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Short-term effects of massage with olive oil on the severity of uremic restless legs syndrome: A double-blind placebo-controlled trial

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ABSTRACT

Background: Although the efficacy of olive oil massage has been established for different disorders, no studies have yet focused on the effect of olive oil massage on restless legs syndrome (RLS). In this study, we aimed to evaluate the short-term effects of massage with olive oil in reducing the severity of uremic RLS.

Methods: This double-blind placebo-controlled trial was conducted on 60 patients with uremic RLS (mean age: 51.96 ± 10.15), who were randomly divided into olive oil and placebo groups. The olive oil group received massage with olive oil, while the placebo group received massage with liquid paraffin twice a week during hemodialysis sessions for three weeks. For each leg, 10 mL of the olive oil or placebo was applied and then massaged for five min from the plantar surface of the foot to the area below the knee. The severity of RLS was rated on the first day and one week after the final massage therapy session by using the International Restless Legs Syndrome Study Group (IRLSSG) Rating Scale.

Results: In terms of different categories of RLS severity, a significant decline was observed only in the olive oil group from the pre- to post-intervention stages ($P = 0.003$). After the intervention, the decline in the total RLS severity was more significant in the olive oil group ($P < 0.001$), compared to the placebo group ($P = 0.019$). Moreover, a significant difference in the total RLS severity ($P < 0.001$) and different categories of RLS severity ($P = 0.002$) was observed after the intervention between the groups in favor of olive oil massage. However, no significant difference was found between groups in pre-intervention stage in this regard ($P = 0.363$ and $P = 0.955$, respectively).

Conclusion: Application of short-term massage with olive oil as a complementary method seems to be effective in reducing the severity of uremic RLS. Further studies are suggested to identify the sustainability of the findings.

1. Introduction

Restless legs syndrome (RLS), also known as Willis-Ekbom disease, is a neurological disorder, characterized by extremely unpleasant sensations in the lower extremities, leading to an irresistible urge to move the legs.[1] Patients with this disorder commonly experience chronic pain, paresthesia or dysesthesia, tingling sensations, and feelings of creeping and burning in the legs.[2] This condition can cause adverse effects, including reduced quality of life and sleep disturbances (i.e., insomnia).[3,4] It is known to frequently occur in patients with chronic renal insufficiency as a result of hemodialysis (HD).[5] Therefore, management of uremic RLS is essential in HD patients.[6]

Abbreviations: BMI, body mass index; CONSORT, consolidated standards of reporting trials; HD, hemodialysis; IRLSSG, International RLS Study Group; RLS, restless legs syndrome

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Some pharmacological treatments have been applied for the management of uremic RLS, leading to serious complications.[7,8] Therefore, considerable attention has been recently paid to nonpharmacological methods. Based on the literature, most patients with RLS are interested in complementary and alternative medicine for alleviating their symptoms.[9,10]

In recent years, massage of the affected leg either alone or with herbal products has been proposed for the management of RLS.[11–16] It has been reported that 76.9% of patients with RLS prefer to massage their legs as one of the common strategies for alleviating unpleasant sensations.[17] Based on recent reviews, massage can be successful in diminishing the symptoms of RLS.[10,11] In a case study, the effect of massage in alleviating the RLS symptoms was reported.[13] Moreover, in a pilot trial, simple massage with lavender oil could significantly decrease the severity of uremic RLS.[12]

Olive oil *(Olea europaea* L.*)* is one of the common herbal products traditionally used for a wide range of purposes.[18,19] Currently, massage with this oil has attracted extensive attention for different disorders.[20–23] Also, some recent trials have indicated the effects of topical olive oil application in the management of different conditions, such as chronic and burning pain, inflammation, and burning sensation.[24–28] However, to the best of our knowledge, no trial has yet evaluated the effect of olive oil massage in reducing the symptoms of RLS. Therefore, we aimed to compare the effects of massage with olive oil and placebo on the severity of uremic RLS.

2. Materials and methods

2.1. Trial design

This was a randomized, double-blind, placebo-controlled, parallel-group trial with a pretest-posttest design. It was registered in the Iranian Registry of Clinical Trials (No. IRCT20130803014251N7). We reported the trial based on the CONSORT Statement,[29] with an emphasis on herbal interventions.[30] Before the study, the Institutional Review Board and Independent Ethics Committee of Qom University of Medical Sciences (Qom, Iran) approved this trial (No. IR.MUQ.REC.1396.97). We also followed the Declaration of Helsinki and obtained written informed consent from all patients before enrollment.

2.2. Patients

We selected all the patients undergoing HD at the Hemodialysis Unit of Kamkar-Arabnia Hospital, affiliated to Qom University of Medical Sciences from January 10, 2018 to April 9, 2018, using the sequential sampling method. The inclusion criteria were as follows: 1) age range of 18–65 years; 2) being fully conscious; 3) having the ability to walk independently with the affected feet; 4) undergoing regular and consecutive HD in at least the past six months; 5) receiving HD at least twice per week in the recruitment unit for three or four hours; and 6) experience of RLS symptoms at least twice a week. On the other hand, the exclusion criteria were as follows: 1) having emergency HD; 2) having sensitivity or allergy to the herbal extracts; 3) using any herbal extracts (topical or oral) in the past three months; 4) presence of any wound, fracture, amputation, and trauma below the knee; 5) having the history of addiction to drugs or alcohol; 6) having any mental disorders, dementia, or intellectual disability; 7) absence from HD sessions more than twice during the intervention; 8) interference of the trial with the patient's treatment, based on the diagnosis of a nephrologist (the first research assistant); and 9) patient's desire to withdraw from the trial.

We estimated the sample size based on a previous trial, comparing the effects of massage with lavender oil (12.41 ± 5.49) and routine care (23.23 ± 4.52) on the severity of uremic RLS ($P < 0.0001$).[12] Based on the findings of this trial and the formula suggested for randomized clinical trials, the sample was measured to be nine patients per group at a confidence level of 99% and power of 0.95. However, to calculate the standard sample size, we performed a pilot study on 10 patients. Based on the pilot results (RLS severity, 23.11 ± 6.19 and 28.31 ± 5.51 in the olive oil and placebo groups, respectively), we estimated 27 patients in each group at type I error of 5% ($\alpha = 0.05$) and type II error of 10% ($\beta = 0.10$). Considering the possibility of 10% attrition, we recruited 30 patients in each group of the study.

2.3. Randomization and blinding

The eligible patients were randomly allocated to two groups of placebo (n = 30) and olive oil (n = 30), using stratified randomization, based on the severity of RLS, serum level of iron, and serum level of ferritin. Randomization was performed only by the main researcher, and all the data were kept confidential during the course of the trial.

Both olive oil and placebo were prepared and labeled by the main researcher in the same anonymous and opaque-covered syringes (10 mL). The patients and two nurses (the second and third research assistants), who performed the interventions, were blinded to the contents of syringes. Also, all the assessments and scorings in the two groups were undertaken by a nurse (the fourth research assistant), who was unaware of the group allocations.

The success of the blinding procedure was evaluated using a "2 × 3 format" technique.[31] The main researcher asked the patients and the outcome assessor (the fourth research assistant) to predict patient allocations using three guessing options (olive oil, placebo, and uncertain). The patients were asked which intervention they believed they had received at the end of the intervention. The outcome assessor was asked to predict the patient allocations during the post-intervention assessment. We considered blinding as successful if the number of "uncertain" responses was high, or the frequency of correct and incorrect guesses was balanced.[31]

2.4. Outcome measures

2.4.1. Demographic and clinical data

For each patient in the trial, demographic and clinical data were collected by a researcher-made form, including items on gender, age, place of residence, marital status, educational level, body mass index (BMI), duration of RLS, family history of RLS, history of anemia, hypertension, and diabetes, HD frequency, and laboratory test results (iron, ferritin, phosphorus, hemoglobin, parathyroid hormone, and urea). For the measurement of BMI, weight in kg was divided by height in ^{m2}. All laboratory test results were obtained from the patients' last laboratory reports.

2.4.2. Diagnosis of RLS

Uremic RLS was diagnosed based on the criteria developed and approved by the International RLS Study Group (IRLSSG). According to IRLSSG, patients with the following criteria were diagnosed with RLS: 1) an irresistible desire to move the legs, usually caused or accompanied by unpleasant and uncomfortable sensations in the legs; 2) beginning or worsening of symptoms during rest or inactivity (i.e., lying or sitting); 3) beginning or worsening of symptoms in the evening or night; and 4) total or partial relief of symptoms by movement (i.e., walking or stretching). Each criterion was scored based on a four-point Likert scale from never (score, 0) to always (score, 3); the total scores range from zero to 12.[32] We evaluated these criteria using the Persian version of IRLSSG, the reliability and validity of which have been previously confirmed among Iranian HD patients.[33,34]

2.4.3. Severity of RLS

The IRLSSG Rating Scale as a valid measure was used to evaluate the severity of RLS symptoms. This 10-item scale was developed and approved by the IRLSSG. Each item is rated using a five-point Likert scale, ranging from zero (lack of RLS) to four (very severe RLS). The total scores range from zero to 40, with higher scores indicating the greater

severity of symptoms.[35] Based on previous studies[32,33]and the total scores, we classified the severity of RLS into mild (score, 0–10), moderate (score, 11–20), severe (score, 21–30), and very severe (score, 31–40). The validity and reliability of the Persian version of this scale have been confirmed among patients undergoing HD.[33,34]

2.4.4. Adverse effects of the intervention

During the trial, we carefully assessed all the patients to record any potential adverse effects (i.e., iching, irritation, skin rash) via face to face examination. The adverse effects were documented via phone calls for patients who were lost to follow-up.

2.5. Data collection

First, the diagnostic criteria were assessed by a blinded nurse (the fourth research assistant) under the supervision of a blinded nephrologist (the first research assistant), and patients who obtained at least a score of four on the IRLSSG were diagnosed with potential RLS; patients who obtained a score of three or less were not considered for further evaluation. To determine the actual diagnosis of RLS, the patients were assessed for mimic conditions by a neurologist and an orthopedics, and those with these conditions were not entered into this study.

Following the diagnosis, the patients were evaluated based on the inclusion criteria, and then, the demographic and clinical data were obtained for each eligible patient. The inclusion criteria checklist and demographic and clinical form were completed based on the patients' interviews and clinical records by the blinded nurse. The IRLSSG Rating Scale was completed by the blinded nurse through interviews before random allocation on the first day (at baseline) and one week after the final massage session.

2.6. Intervention

We educated the patients about the standard care of HD using the face-to-face technique at the participating unit. We asked all the patients to take only the prescribed drugs and avoid the use of any other medications or herbal extracts. Also, we requested all the patients to wash their legs from the knee to toes with 1000 mL of normal saline solution (0.9%) before each HD session.

Patients in the olive oil group received olive oil massage, while those in the placebo group received placebo massage. At least one hour after the beginning of each HD session, about 10 mL of either olive oil or placebo was applied to one leg from the plantar surface of the foot to the area below the knee. Then, the target leg was massaged immediately for five min with the palm of the hand or fingers using the light pressure stroking technique. Based on an earlier trial,[36] we considered this type of technique as light and rhythmic, involving gentle circular rubbing movements toward left and right without any deep pressure.

Massage was initiated from the plantar surface of the foot towards the heel and dorsal surface of the foot towards the ankle. The posterior and anterior sides of the leg were then massaged up to the knee. The same technique was applied instantly for the other leg. We asked all the patients to let olive oil and placebo dry spontaneously without any manipulation.

We used refined, pure, odorless olive oil (Loyeh Ind., Gilan, Iran; health production license No., 47/10794; production serial No., PZS1626815). Topical administration of this type of olive oil did not show any adverse effects in a previous trial.[37] Also, based on our pilot study, topical application of this oil had no adverse effects. Oral lemonade liquid paraffin was used as placebo (Farabi Pharmaceutical & Cosmetic Co., Tehran, Iran; health production license No., d/5/42/8440; production serial No., 9555), which was identical to olive oil in terms of appearance and waxy nature.

We performed the intervention in the recruitment unit, attended by patients for their routine HD session in one of the morning, evening, and night shifts. During all massage therapy sessions, patients in both groups lied down in an electric HD chair in a comfortable position, and the legs were supported on the chair during the massage. Moreover, all patients were advised not to self-massage outside of the nurse-delivered intervention. The intervention was performed twice a week during three weeks, and the total intervention time was 60 min (considering five min per leg). Two blinded nursing assistants (one female assistant for female patients and one male assistant for male patients to observe ethical consideration) performed massages, who were always the same per patient to limit any bias. Prior to the intervention, the assistants were trained on how to apply the massage in a formal session by the main researcher, who had experience in massage therapy and application of herbal oils.[36–38]

2.7. Statistical analysis

The data were analyzed in SPSS version 22 by the fifth research assistant. The homogeneity of groups was assessed using independent samples *t*-test, Fisher's exact test, and Chi-square test. Independent samples *t*-test and paired sample *t*-test were also used to examine intergroup and intragroup differences in the RLS scores, respectively. Also, to compare different categories of RLS severity between and within the groups, we used the Mann-Whitney and Wilcoxon tests, respectively. *P*-value less than 0.05 was considered statistically significant.

3. Results

3.1. Follow-up

Among 60 patients included in the study, three from the olive oil group and two from the placebo group were excluded due to discontinuing the intervention and being lost to follow-up. In total, 55 patients (olive oil group, 27; placebo group, 28) completed the trial and were recruited for the final analysis (Fig. 1). At the end of the trial, the compliance rate was estimated at 91.66%.

3.2. Patients' characteristics

There were no significant differences between the two groups regarding the demographic and clinical characteristics (Table 1).

3.3. Success of blinding

Most of the patients in the olive oil group (55.6%) and placebo group (57.1%) were uncertain about the intervention they had received. Also, the outcome assessor was unable to predict the group allocation in most patients from the olive oil (66.7%) and placebo (64.3%) groups. The predictions of patients (P = 0.913) and the outcome assessor (P = 0.954) were not significantly different between the olive oil and placebo groups, suggesting the success of blinding.

3.4. RLS severity

Before the intervention, independent samples *t*-test did not show any significant differences in the total score of RLS severity between the olive oil and placebo groups ($t = -0.91$, $P = 0.363$). However, the results of this test demonstrated a significant difference in the total score of RLS severity between the two groups after the intervention ($t = -3.89$, $P < 0.001$). To some extent, the same results were obtained for the items of RLS severity before and after the intervention (Table 2). On the other hand, no significant intergroup difference was observed before the intervention in the categories of RLS severity ($P = 0.955$), whereas after the intervention, a significant difference was observed between the groups ($P = 0.002$; Table 3).

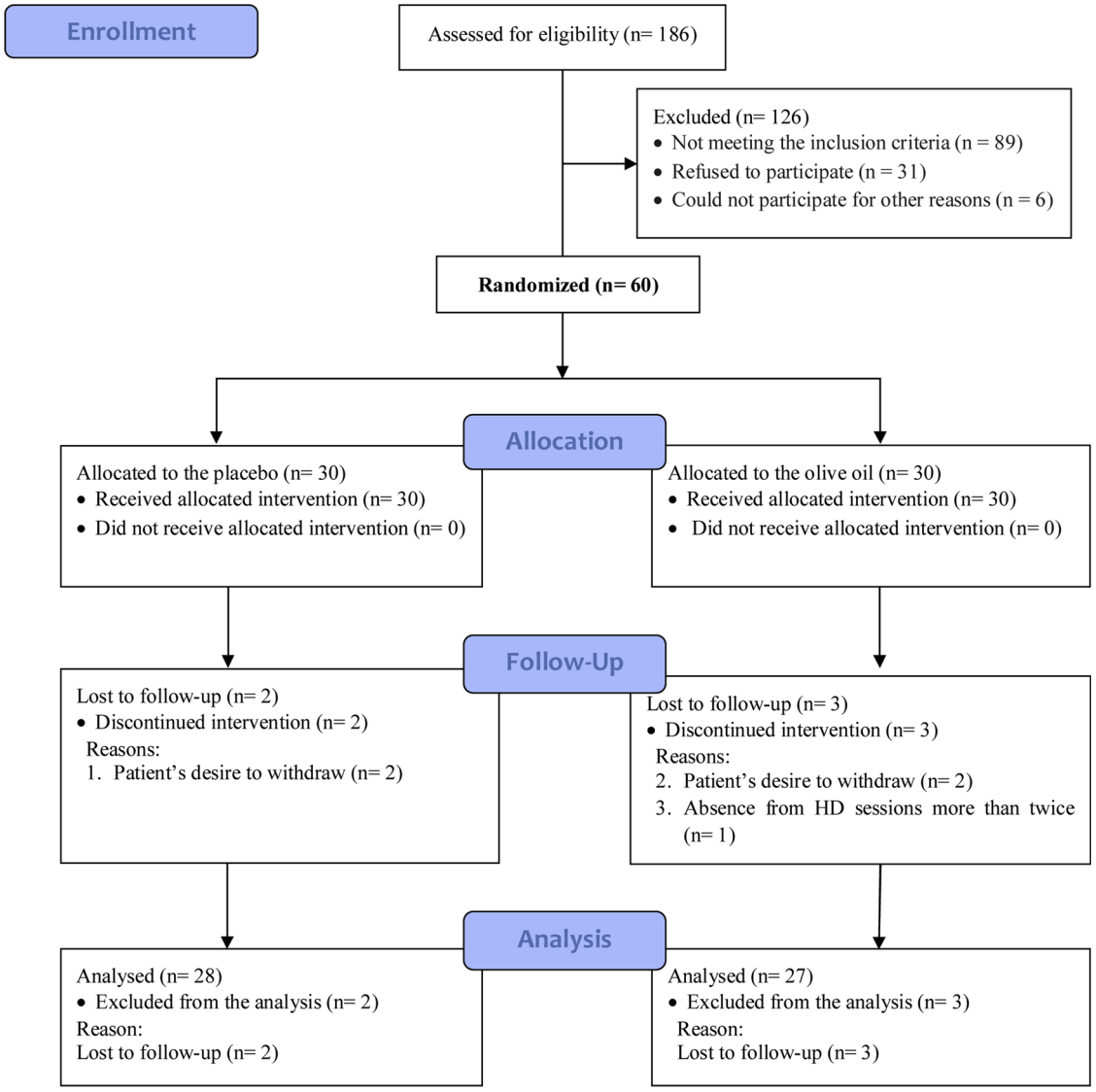

Fig. 1. CONSORT flow diagram of the patients.

Based on the paired sample *t*-test results, the total score of RLS severity decreased significantly after massage with both olive oil ($t = 4.79$, $P < 0.001$) and placebo ($t = 2.50$, $P = 0.019$). According to the intragroup data, similar results were found to some extent for the items of RLS severity (Table 2). However, with respect to the categories of RLS severity, a significant reduction was found after the intervention only in the olive oil group ($P = 0.003$; Table 3).

3.5. Adverse effects

None of the patients experienced any adverse effects related to the intervention.

4. Discussion

As far as we know, this is the first attempt to assess the effects of olive oil massage on RLS severity in patients undergoing HD. We administered 10 mL of olive oil using light pressure stroking technique twice a week to reduce uremic RLS severity. Our findings indicated that after the intervention, the RLS scores were significantly lower in the olive oil group, compared to the placebo group. According to the items of the IRLSSG Rating Scale, the intervention was more effective in occurrence of RLS symptoms during a week (item 7), but it had no significant effects on sleep disturbance (item 4) or tiredness/sleepiness (item 5).

Based on our findings, olive oil led to a greater reduction in the RLS scores, compared to the placebo. The mean score of RLS reduced by 53.14% compared to the baseline in the olive oil group, whereas it decreased by 16.31% in the placebo group. Also, severe RLS changed to moderate severity in the olive oil group from baseline to post-intervention, whereas this change was not observed in the control group.

There is limited available evidence on the effects of massage either alone or in combination with herbal oils on the severity and symptoms of RLS.[12–15] In a recent single-blind trial on patients undergoing HD, it was proposed that 10 min of simple effleurage aroma massage of legs with 10–15 mL of lavender oil (twice a week during three weeks) significantly decreased the RLS scores at the end of the trial in comparison with routine care.[12] Although the total dosage of intervention was the same as our study (60 min), a major methodological difference should be taken into consideration. We compared massage with olive oil and placebo, but in the discussed trial, massage was applied only for the intervention group, and the controls received no massage. Accordingly, it is unclear whether the observed effect was due to massage, herbal oil application, or both.

In another trial, it was reported that foot reflexology massage (three sessions a week, 30–40 min in each session, for one month; total

Table 1
Comparison of demographic and clinical characteristics of the olive oil and placebo groups.

Characteristics		Olive oil group (n = 27)	Placebo group (n = 28)	Test results	*P-value*
Age		50.55 ± 11.07	53.71 ± 11.55	t= -1.03†	0.306
BMI (kg/m^2)		27.56 ± 5.69	27.10 ± 6.28	t = 0.28†	0.778
Gender	Male	12 (44.4)	16 (57.1)	χ^2= 0.88††	0.138
	Female	15 (55.6)	12 (42.9)		
Place of residence	City	26 (96.3)	25 (92.9)	Fisher's exact	0.611
	Village	1(3.7)	3 (11.1)		
Marital status	Single	2 (7.4)	3 (10.7)	Fisher's exact	0.807
	Married	21 (77.8)	20 (71.5)		
	Widow	4 (14.8)	5 (17.8)		
Educational level	Illiterate	20 (84.1)	21 (75.0)	Fisher's exact	> 0.97
	Less than diploma	2 (7.4)	3 (10.7)		
	Diploma	4 (14.8)	4 (14.3)		
	Collegiate	1 (3.7)	0 (0.0)		
Duration of RLS (month)		12.88 ± 11.27	14.03 ± 10.48	t= -0.39†	0.698
Family history of RLS	Yes	2 (7.4)	2 (7.1)	Fisher's exact	> 0.97
	No	25 (92.6)	26 (92.9)		
Anemia	Yes	2 (7.4)	0 (0.0)	Fisher's exact	0.236
	No	25 (92.6)	28 (100.0)		
Hypertension	Yes	14 (51.3)	21 (75.0)	χ^2= 3.18††	0.074
	No	13 (48.7)	7 (25.0)		
Diabetes	Yes	10 (37.0)	13 (46.4)	χ^2= 0.98††	0.480
	No	17 (63.0)	15 (53.6)		
Hemodialysis frequency (per week)	2 times	4 (14.8)	1 (3.6)	Fisher's exact	0.325
	3 times	21 (77.8)	26 (92.8)		
	4 times	2 (7.4)	1 (3.6)		
Laboratory results	Iron (mcg/dL)	73.48 ± 27.39	64.92 ± 23.93	t = 1.23†	0.223
	Ferritin (ng/dL)	458.88 ± 208.63	506.21 ± 234.98	t= -0.78†	0.434
	Phosphorus (mg/dL)	5.63 ± 1.06	5.38 ± 1.11	t = 0.85†	0.397
	Hb (g/dL)	12.32 ± 1.37	12.41 ± 1.14	t= -0.28†	0.780
	PTH (pg/mL)	537.32 ± 309.28	523.02 ± 397.97	t = 0.14†	0.883
	Urea (mg/dL)	112.77 ± 27.65	125.00 ± 29.93	t= -1.57†	0.122

BMI: Body mass index, Hb: Hemoglobin, PTH: Parathyroid hormone, RLS: Restless leg syndrome. Data were presented as mean ± standard deviation or number (percent).
† Independent samples *t*-test.
†† Chi-square test.

intervention time: 360–480 min) significantly reduced the severity of uremic RLS, compared to the control group.[15] In a case report, it was revealed that 45 min of massage (sports massage and basic Swedish massage techniques in combination with myofascial release, trigger point therapy for deep tissues, and stretches) in the region of RLS twice a week decreased the symptoms of RLS (i.e., tingling sensation, urgency to move the legs, and sleeplessness) more effectively than the prescribed drugs; however, the symptoms recurred two weeks following the intervention.[13] The discrepancy between our results and the mentioned findings could be attributed to different massage techniques, intervention times, follow-up periods, and study designs.

In the current trial, patients who received olive oil massage experienced less severe RLS symptoms, compared to the control group. Therefore, the observed effect in our trial is likely to be related to the topical application of olive oil rather than massage; nevertheless, this effect might have been enhanced by massage. Although no mechanism of action has been described for the effect of topical olive oil on RLS, the analgesic activity of this oil[26,27,40,41]might have been effective in reducing chronic pain of RLS which is characterized by painful sensations in the legs.[39]

Recently, some trials have confirmed the analgesic effects of topical olive oil on different painful conditions.[26,27,40,41] Topical administration of 1 g of Iranian virgin olive oil on the affected knee three times a day significantly alleviated pain in patients with knee osteoarthritis at the end of the second, third, and fourth weeks of intervention, compared to the topical administration of the same amount of piroxicam gel.[26] In another trial on female athletes with anterior knee chronic pain, it was found that phonophoresis over the target knee with 10 g of Iranian virgin olive oil was associated with a significant decrease in pain at the end of the sixth session of the intervention, compared to 10 g of piroxicam gel and 10 g of base gel (placebo).[27] In patients with burning mouth syndrome, which is characterized by chronic oral mucosal pain, it was found that application of lycopene-enriched virgin olive oil in spray form on the mouth (three times a day) significantly decreased pain at the end of the intervention; nonetheless, in the placebo group, the same result was obtained.[41] Comparison of the mentioned findings and our results should be made with caution because of the application of different types of olive oil (brands, percentages, and concentrations) and differences in patients' conditions, treatments, and follow-up periods.

The present trial had some limitations. Although a multidisciplinary team consists of a nephrologist, a neurologist, and an orthopedist confirmed the RLS of patients, we used the 2003 IRLSSG criteria and also could not evaluate peripheral neuropathy as an important confounding variable due to the limited equipments in the recruitment unit. Second, we performed the intervention during HD sessions and twice a week, as we were unable to change the environment of the intervention and HD time, based on the therapeutic protocol of the recruitment unit. Third, the RLS severity might be reversed to pretreatment status within a short time; however, we could not perform a long-term follow-up and only evaluated the outcomes one week after the final massage session. Finally, no laboratory evaluations were performed to ensure the safety of olive oil.

5. Conclusion

Application of short-term massage with olive oil could reduce the uremic RLS severity without any adverse effects. We recommend future studies to assess the long-term effects of this oil either alone or in combination with massage on RLS severity and its symptoms (i.e., fatigue, exhaustion, and pain), considering the laboratory evaluations and the new diagnostic criteria for RLS.[42] Also, a longer follow-up

Table 2
Comparison of the restless legs syndrome severity between and within the olive oil and placebo groups before and after the intervention.

The IRLSSG Rating Scale*		Olive oil group (n = 27)	Placebo group (n = 28)	*P-value*†
Item 1) Discomfort of RLS in the legs	Before intervention	2.81 ± 0.83	2.75 ± 0.84	0.776
	After intervention	1.70 ± 0.86	2.28 ± 0.80	0.013¥
	P-value††	< 0.001¥	0.017¥	
Item 2) Needing to move around	Before intervention	2.66 ± 1.03	2.67 ± 0.61	0.959
	After intervention	1.37 ± 0.56	1.96 ± 0.92	0.006¥
	P-value††	< 0.001¥	0.004¥	
Item 3) Relief of symptoms by moving the legs	Before intervention	2.37 ± 0.92	2.35 ± 1.02	0.960
	After intervention	1.85 ± 0.86	2.35 ± 0.86	0.035¥
	P-value††	0.056	< 0.001¥	
Item 4) Disturbance of sleep	Before intervention	2.55 ± 1.25	2.67 ± 1.33	0.726
	After intervention	1.22 ± 0.93	1.78 ± 1.13	0.050
	P-value††	< 0.001¥	0.009¥	
Item 5) Tiredness/sleepiness	Before intervention	1.88 ± 0.93	1.85 ± 1.20	0.914
	After intervention	1.03 ± 1.05	1.35 ± 1.12	0.283
	P-value††	0.005¥	0.124	
Item 6) Severity of RLS symptoms as a whole	Before intervention	2.77 ± 0.80	2.85 ± 1.04	0.754
	After intervention	1.74 ± 0.71	2.28 ± 0.65	0.005¥
	P-value††	< 0.001¥	0.005¥	
Item 7) Occurrence of RLS symptoms during a week	Before intervention	2.55 ± 1.05	2.57 ± 1.03	0.955
	After intervention	2.33 ± 1.00	3.28 ± 0.85	< 0.001¥
	P-value††	0.282	0.001¥	
Item 8) Severity of RLS symptoms on a day	Before intervention	1.51 ± 0.97	1.64 ± 1.09	0.659
	After intervention	1.37 ± 0.68	2.07 ± 0.85	0.002¥
	P-value††	0.537	0.056	
Item 9) Disturbance of daily affairs	Before intervention	1.66 ± 0.78	2.25 ± 0.96	0.018¥
	After intervention	1.11 ± 0.89	1.78 ± 0.91	0.008¥
	P-value††	0.029¥	0.091	
Item 10) Disturbance of mood	Before intervention	1.81 ± 1.03	2.53 ± 0.88	0.008¥
	After intervention	1.03 ± 1.01	1.60 ± 0.83	0.027¥
	P-value††	0.017¥	0.001¥	
Total	Before intervention	22.62 ± 5.98	24.17 ± 6.50	0.363
	After intervention	14.77 ± 5.90	20.78 ± 5.54	< 0.001¥
	P-value††	< 0.001¥	0.019¥	

Data were presented as the mean ± standard deviation.
¥ Statistically significant at the 0.05 level.
* The International Restless Legs Syndrome Study Group (IRLSSG) Rating Scale: Each item is rated using a five-point Likert scale, ranging from zero (lack of restless legs syndrome) to four (very severe restless legs syndrome). The total scores ranged from zero to 40, with higher scores indicating the greater severity of symptoms.35.
† Independent samples *t*-test.
†† Paired sample *t*-test.

Table 3
Comparison of different categories of the severity of restless legs syndrome between and within the olive oil and placebo groups before and after the intervention.

	Severity of restless legs syndrome*	Before intervention	After intervention	Test results†	*P-value*
Olive oil group (n = 27)	Mild	1 (3.7)	5 (18.5)	Z = -2.98	0.003
	Moderate	8 (29.6)	18 (66.7)		
	Severe	17 (63.0)	3 (11.1)		
	Very severe	1 (3.7)	1 (3.7)		
Placebo group (n = 28)	Mild	1 (3.6)	2 (7.1)	Z = -0.68	0.491
	Moderate	10 (35.7)	9 (32.1)		
	Severe	14 (50.0)	16 (57.1)		
	Very severe	3 (10.7)	1 (3.6)		
Test results††		Z = -0.05	Z = -3.15		
P-value		0.955	0.002		

Data were presented as number (percent).
* Based on the total scores of the International Restless Legs Syndrome Study Group (IRLSSG) Rating Scale, the severity of restless legs syndrome was classified into mild (score, 0–10), moderate (score, 11–20), severe (score, 21–30), and very severe (score, 31–40).
† Wilcoxon test.
†† Mann-Whitney test.

period is helpful to identify the sustainability of the findings and provide more reliable data on the safety and efficacy of olive oil massage.

Ethical confirmation

The Institutional Review Board and Independent Ethics Committee of Qom University of Medical Sciences, Qom, Iran, approved this trial (No. IR.MUQ.REC.1396.97).

Trial registration

This trial was registered in the Iranian Registry of Clinical Trials (No. IRCT20130803014251N7) on December 13, 2017.

Authors' contributions

MN: Study conception and design, data collection, data interpretation, and manuscript preparation; MA: study conception and design, data collection, and critical revision of the paper; HS: clinical supervision, data collection, and critical revision of the paper; ZY: data analysis and interpretation and critical revision of the paper; FH and HY: intervention, data collection, and critical revision of the paper; MHA: study conception and design, data analysis and interpretation,

and critical revision of the paper. All the authors read and approved the final manuscript before submission.

Conflict of interest

The authors declared no conflict of interest.

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