.23
	Swedish massage	sham	-0.10	420.0	.64
Immediately after the	Reflexology	Swedish massage	-7.80	152.0	<.001
intervention	Reflexology	sham	-12.67	0.001	<.001
	Swedish massage	sham	-4.87	256.0	.003
One month after the	Reflexology	Swedish massage	-0.10	424.0	.69
intervention	Reflexology	sham	-0.27	444.5	.93
	Swedish massage	sham	-0.17	428.5	.74

\* Mann-Whitney U test

#### TABLE 5. Determining and Comparing the Intergroup Mean Scores of Sleep Quality

Group	Reflexology		Swedish Massage		Sham		Kruskal-Wallis	p
Variable	Mean	SD	Mean	SD	Mean	SD	Test	value
Before the intervention	14.53	1.14	14.37	1.13	14.57	1.14	0.106	.95
Immediately after the intervention	9.97	1.40	12.57	2.40	14.57	1.14	46.60	<.001
One month after the intervention	15.50	.82	15.53	.86	15.43	0.82	0.26	.87
Friedman test	57.	22	55.	36		44		
<i>p</i> value	<.001		<.001		.057			

SD: standard deviation

means that with the cessation of the intervention, sleep quality decreased again (Table 5).

Based on the results of Mann-Whitney U test, sleep quality difference immediately after the intervention was significantly better in the reflexology group than the Swedish massage (p < .001) and sham groups (p < .001). In addition, scores for immediately after the intervention were significantly better in the Swedish massage group than the sham group (p = .003) (Table 6).

Immediately after the intervention, among the seven different dimensions of sleep quality, the following were significantly better for foot reflexology than the Swedish foot massage and sham group: sleep disturbances, sleep latency, sleep duration, and subjective sleep quality. In terms of other three dimensions, there was no difference among the three groups at different times.

#### DISCUSSION

The results of the present study showed that foot reflexology and Swedish foot massage both improved the restless leg syndrome and sleep quality of patients undergoing hemodialysis immediately after the intervention. The patients in the foot reflexology group had fewer signs of restless leg syndrome and sleep quality than the Swedish foot massage group. However, one month after the intervention, results showed a decrease in improvement of restless leg syndrome and sleep quality in both intervention groups. Furthermore, Ghasemi et al.<sup>(28)</sup> claimed that plantar reflexology could reduce the RLS intensity among the patients. Furthermore, Ozdemir et al.<sup>(37)</sup> argued that plantar reflexology could reduce fatigue, pain, and muscle cramps among hemodialysis patients. According to Wang et al.<sup>(38)</sup>, reflexology reduces the symptoms of cramping in the interval between two dialysis sessions among hemodialysis patients.

Thus, the effect on the nervous system is considered as the main mechanism of treatment in reflexology, so that the pressure applied to a specific part of the skin stimulates the nerve reflexes and transmits impulses to the brain; it also stimulates the nervous chemical system, balances the enzymes, and regulates the endocrine function,<sup>(27)</sup> which seems to be effective in reducing the complications of various diseases such as RLS among hemodialysis patients.<sup>(27)</sup>

A case report found that massage, including sports massage and basic Swedish massage techniques, reduces the RLS symptoms and is even more effective than prescribed medications.<sup>(39)</sup> In another study, Nasiri et al.<sup>(40)</sup> indicated that using short-term massage with olive oil as a complementary method reduced the severity of uremic RLS. Ajorpaz et al.<sup>(41)</sup> proved the beneficial effect of effleurage massage with lavender and glycerin oils in reducing RLS symptoms among hemodialysis patients.

In addition, Burbank et al.<sup>(42)</sup> found that utilizing vibrating pads by RLS patients did

Difference	Group (I)	Group (J)	Mean Changes (I-J)	Mann-Whitney Test Statistics	p value <sup>a</sup>
Before the intervention	Reflexology	Swedish massage	0.17	431.5	.77
	Reflexology	sham	-0.03	441.5	.89
	Swedish massage	sham	-0.20	434	.80
Immediately after the intervention	Reflexology	Swedish massage	-2.6	175.5	<.001
	Reflexology	sham	-4.6	5	<.001
	Swedish massage	sham	-2	256	.003
One month after the	Reflexology	Swedish massage	-0.034	442.5	.91
intervention	Reflexology	sham	0.067	426	.70
	Swedish massage	sham	0.10	419.5	.63

TABLE 6. Comparing Intervention Group Mean Score Changes of Sleep Quality Before, Immediately After the Intervention, and One Month After the Intervention

<sup>a</sup>Mann-Whitney U test.

not cause a significant progress in reducing the severity of RLS symptoms, which can be due to the type of intervention and severity of the related symptoms. Therefore, massage reduces stress and anxiety, relieves muscle cramps, strengthens the immune system, relieves fatigue caused by disease, improves blood circulation, and reduces insomnia.

In the study of Sajadi et al.,<sup>(43)</sup> results showed that reflexology massage improved sleep quality in patients with multiple sclerosis. Also, Alinia-Najjar et al.<sup>(44)</sup> reported that four days of reflexology in patients with burn injuries admitted to the intensive care unit improved their sleep quality. In line with our results, Abbassi Fakhravari et al.<sup>(45)</sup> stated the beneficial effect of reflexology on improving the patients' sleep quality. The reflexology time in both these last three studies was 10 minutes for each foot, which can indicate the importance of the duration of the massage to a certain extent with its beneficial effect on the study variables. In the study of Samarehfekri et al.,<sup>(46)</sup> foot reflexology improved the patients' sleep quality after kidney transplantation. In this study, one week after the intervention, compared to the first day of the intervention, the rate of improvement in sleep quality increased; however, in our present study, one month after the end of the intervention, the rate of improvement in sleep quality decreased. Thus, it can be seen that reflexology has effect for a certain period of time and, after that period, if this massage is not performed, its effectiveness will decrease. However, Toygar et al.<sup>(47)</sup> found that reflexology had little effect on the sleep quality of patients with cancer.

The results of a study by Emamverdi et al.<sup>(25)</sup> showed that reflexology and acupressure improved the sleep quality of patients undergoing hemodialysis to the same extent. In the Emamverdi study, there was no statistically significant difference between the two intervention groups (reflexology massage and acupressure) in terms of the overall score of sleep quality, which could be due to the emphasis on massage of one point (the Shenmen point) in this study. However, in the present study, there was a statistically significant difference between the overall score of sleep quality in patients receiving reflexology and those receiving Swedish massage. In the present study, the emphasis was on reflexology at 21 points (in patients receiving reflexology).

Reflexologists believe that massaging reflexology points using unique techniques increases the blood flow to related organs and also helps to repair the damaged areas.<sup>(38)</sup> Touch (massage) speeds up blood circulation, helps the digestive system and its function, stimulates the lymphatic system, has a great effect on the nervous system, relieves stress, and reduces heart rate and blood pressure.<sup>(27)</sup> The study of Kashani and Kashani<sup>(48)</sup> indicated that massage was effective in the management of sleep disorders in cancer patients. Massage has been shown to improve sleep quality in patients with hypertension, cancer, ischemic heart disease, and those undergoing coronary artery bypass graft surgery.<sup>(49,50)</sup> A study by Malekshahi et al.<sup>(51)</sup> showed that foot massage had a positive effect on the sleep quality. Their study showed that a brief night foot massage could be useful for sleep disorders and some problems like short night sleep. Also, Smith et al.<sup>(52)</sup> reported that three sessions of Swedish massage (effleurage and petrissage) for one week was effective in reducing pain, stress, and sleep disorders in 20 cancer patients. In a similar study by Field et al.,<sup>(53)</sup> 30 minutes of shallow and deep massage on 14 patients with low back pain and sleep disturbances showed a reduction in pain and sleep disturbance in the intervention groups. Arslan et al.<sup>(54)</sup> found that foot massage and back massage were effective in lowering blood pressure and improving the sleep quality. Oshvandi et al.<sup>(55)</sup> reported that sleep quality improved significantly after 20 minutes of foot massage for six nights in people with ischemic heart disease. In the study of Jane et al.<sup>(56)</sup> on massage therapy, there was no statistically significant difference in patients with metastatic bone pain in terms of sleep quality and pain. Also, the experience of bone pain interfered with massage therapy. In the study by Jane and colleagues, it appeared that the beneficial effects of massage increased in additional sessions, and these effects had already been reported in studies on patients with cancer.<sup>(56)</sup>

The results of various studies suggest that massage techniques can be easily applied to the foot area, and the proximity of neural networks to the foot surface facilitates the massage effect.<sup>(57,58)</sup> Massage can be performed and taught as a useful method to improve restless leg syndrome and sleep quality of patients in hemodialysis unit. In the present study, we also observed an improvement in restless leg syndrome and sleep quality in patients undergoing hemodialysis using Swedish massage, with the difference that the effect of reflexology was able to increase the improvement in restless leg syndrome and sleep quality more than Swedish massage.

The present study had some limitations such as patients' withdrawal during the intervention due to worsening physical conditions or going through transplant process. It is also recommended that future studies evaluate the effect of reflexology foot massage on other symptoms of hemodialysis patients such as anxiety and stress, and clinical outcomes such as urinary output and biochemical tests, to evaluate the results of these cases on sleep quality and restless legs syndrome in these patients.

## CONCLUSION

The results of the present study showed that, immediately after the foot reflexoloav and the Swedish massage, restless leg syndrome and sleep quality improved in patients undergoing hemodialysis. In comparison, the patients in the foot reflexology group had better restless leg syndrome and sleep quality than the Swedish foot massage group. Due to the limitations in performing proper sports activities in all age groups of patients undergoing hemodialysis and problems such as poor restless leg syndrome and sleep guality in some of these patients, it seems necessary to use a simple and regular treatment method such as foot massage. This method can reduce these complications in patients undergoing hemodialysis. Foot reflexology massage can be an effective, simple, low-cost, and applicable intervention treatment that can be easily taught to nurses and patients' companions in different wards of medical centers and performed for patients.

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## CONFLICT OF INTEREST NOTIFICATION

The authors declare there are no conflicts of interest.

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## REFERENCES

- 1. Urquhart-Secord R, Craig JC, Hemmelgarn B, Tam-Tham H, Manns B, Howell M et al. Patient and caregiver priorities for outcomes in hemodialysis: an international nominal groups technique study. *Am J Kidney Dis.* 2016 Sep 1;68(3):444–454.
- Bikbov B, Purcell CA, Levey AS, Smith M, Abdoli A, Abebe M, et al. Global, regional, and national burden of chronic kidney disease, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. *The Lancet*. 2020;395(10225): 709–733.
- 3. Abassi MR, Safavi A, Haghverdi M, Saedi B. Sleep disorders in ESRD patients undergoing hemodialysis. *Acta Medica Iranica*. 2016:176–184.
- Rostami F, Ramezani Badr F, Amini K, Pezeshki A. Effect of a self-care educational program based on Orem's model on stress in patients undergoing hemodialysis. *Prevent Care Nurs Midwif J.* 2015;5(1):13–22.
- 5. Zhang LY, Ma XY, Lin J, Liu WH, Guo W, Yin L, et al. Prevalence and risk factors of restless leg syndrome in hemodialysis patients. *Nature Sci Sleep*. 2020;12:19.
- Ezzat H, Mohab A. Prevalence of sleep disorders among ESRD patients. *Renal Failure*. 2015;37(6):1013–1019.
- 7. Koc M. The effect of cognitive-behavioral therapy on stuttering. *Soc Behav Personal*. 2010;38(3): 301–309.

- 8. Farrokhian R, Soleimani M, Sheikhi MR, Alipour M. Effect of foot reflexology massage on sleep quality in hemodialysis patients: a randomized control trial. *Avicenna J Nurs Midwif Care*. 2017;24(4): 213–220.
- 9. Findling RL, Robb A, Bose A. Escitalopram in the treatment of adolescent depression: a randomized, double-blind, placebo-controlled extension trial. *J Child Adol Psychopharm*. 2013;23(7):468–480.
- Manley HJ, McClaran ML, Overbay DK, Wright MA, Reid GM, Bender WL, et al. Factors associated with medication-related problems in ambulatory hemodialysis patients. *Am J Kidney Dis.* 2003;41(2):386–393.
- Song YY, Hu RJ, Diao YS, Chen L, Jiang XL. Effects of exercise training on restless leg syndrome, depression, sleep quality, and fatigue among hemodialysis patients: a systematic review and meta-analysis. *J Pain Sympt Manag.* 2018;55(4):1184–1195.
- 12. Kemppainen LM, Kemppainen TT, Reippainen JA, Salmenniemi ST, Vuolanto PH. Use of complementary and alternative medicine in Europe: healthrelated and sociodemographic determinants. *Scand J Public Health*. 2018;46(4):448–455.
- Taghipour A, Bahrami Taghanaki H, Hosienzade H, Noras M. Ethical and legal challenges in complementary and alternative medicine. Iran J Med Ethics Hist Med. 2016;9(3):23–31.
- 14. Najafi Ghezeljeh T, Salehzadeh H, Rafii F. Comparison of the effect of Swedish massage and preferred music intervention on anxiety in patients with chronic heart failure. *Iran J Cardiovasc Nurs*. 2016;5(1):36–43.
- Chen S-C, Yu BY-M, Suen LK-P, Yu J, Ho FY-Y, Yang J-J, et al. Massage therapy for the treatment of attention deficit/hyperactivity disorder (ADHD) in children and adolescents: a systematic review and meta-analysis. *Complement Ther Med.* 2019; 42:389–399.
- Smith CA, Levett KM, Collins CT, Dahlen HG, Ee CC, Suganuma M. Massage, reflexology and other manual methods for pain management in labour. *Cochrane Database System Rev.* 2018(3).
- 17. Hasanpour M, Mohammadi MM, Shareinia H. Effects of reflexology on premenstrual syndrome: a systematic review and meta-analysis. *BioPsychoSocial Med*. 2019;13(1):1–12.
- Sadat Kahangi L, Moeini M, Babashahi M. The effects of reflexology on anxiety levels before coronary artery bypass graft surgery. *J Res Behav Sci.* 2012;9(5):85–92.
- 19. Barreto DM, Batista MV. Swedish massage: a systematic review of its physical and psychological benefits. *Adv Mind-Body Med*. 2017;31(2):16–20.
- 20. Kashani E, Mirhosseini Z, Rastaghi S, Rad M. The Effect of the cool dialysate on the restless leg syndrome in hemodialysis patients: randomized triple-blind clinical trial. *Iran J Nurs Midwif Res.* 2019;24(3):200.

- 21. Iranian Consortium of Dialysis (ICD). *Iranian Dialysis Yearbook*. Tehran: ICD; 2017.
- 22. Moghadasian S, Hagh MH, Hokmabadi LA. Lifestyle of hemodialysis patients in comparison with outpatients. *J Caring Sci*. 2012;1(2):101–107.
- 23. Movahed Majd M, Enayat H, Rayanpour R, Fouladi K. Women and non-conventional medicine: a study of related factors to the use of traditional and complementary medicine by women. *Sadra Med J*. 2019;7(3):273–286.
- 24. Sheikhrabori A, Dehghan M, Ghaedi F, Khademi GR. Complementary and alternative medicine usage and its determinant factors among diabetic patients: an Iranian case. *J Evid-Based Complement Alt Med.* 2017;22(3):449–454.
- 25. Emamverdi M, Mohammadpour A, Badiee Aval S, Sajjadi M. Comparing the effects of reflexology massage and acupressure on the quality of sleep in hemodialysis patients: a randomized clinical trial. *J Mazandaran Univ Med Sci.* 2019;29(176):34-46.
- 26. Azimpour S, Hosseini HS, Eftekhari A, Kazemi M. The effects of vibration and massage on severity of symptoms of restless leg syndrome and sleep quality in hemodialysis patients: a randomized cross-over clinical trial. *J Renal Injury Prevent*. 2018;8(2):106–111.
- 27. Khojandi S, Shahgholian N, Karimian J, Valiani M. Comparison the effect of two methods of reflexology massage and stretching exercises on the severity of restless leg syndrome among patients undergoing hemodialysis [in Persian]. *Iran J Nurs Res.* 2015;10(1):86–94.
- 28. Ghasemi M, Rejeh N, Heravi-Karimooi M, Davood Tadrisi S, Samady Kia P. The effectiveness of foot reflexology in the severity of restless leg syndrome in female patients undergoing dialysis: a randomized controlled trial. *Crit Care Nurs*. 2018;11(2):1–6.
- 29. Saedi F, Barkhordari-Sharifabad M, Javadi-Estahbanati M, Fallahzadeh H. Sexual function, social isolation, loneliness and self-esteem in patients undergoing hemodialysis. *Sex Disabil*. 2019;37(3):401–413.
- 30. Habibzade H, Khalkhali H, Ghaneii R. Study of the relationship between restless leg syndrome and sleep disturbance among patients in Critical Care Units [in Persian]. *Iran J Crit Care Nurs.* 2011;4(3):153–158.
- 31. Mortazavi M, Vahdatpour B, Ghasempour A, Taheri D, Shahidi S, Moeinzadeh F, et al. Aerobic exercise improves signs of restless leg syndrome in end stage renal disease patients suffering chronic hemodialysis. *Sci World J.* 2013;2013.
- 32. Roshanravan M, Jouybari L, Bahrami Taghanaki H, Vakili M, Sanagoo A, Amini Z. Effect of foot reflexology on fatigue in patients undergoing hemodialysis: a sham-controlled randomized trial. J Mazandaran Univ Med Sci. 2016;26(137):32–41.
- 33. Baral S, Pant V, Shah DS. Dialysis adequacy in ESRD patients on maintenance hemodialysis in a tertiary care center. *J Inst Med*. 2017;39(2):29–32.

- 34. Buysse DJ, Reynolds III CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Res.* 1989;28(2):193–213.
- 35. Tse H. Sole Guidance: Ancient Secrets of Chinese Reflexology to Heal the Body, Mind, Heart, and Spirit. Carlsbad, CA: Hay House, Inc; 2016.
- 36. Gholami-Motlagh F, Jouzi M, Soleymani B. Comparing the effects of two Swedish massage techniques on the vital signs and anxiety of healthy women. *Iran J Nurs Midwif Res.* 2016;21(4):402.
- Özdemir G, Ovayolu N, Ovayolu Ö. The effect of reflexology applied on haemodialysis patients with fatigue, pain and cramps. *Int J Nurs Pract*. 2013;19(3):265–273.
- 38. Wang MY, Tsai PS, Lee PH, Chang WY, Yang CM. The efficacy of reflexology: systematic review. *J Adv Nurs.* 2008;62(5):512–520.
- 39. Russell M. Massage therapy and restless leg syndrome. *J Bodywk Movement Ther.* 2007;11(2): 146–150.
- 40. Nasiri M, Abbasi M, Khosroabadi ZY, Saghafi H, Hamzeei F, Amiri MH, et al. Short-term effects of massage with olive oil on the severity of uremic restless leg syndrome: a double-blind placebo-controlled trial. *Complement Ther Med*. 2019;44:261–8.
- 41. Ajorpaz NM, Rahemi Z, Aghajani M, Hashemi SH. Effects of glycerin oil and lavender oil massages on hemodialysis patients' restless leg syndrome. *J Bodywk Movement Ther*. 2020;24(1):88–92.
- 42. Burbank F, Buchfuhrer MJ, Kopjar BJR. Sleep improvement for restless leg syndrome patients. Part I: Pooled analysis of two prospective, double-blind, sham-controlled, multi-center, randomized clinical studies of the effects of vibrating pads on RLS symptoms. *Res Rev Parkinsonism*. 2013;3:1–10.
- 43. Sajadi M, Davodabady F, Ebrahimi-Monfared M. The effect of foot reflexology on fatigue, sleep quality and anxiety in patients with multiple sclerosis: a randomized controlled trial. *Arch Neurosci*. 2020;7(3):e102591.
- 44. Alinia-Najjar R, Bagheri-Nesami M, Shorofi SA, Mousavinasab SN, Saatchi K. The effect of foot reflexology massage on burn-specific pain anxiety and sleep quality and quantity of patients hospitalized in the burn intensive care unit (ICU). *Burns*. 2020;46(8):1942–1951.
- 45. Abbassi Fakhravari A, Bastani F, Haghani H. The effect of foot reflexology massage on the sleep quality of elderly women with restless leg syndrome. *J Client-Centered Nurs Care*. 2018;4(2):96–103.
- 46. Samarehfekri A, Dehghan M, Arab M, Ebadzadeh MR. Effect of foot reflexology on pain, fatigue, and quality of sleep after kidney transplantation surgery: a parallel randomized controlled trial. *Evid-Based Complement Altern Med*. 2020;2020.

- 47. Toygar I, Yeşilbalkan ÖU, Malseven YG, Sönmez E. Effect of reflexology on anxiety and sleep of informal cancer caregiver: randomized controlled trial. *Complement Ther Clin Pract*. 2020;39:101143.
- 48. Kashani F, Kashani P. The effect of massage therapy on the quality of sleep in breast cancer patients. *Iran J Nurs Midwif Res.* 2014;19(2):113.
- 49. Padilla R, Domina A. Effectiveness of sensory stimulation to improve arousal and alertness of people in a coma or persistent vegetative state after traumatic brain injury: a systematic review. *Am J Occup Ther.* 2016;70(3):7003180030p1-p8.
- 50. Vora CK, Mansoor GA. Herbs and alternative therapies: relevance to hypertension and cardiovascular diseases. *Curr Hypertens Rep.* 2005;7(4):275–280.
- 51. Malekshahi F, Aryamanesh F, Fallahi S. The effects of massage therapy on sleep quality of patients with end-stage renal disease undergoing hemodialysis. *Sleep Hypnosis*. 2018;20:91–95.
- 52. Smith MC, Kemp J, Hemphill L, Vojir CP. Outcomes of therapeutic massage for hospitalized cancer patients. *J Nurs Scholarship*. 2002;34(3):257–262.
- 53. Field T, Hernandez-Reif M, Diego M, Fraser M. Lower back pain and sleep disturbance are reduced following massage therapy. *J Bodywk Movem Ther*. 2007;11(2):141–145.
- 54. Arslan G, Ceyhan Ö, Mollaoğlu M. The influence of foot and back massage on blood pressure and sleep quality in females with essential hypertension: a randomized controlled study. *J Hum Hyperten*. 2021;35(7):627–637.
- 55. Oshvandi K, Abdi S, Karampourian A, Moghimbaghi A, Homayoubfar S. The effect of foot massage on quality of sleep in ischemic heart disease patients hospitalized in CCU. *J Crit Care Nurs*. 2014;7(2):66–73.
- 56. Jane SW, Chen SL, Wilkie DJ, Lin YC, Foreman SW, Beaton RD, et al. Effects of massage on pain, mood status, relaxation, and sleep in Taiwanese patients with metastatic bone pain: a randomized clinical trial. *Pain*. 2011;152(10):2432–2442.
- 57. Ju MS, Lee S, Bae I, Hur MH, Seong K, Lee MS. Effects of aroma massage on home blood pressure, ambulatory blood pressure, and sleep quality in middle-aged women with hypertension. *EvidBased Complement Alt Med*. 2013;2013.
- 58. Givi M. Durability of effect of massage therapy on blood pressure. *Int J Prevent Med*. 2013;4(5):511.

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