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THE EFFECT OF VIBRATION VERSUS MASSAGE THERAPY ON RESTLESS LEG SYNDROME SEVERITY AMONG PATIENTS ON HEMODIALYSIS

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Abstract

Background: Restless legs syndrome (RLS) is a condition that causes a very strong urge to move the legs. The urge to move usually is caused by an uncomfortable feeling in the legs. It typically happens in the evening or at night when sitting or lying down. Moving eases the discomfort for a short time. It is commonly known to cause morbidity in patients on hemodialysis, making them prone to chronic mental health illnesses such as depression and anxiety, and also adversely impact their life. Non-pharmacological treatment of this syndrome involve using reflexology, cool dialysate, massage therapy and vibration therapy to alleviate this condition. **Aim:** to investigate the effect of vibration versus massage therapy on restless leg syndrome severity among patients on hemodialysis. **Design:** Quasi-experimental (pre/post) design was used. **Sample:** Purposive sample of 60 adult patients were divided randomly into vibration therapy group and massage therapy group; 30 patients /group were enrolled in the current study. **Setting:** The current study was carried out at the hemodialysis unit in one of Cairo university affiliated hospital, Egypt. **Tools:** Two tools were utilized for data collection; **Tool I:** Personal and Medical Background Information Form, **Tool II:** The International Restless Legs Syndrome Study Group Rating Scale (IRLS). **Results:** The mean age among vibration therapy group and massage therapy group were (47.3±12.7), (50.1±14.2) respectively. 60 % of both groups were females. There was a highly statistically significant difference in the total mean scores of restless leg syndrome severity scores among the pre-intervention, two weeks and four weeks after intervention phases in both vibration and massage therapy groups (P = 0.00*). **Conclusion:** There was highly statistically significant difference in the total mean scores of the restless leg syndrome severity scores between massage therapy and vibration therapy groups after four weeks of intervention so, the study concluded that, both vibration and massage therapy were effective in reducing RLS severity, while massage therapy was more effective. **Recommendation:** vibration and massage therapy should be added as a possible non- pharmacological intervention in managing restless leg syndrome.

Keywords: Hemodialysis, Restless Leg Syndrome, CAM, Vibration Therapy, Massage Therapy, Nursing Intervention.

BACKGROUND

Hemodialysis (HD) is the commonest treatment modality of kidney replacement therapy in the world, accounting for approximately 69% of all renal replacement therapy (RRT) and 89% of all dialysis (Bello et al., 2022).It is a technique that is used to accomplish the extracorporeal removal of waste substances such as urea, creatinine and free water from

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the blood when kidneys are in a state of renal replacement therapies (Ahmed, Abd Elzaher & Sabra, 2021; Marta, Mashfufa, Setyowati, Aini & Mazidah, 2023).

There are multiple complications of HD that include infection (local or systemic), cardiovascular events as (ischemic heart disease (IHD), stroke, hypotension, fluid overload, pericarditis) and respiratory complications as (pulmonary edema). Furthermore, gastrointestinal complication as (nausea, vomiting). Others such as anemia, metabolic bone disease, itching, sleep disturbance and aching are also common. HD access site complications and psychological disorders (depression, anxiety, and mood changes) can occur after starting HD. Finally neuromuscular complication as (muscle cramps, restless legs syndrome) (Habas et al., 2021). Restless legs syndrome (RLS), or (Willis-Ekbom disease), is a frequent complaint of hemodialysis patient. It is an abnormal, uncomfortable neurological sensory motor disorder that is characterized by pain, tingling, and numbness that present in the legs. These symptoms have a circadian pattern, with symptoms worsening at rest and night time (Park, Amborgi and Hade 2020). Its symptoms was first described in 1672 by Sir Thomas Willis, then Karl-Axel Ekbom described and named the disease as a modern clinical entity in the 20th century (Mahato et al. 2020; Gossard, Trotti, Videnovic & Louis, 2021; Tsai et al. 2022).

The onset of RLS is more common in young adults and is approximately twice as frequent in women as it is in men. (Elsodany & Adam, 2022; Vlasie, Trifu, Lupuleac, Kohn & Cristea, 2022). It has been reported that only about 16% of all patients with RLS receive appropriate treatment (Yuna et al., 2021), due to ignorance of RLS that resulted in non-seeking of medical help by the patients (Hosseini, Kazemi & Azimpour, 2017; Joseph et al., 2022). Restless leg syndrome is a common neurological disorder affecting up to 15% of the general population (Antelmi et al., 2022; Abdelkader, Boghdady & Elsehrawy, 2023). As a secondary condition, RLS is associated with different pathologies, with higher prevalence rates: chronic kidney disease (up to 68%), iron deficiency anemia, uremia, neuropathy, idiopathic pulmonary fibrosis, irritable bowel syndrome, inflammatory bowel disease, rheumatoid arthritis, and others (Plotogea et al., 2022).

The FDA has currently approved three dopamine agonists for treating RLS includes (pramipexole, ropinirole, rotigotine) (Mansur, Castillo, & Cabrero, 2023), in addition to, levodopa, α2δ agonists (gabapentin, pregabalin), iron supplementation and opioids are other types of pharmacotherapy (Anguelova, Vlak, Kurver,s & Rijsman, 2020; Osses-Rodríguez, Urrea-Rodríguez, & Jiménez-Genchi, 2021), however, Dopamine replacement therapies when they are taken for a long period of time (several months or more), augmentation may occur, which worsens the symptoms (Yuna et al., 2021). Moreover, pramipexole and ropinirole adverse effects, including addiction and extreme weight gain (Gao et al., 2021; Mansur, Castillo & Cabrero, 2023). Non-pharmacological treatment, also called complementary and alternative medicine (CAM) can be helpful for treating intermittent or mild symptoms of RLS, which may be the only treatment necessary. However, for patients with advanced levels of RLS, non-pharmacological measures should also be considered and recommended as complementary treatment to prescription medication. Non-pharmacological treatments that can be helpful for RLS also

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called complementary and alternative medicine (CAM), including massage, stretching, walking, cognitive distraction, warm or cold baths (Buchfuhrer et al., 2021; Fauzi & Triaswati, 2021; Hu, et al., 2020) and vibration therapy (Akbaş & Yaman Sözbir, 2021).

Vibration therapy is considered one form of CAM that can be used for the treatment of RLS. Vibration therapy has been used as a clinical intervention, in which mechanical vibration is transmitted to a part or to the whole body of the individual aiming for an improvement in the performance (Basu, Vaidya, Palekar, Baxi, & Khandare, 2019; de Sá-Caputo, Seixas, Taiar, & Bernardo-Filho, 2022; Himes, et al., 2021). Massage therapy as (effleurage) is another type of CAM that is used to relax and reduce the pain of patients and it 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 (Aljasani & Abed, 2023; Ghanbari et al., 2022). Massage therapy aims to stimulate body meridian, improve blood circulation, boost metabolism, regulate the endocrine system, improve the function of autonomic nerves, and to eliminate the symptoms of systemic or local discomfort (Han et al., 2021; Siburian & Silaban, 2023).

A nurse plays an important role in the care of a patient with restless legs syndrome for example, directing patients to make simple lifestyle changes that can be helpful in alleviating symptoms of restless legs syndrome in the form of soaking in a warm bath and massaging the legs that can relax the muscles, apply warm or cool packs, exercise and using a foot wrap or a vibrating pad. In addition to nurses often deal with a large number of patients who use CAM therapies and can be a valuable source of information about CAM treatments for patients. On the other hand, supporting nurses to use CAM is not an attempt to challenge conventional therapies but an attempt to improve the quality of patient care (Dehghan et al., 2022), so the knowledge and attitude of physicians and nurses towards these methods are very important. It is recommended that nurses and physicians should have comprehensive information on CAM so that they can warn patients about the risks and side effects of these treatments and respond to their questions (Zeighami & Soltani-Nejad, 2020).

Significance of the Study

Restless leg syndrome is a sensorimotor disorder that impacts sleep quality in sufferers, and often co-morbid with moderate to severe depressive symptoms (AlShareef, 2023), in addition, it causes poor dietary patterns, microvasculopathy, hypoxia, and dementia (Kim et al., 2023). Furthermore, it is also associated with increased cardiovascular events and mortality (Chen et al., 2022).The prevalence of RLS is ranging from 6.6% to 83% in patients with ESRD and on maintenance hemodialysis. Unfortunately, despite intensive research efforts over the last 20 years, restless leg syndrome remains a neglected diagnosis, has not received enough recognition and attention, and has undertreated rate that might reach more than 10% (Xu, Li, Zhang, Wang & Li, 2023; AlShareef, 2023).

Non-pharmacological options include physical therapy; magnetic, electrical, massage therapy, vibratory stimulation and pneumatic compression devices. These may be used as complementary treatments when pharmacological treatment fails to achieve the

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desired response in treating RLS (Osses-Rodríguez, Urrea-Rodríguez & Jiménez-Genchi, 2021). In fact, there are limited studies about using non-pharmacological methods such as massage and vibration therapies in such cases to improve symptoms and patient's quality of life without causing side effect. According to Silber & Avidan (2022), non-pharmacologic therapies may be sufficient for symptom relief in patients with mild symptoms of RLS, and in patients with more severe symptoms. Non-pharmacologic measures are worth reviewing, as they may limit medication requirements. In addition, non-pharmacological treatments have been shown to be effective for RLS and this treatment has some advantages in symptomatic RLS patients who do not respond to or do not tolerate the classic pharmacological treatments. It may bring brand new solutions to these patients. On the other hand, these methods are non-invasive, safe, and have no significant side effects (Robert, 2022). Nurses and other health-care workers should be involved in starting or participating in a variety of research projects in this field. As a result, patients can get evidence-based practice on a variety of topics (Elfaki, 2022).

Aim of the Study

This study aimed to investigate the effect of vibration versus massage therapy on restless leg syndrome severity among patients on hemodialysis.

Research Hypothesis

H_1: The pre-total mean restless leg syndrome severity scores of patients on hemodialysis who receive vibration therapy will be different than post-total mean scores*.

H_2: The pre-total mean restless leg syndrome severity scores of patients on hemodialysis who receive massage therapy will be different than their post-total mean scores*.

H_3: The post-total mean restless leg syndrome severity scores of patients on hemodialysis who receive vibration therapy will be different than the post-total mean restless leg syndrome severity scores** of patients on hemodialysis who receive massage therapy.

*Post-total mean scores; will be calculated twice, after two weeks and after four weeks

**Post-total mean scores; will be calculated

MATERIALS AND METHODS

Research Design

Quasi experimental (pre/posttest design) was utilized in this study. The quasi-experimental research design emerged because randomized experiments are not always feasible to study the things that merit inquiry. While the purpose of quasi-experimental design is to discover the effects of a cause by manipulating the cause then measuring the effects), quasi-experiments do not employ random assignment to various conditions. Instead, assignment occurs by self-selection (certain subjects choosing treatment) or administrator selection (others decide which subjects receive treatment), and essentially, quasi-experimental design does not have a true control group (Muse & Baldwin, 2021).

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Sample

A purposive sample of sixty adult male and female patients who have a confirmed diagnosis of chronic renal failure and been on regular hemodialysis for at least three months and fulfilled the inclusion criteria were recruited for this study. The selected patients were typified to meet the inclusion criteria as determined by international restless leg syndrome study group (IRLSSG) to confirm the diagnosis of RLS as having the following;

(a) An urge to move the extremities, frequently associated with paresthesias /dysesthesias;

(b) Temporary relief of the urge with movement;

(c) Onset or worsening of the symptoms at rest or inactivity; and

(d) Worsening or onset of symptoms in the evening or at night (Gossard, Trotti, Videnovic & St Louis, 2021).

This number was calculated using sample equation:

$$n=\frac{z^2*p*(1-p)/e^2}{1+\frac{z^2*p*(1-p)}{e^2*N}}$$

Patients recruited to this study according to the following inclusion criteria. (a) presented with secondary moderate RLS (a score of 11 to 20) or more, (b) fully conscious (c) have no apparent leg ulcer or wound, (d) no skin redness of the leg, (e) no history of deep venous thrombosis (DVT) or any other vascular problems, (f) no slides and screws in the leg. After that the sample was randomly assigned to vibration therapy group and massage therapy group based on the days of the week as following, Saturday, Monday, and Wednesday were assigned to vibration therapy. While, Sunday, Tuesday and Thursday were assigned to massage therapy.

Setting

The current study was carried out at the hemodialysis unit which is located in a hospital affiliated to Cairo University, Egypt. The unit is free of charge, receiving male and female patients for hemodialysis. The unit includes ten hemodialysis rooms with capacity of about 43 beds and supported by administrative offices, one nurse's room, one library and one doctor's room.

Data Collection Tools

Three tools were used to collect data at three times of assessment (pre-intervention, two weeks and four weeks after interventions) as follows:

1. **Personal and Medical Background Information Form** which was developed by the researcher based on literature review and included two sections as follows: the first section was designed to collect data specific to each patient which included: patient's age, gender, marital status, level of education …etc. The second section included

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medical data such as, duration of hemodialysis, stages of RLS and other medical comorbid diseases.

2. **The International Restless Legs Syndrome Study Group Rating Scale (IRLS),** which was adopted for using in this study. The IRLS was developed by the international restless legs syndrome study group in (2003). The scale comprised of ten questions; each question scored between 0 and 4. The content validity of the tool was verified scientifically and its reliability was established as 95% (Azimpour, Hosseini, Eftekhari & Kazemi, 2019). Generally, an IRLS score between 1 and 10 was mild, 11 to 20 was moderate, 21 to 30 was severe, and 31 to 40 was very severe RLS.

Procedure

This study was carried out through three consecutive phases: preparatory, implementation and evaluation phase.

(a) Preparatory Phase

In this phase the researcher interviewed each patient individually who met the diagnostic and inclusion criteria for the study and informed each patient with the aim and the nature of study and the previously mentioned ethical considerations. Those patients who were eligible and agreed to participate in the study were asked to sign the consent form.

Then the total samples were randomly assigned to vibration therapy group and massage therapy group based on the days of the week. Saturday, Monday, and Wednesday were assigned to the vibration therapy group and Sunday, Tuesday, and Thursday were assigned to massage therapy group. This took approximately (45 minutes).

(b) Implementation Phase

In this phase Patients who were assigned for the vibration therapy group were given vibration therapy sessions for four weeks on both legs by the researcher. Three sessions per week, and each session lasted for ten minutes, five minutes for each leg according to standardized measure mentioned by scientific researches (Azimpour, Hosseini, Eftekhari, Kazemi, 2019; Hosseini, Kazemi & Azimpour, 2017). All sessions had been held while patient is taking the hemodialysis session, which lasts for an average of 3.5 hours (Laura et al., 2019).

The other thirty eligible patients group who were assigned to massage therapy were given massage therapy sessions for four weeks on both legs by the researcher. Three sessions per week, and each session lasted for ten minutes, five minutes for each leg according to the mentioned scientific researches. (Cochrane Central Register of Controlled Trials, 2021; Doner & Tasci, 2022; Nasiri et al., 2019).

The massage type that was used by the researcher is effleurage massage which is made up of long, stroking movements that were performed using a flat hand or fingers and the strokes were applied from the bottom of the legs upwards towards the lymphatic nodes (Nasiri et al., 2019).

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(c) Evaluation Phase

This phase was done twice for all the patients in the study (firstly, two weeks after the starting of vibration or massage therapy and finally after four weeks from the starting of the vibration or massage therapy). In this phase the severity of restless leg syndrome was measured by International Restless Legs Syndrome Rating Scale (IRLS), and sleep quality was measured by Pittsburgh Sleep Quality Index (PSQI), it took about 20 minutes per each time.

Ethical Consideration

An approval of the ethical committee at Faculty of Nursing Cairo-University was obtained to conduct the study. An official permission was obtained from the Medical Director of hemodialysis unit at El-Kasr- El-Eny. Informed written consent was obtained from the patients after explaining the purpose, nature of the study and stating the possibility to withdraw at any time. To ensure confidentiality; data will not be accessed by any other party without taking permission and the study will pose no risk for the patients.

Data Analysis

A statistical Package for Social Science (SPSS) Version 20. Data were used for statistical analysis of data. Parametric inferential statistics as descriptive (mean_+SD), ttest were used to examine the differences between the study variables as well as analysis of variance to examine correlations. Probability (p-value) less than 0.05 was considered significant and less than 0.001 considered as a highly significant.

RESULTS

Table 1: Frequency and Percentage Distribution of Personal Characteristics between the Vibration Therapy Group and Massage Therapy Group (N=60)

Variable	Vibration Therapy Group (N= 30)		Massage Therapy Group (N= 30)		X^2 (p-value)
	No %		No %		
Age					1.7 0.41
20<40	5	16.7	8	26.7	
40<60	21	70.0	16	53.3	
60≤80	4	13.3	6	20.0	
Mean± SD	47.3±12.7		50.1±14.2		
Gender Male Female	 12 40.0 18 60.0		 12 40.0 18 60.0		00 1.0
Marital Status Single Married Widow Divorced Separated	 8 26.7 15 50.0 3 10.0 2 6.7 2 6.7		 4 13.3 18 60.0 5 16.7 3 10.0 0 0.0		4.3 0.36
Education Can't read and write	 11 36.7		 10 33.3		1.9 0.85

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Can read and write Primary education Preparatory education Secondary education University education	4 13.3 2 6.7 3 10.0 4 13.3 6 20.0	5 16.7 5 16.7 3 10.0 3 10.0 4 13.3	
Residence Rural Urban	 12 40.0 18 60.0	 4 13.3 26 86.7	 5.4 0.02*
Occupation work Don't work	 2 6.7 28 93.3	 4 13.3 26 86.7	 0.74 0.38

(*) statistical significant at p<0.05. (**) highly statistical significant at p<0.00.

Table (1) revealed that regarding studied patients age, 70% of vibration therapy group and 53.3% of massage therapy group their age ranged between 40 to less than 60 years with mean age (47.3±12.7), (50.1±14.2) of vibration therapy group and massage therapy group respectively.

About gender, 60 % of vibration therapy group and massage therapy group were females. In relation to marital status, 50% of vibration therapy group and 60% of massage therapy group were married. Regarding educational level, 36.7% of vibration therapy group and 33.3% of massage therapy can't read and write. As for residence 60% of vibration therapy group and 86.7% of massage therapy group came from urban areas.

Furthermore, concerning occupation, 93.3% of vibration therapy group and 86.7% of massage group were not working. There was only statistically significant difference between the two groups regarding place of residence ($X^2 = 5.4$, $p < 0.02$).

Table 2: Frequency and Percentage Distribution of Medical Background Data between Vibration Therapy Group and Massage Therapy Group (N= 60)

Variable	Vibration Therapy Group (N= 30)		Massage Therapy Group (N= 30)		X^2 (p-value)	X^2 P-(Value)
	No %		No %			
Duration of hemodialysis Less than one year More than one year	 3 27	 10.0 90.0	 0 30	 0.0 100.0	3.1 0.07	3.1 0.07
Degree of RLS Moderate Severe Very severe	6 20.0 24 80.0 0 0.0		4 13.3 24 80.0 2 6.7		2.4 0.3	2.4 0.3
Comorbid disease None Diabetes Hypertension Liver disease Heart disease Others	12 40.0 2 6.7 12 40.0 1 3.3 1 3.3 2 6.7		6 20.0 4 13.3 12 40.0 5 16.7 1 3.3 2 6.7		5.3 0.37	5.3 0.37

(*) statistical significant at p<0.05. (**) highly statistical significant at p<0.00.

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Table (2) clarified that, 90% of vibration therapy group and 100% of massage therapy group were on dialysis for more than one year. In relation to the degree of restless leg syndrome, 80% of both groups had severe degree.

Moreover, regarding other comorbid diseases, 40% of vibration therapy group as well as massage therapy group had hypertension. . There were no statistically significant differences among the two groups regarding all the demographic characteristics (p>0.05).

Table 3: Restless Leg Syndrome Severity Scores in Vibration Therapy Group Regarding Pre-Intervention, Two Weeks after Intervention and 4weeks after Intervention Phases (N=30)

Items Rating of RLS symptoms	Vibration Therapy Group (N =30)							
	Pre-intervention		2 weeks after		4 weeks after		ANOVA (p-value)	
	Mean ±	SD	Mean ±	SD	Mean ±	SD		
Discomfort in legs or arms	2.77	0.43	1.97	0.18	1.40	0.50	90.929	0.00*
Need to move around	2.77	0.43	1.97	0.18	1.43	0.50	85.800	0.00*
Relief of arm or leg discomfort from moving around	2.57	0.57	1.73	0.64	1.40	0.56	30.969	0.00*
Sleep disturbance	2.50	0.73	1.70	0.60	1.27	0.52	30.350	0.00*
Tiredness during the day	2.37	0.72	1.60	0.56	1.23	0.50	27.682	0.00*
RLS as a whole	2.77	0.43	1.90	0.31	1.37	0.49	86.678	0.00*
How often get symptoms	2.77	0.68	1.80	0.41	1.33	0.48	56.170	0.00*
Severity on average	2.57	0.57	1.83	0.53	1.43	0.50	34.629	0.00*
Effect on daily life	2.20	0.66	1.53	0.51	1.17	0.38	29.317	0.00*
Effect on mood disturbance	2.00	0.69	1.43	0.57	1.07	0.37	21.191	0.00*
Total	25.27	4.30	17.47	2.70	13.10	3.21	94.7	0.00*

(*) statistical significant at p<0.05. (**) highly statistical significant at p<0.00.

Table (3) presents that there were highly statistically significant differences among vibration therapy group in pre-intervention, two weeks after intervention and four weeks after intervention regarding, discomfort in the arm and leg, need to move around, relief of arm or leg discomfort from moving around, sleep disturbance, tiredness during the day, RLS as a whole, how often, severity on average, effect on daily life and effect on mood disturbance (P = 0.00*).

Moreover the results also devoted that there was a highly statistically significant difference in the total mean scores of restless leg syndrome severity scores among the pre-intervention, two weeks after intervention and four weeks after intervention phases (P = 0.00*).

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Table 4: Restless Leg Syndrome Severity Scores in Massage Therapy Group Regarding Pre-Intervention, Two Weeks after Intervention and 4weeks after Intervention Phases (N=30)

Items	Massage Therapy Group (N =30)							
	Pre-intervention		2 weeks after		4 weeks after		ANOVA	(p-value)
	Mean ±	SD	Mean ±	SD	Mean ±	SD		
Discomfort in legs or arms	2.90	0.66	1.77	0.50	0.97	0.56	84.836	0.00*
Need to move around	3.00	0.45	2.10	0.66	1.23	0.68	63.517	0.00*
Relief of arm or leg discomfort from moving around	2.23	0.63	1.30	0.53	1.00	0.53	39.028	0.00*
Sleep disturbance	2.77	0.68	1.70	0.47	0.93	0.52	80.364	0.00*
Tiredness during the day	2.40	0.62	1.40	0.50	0.90	0.48	60.657	0.00*
RLS as a whole	2.83	0.70	1.77	0.43	0.97	0.41	93.431	0.00*
How often get symptoms	3.00	0.87	1.77	0.43	1.30	0.47	59.809	0.00*
Severity on average	2.57	0.50	1.70	0.47	1.07	0.52	68.729	0.00*
Effect on daily life	2.10	0.84	1.30	0.70	0.73	0.45	30.112	0.00*
Effect on mood disturbance	2.13	0.68	1.33	0.55	0.80	0.41	43.644	0.00*
Total	25.93	4.10	16.13	3.12	9.90	3.63	148.1	0.00*

(*) statistical significant at p<0.05. (**) highly statistical significant at p<0.00.

Table (4) highlights that there were highly statistically significant differences among massage therapy group in the pre-intervention, two weeks after intervention and four weeks after intervention regarding, discomfort in the arm and leg, need to move around, relief of arm or leg discomfort from moving around, sleep disturbance, tiredness during the day, RLS as a whole, how often, severity on average, effect on daily life and effect on mood disturbance (P= 0.00*). additionally, the results also asserted that there was a highly statistically significant difference in the total mean scores of restless leg syndrome severity scores among the pre-intervention, two weeks after intervention and four weeks after intervention phases (P = 0.00*).

Table 5: Difference in Restless Leg Syndrome severity scores in Both Groups Regarding Pre-Intervention, Two Weeks after Intervention and 4weeks after Intervention Phases (N=60)

Phase	X^2	(P- value)
Pre-intervention	0.6	0.73
2 weeks after	0.63	0.42
4 weeks after	10.6	0.005*

(*) statistical significant at p<0.05. (**) highly statistical significant at p<0.00.

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Table (5) shows that there was a highly statistically significant difference in the total mean scores of the restless leg syndrome severity scores between massage therapy group and vibration therapy group after four weeks of intervention (X^2 = 10.6, P =0.005*).

DISCUSSION

Demographic data of the present study showed that, the majority of both vibration therapy and massage therapy groups have an age ranges between 40 years to less than 60 years with mean age and standard deviation of (47.3±12.7) and (50.1±14.2) respectively; which could clarify the homogeneity of the studied subjects. This finding is consistent with a study by Ghanbari et al. (2022) that concerned with comparing the effect of reflexology and Swedish massage on restless legs syndrome and sleep quality in patients undergoing hemodialysis, which reported that the mean age and standard deviation were (51.66 ± 5.42), (51.56 ± 5.24) and (51.56 ± 5.50) respectively.

On the other hand a study conducted by Siburian and Silaban (2023) revealed that results regarding age showed that the majority of the respondents (81.3%) in the intervention group were late elderly with an average age of 60.22 years (SD = 3.53) while for the control group the majority of respondents (81.3 %) were late adults with an average age of 57.93 years (SD=2.99)

Regarding gender, the current study findings revealed that, the highest percent of both vibration therapy and massage therapy groups (60%) were female, this finding was matched with study done by Zhang et al (2020) entitled as **"**prevalence and risk factors of restless legs syndrome in hemodialysis patients" denoted that the prevalence of RLS in males was significantly lower than that of the females (35.9%, 71/198 vs 46.8%, 73/156; p = 0.038). Syam, Desoky & Eldesoky (2022) asserted that females were more prevalent in around two thirds (66.7%) of both study groups.

Concerning marital status (50%) of the vibration therapy group and (60%) of the massage therapy group were married. This finding coincides with a study done by Syam, Desoky & Eldesoky (2022) showed that (60%) of study group and (66.7%) of control group were married.

In reference to education level, slightly more than one third (36.7%) of vibration therapy group and one third (33.3%) of massage therapy group couldn't read and write, in addition (13.3%) of vibration therapy group and (16.7%) of massage therapy group could read and write. Moreover, (10%) of both group were elementary group, which clarify that the majority of participants with low educational level. This finding agreed with a study accomplished by Togay & Akyüz, (2023) that examine the effects of socio-demographic features and disease-related data of patients with hemodialysis on the quality of life revealed that 34% of the participants were illiterate, 15.5% were literate.

According to residence more than half and more than two thirds of vibration therapy group and massage therapy group respectively were from urban areas. This finding correspond to study by Mahato et al. (2020) who studied factors associated with quality of life among

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chronic kidney disease patients in Nepal: a cross-sectional study on 440 participants stated that more than half (62.95%) of the study group were from villages.

Regarding to occupation the majority of both groups were not working, and this finding may explain the fact that the setting of the study was in governmental hospital that mostly resorted by people with low income. This result paralleled with a study done by Alshammari et al. (2023), which concluded that the majority of study group were not working. Also a study done by Mahato et al. (2020) showed that the majority (82.95%) of the study group were not working. However dissimilar study by Abdelkader, Boghdady & Elsehrawy (2023) who studied factors affecting sleep pattern disturbance for hemodialysis patients in Port Said hospitals, concluded that the highest percentage of studied patients (35.8%) still in the work

In relation to the degrees of restless leg syndrome among the patients in this study it was found that, more than two thirds of both groups had severe stage of RLS followed by (20%), (13.3%) of vibration therapy and massage therapy groups had moderate stage of RLS, this result is congruent with a study conducted by Syam, Desoky & Eldesoky (2022) found that nearly all patients were suffering from moderate and severe RLS. Another supported study conducted by Moon (2022) stated that out of 40 patients with RLS, the stages of RLS were moderate in 16 (40.0%), severe in 17 (42.5%) and only one (2.5%) was very severe RLS

As for the presence of comorbid medical condition, more than one third of patients in both groups had hypertension (HTN), this finding matched with a result tested by Moon (2022), which proved that 29 (72.5%) of participants with RLS had HTN. Meanwhile, this finding is not congruent with the result of a study entitled by “restless leg syndrome and associated factors in patients with end-stage renal disease on hemodialysis” which revealed that Diabetes Mellitus was found in 45 (47.87%) out of 94 patients of the study group (Ali, et al. 2022).

Finding related to hypothesis (1). The pre-total mean restless leg syndrome severity scores of patients on hemodialysis who receive vibration therapy will be different than post-total mean scores.

In the current study it was observed that, the pre-total mean score of restless leg syndrome severity had significantly decreased among the vibration therapy group patients after two and four weeks, of application of vibration therapy. Highly significant improvements related to all items of the international restless legs syndrome study group rating scale (IRLS) were found. This finding could be attributed to the fact that the machine vibrates and then transmits energy to the leg, forcing its muscles to contract and relax dozens of times each second, furthermore, this technique increases skin blood flow, augments muscle blood volume, enhances circulation, reduce muscle contraction, improve muscle relaxation and consequently improve the severity of restless leg syndrome.

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There are a few published studies on the use of vibration therapy to compare or contrast with the outcomes of the current study. The findings supported by Park, Ambrogi & Hade (2020) who conducted a randomized prospective pilot trial for the efficacy of the MMF07 foot massager and heat therapy for restless legs syndrome demonstrates that participants using a foot massage device for four weeks experienced improvement in RLS severity scores, the primary study outcome measure compared to those in the other groups. Another supportive study done by Hosseini, Kazemi & Azimpour (2017) that examined the effect of vibration on the severity of restless legs syndrome in hemodialysis patients concluded that vibration leads to significantly decreased severity of symptoms of RLS in hemodialysis patients.

Finding related to hypothesis (2). The pre-total mean restless leg syndrome severity scores of patients on hemodialysis who receive massage therapy will be different than their post-total mean scores.

Regarding the hypothesis (2) the current study findings illustrated that the pre-total mean score of restless leg syndrome severity had significantly decreased among the massage therapy group patients after two and four weeks of application of massage therapy. High significant improvements related to all items of the international restless legs syndrome study group rating scale (IRLS) were found. This finding could be clarify that, massage therapy has a potential of stimulating the nervous system and transferring sensory stimuli to the brain by accelerating secretion of dopamine and it is known to boost circulation, because the pressure provided during the massage helps move blood through congested areas and releasing that pressure makes new blood flow in, while also improving circulation of the lymph fluid that removes metabolic waste from muscles and internal organs (Deetz & Petrie, 2022).

In this regard, a supportive study performed by Döner & Taşcı (2022), that examine the effect of massage therapy with lavender oil on severity of restless legs syndrome and quality of life in hemodialysis patients, it showed that RLS severity significantly decreased in all follow-up weeks in the study group and recommended that, in HD patients, massage with lavender oil lessened the severity of RLS and improved the QoL. Furthermore, the finding of a study that tested the effects of foot massage on hemodialysis patients' sleep quality and restless leg syndrome: a comparison of lavender and sweet orange essential oil topical application, showed that the mean score of RLS severity in the intervention groups were significantly different compared with the control group in all three times of data collecting (Oshvandi, Mirzajani Letomi, Soltanian & Shamsizadeh, 2021).

A contrary systematic review study conducted by Gasibat, Rafieda & Aween (2024) explored the influence of therapeutic massage on muscle recovery, physiological, psychological and performance in sport revealed that, compared with the active control, five studies found no obvious advantage. Comparing massage with an inactive control, four studies reported massage to have a significant and considerable effect, whereas three studies did not. For massage compared with other therapies, three studies reported massage to have a measurable and considerable effect, whereas two studies did not. Massage as a stand-alone treatment provided a considerable and substantial benefit in

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two studies, whereas one study found no significant impact on muscle healing, performance, physiological, and psychological.

Finding related to hypothesis (3). The post-total mean restless leg syndrome severity scores of patients on hemodialysis who receive vibration therapy will be different than the post-total mean restless leg syndrome severity scores of patients on hemodialysis who receive massage therapy.

Pointing to hypothesis (3). The current study findings concluded that there was highly statistically significant difference in the total mean scores of the restless leg syndrome severity scores between massage therapy group and vibration therapy group after four weeks of intervention. The massage therapy group showed better improvement in the severity of restless leg syndrome.

The previous results matched with A study entitled “Aromatherapy massage vs. foot reflexology on the severity of restless legs syndrome in female patients undergoing hemodialysis” conducted by Ghasemi et al. (2021), proved that aromatherapy massage was shown to be more effective than reflexology on the alleviation of RLS severity in female patients undergoing hemodialysis. Another study performed by Gönenç & Terzioglu (2020) that examine the effects of massage and acupressure on relieving labor pain, reducing labor time, and increasing delivery satisfaction. The results of this study indicate that the dual application of massage and acupressure is relatively more effective than either therapy applied alone and that massage is more effective than acupressure. At the same line, Mammadov & Tas (2024) tested the effect of acupressure and massage on labor pain and birth satisfaction through a randomized controlled trial stated that, the massage application is more effective than acupressure application in reducing labor pain and increasing birth satisfaction.

On the other hand, a study of applying foot reflexology, Swedish massage, and sham therapy which include (a simple touch of the knee down to the sole of the foot without pressing the reflexology standard with the same conditions and time as the experimental groups) for four weeks showed that immediately after the foot reflexology 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 symptoms (Ghanbari et al. 2022). A study by Aljasani & Abed (2023) that compare stretching exercises and leg massage on the severity of restless legs syndrome for hemodialysis patients concluded that stretching exercises and massage were effective in decreasing the severity of restless legs syndrome, with stretching exercises being more effective.

In relation to vibration therapy a comparative study that examine the effect of percussor versus hand held vibrator in the treatment of myofascial trigger point on upper trapezius muscle which done by Basu, Vaidya, Palekar, Baxi & Khandare (2019), conclude that both percussor and hand held vibrator are effective individually in reducing the pain and increase the pain pressure threshold. But percussor is more effective than hand held vibrator in the treatment of myofascial trigger point in upper trapezius muscle. Another

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systematic review study which performed by Wang, et al. (2020), presented that after reviewing seven studies that used whole body vibration therapy on pain and functional ability in people with non-specific low back pain, the results showed that there is limited evidence suggests that whole body vibration therapy is beneficial for non-specific low back pain when compared with other forms of interventions (stability training, classic physiotherapy, routine daily activity).

As well as, Çelebi (2022), that investigated the pain relief effects of chewing gum and mechanical vibration methods on orthodontic pain caused by the initial archwire among 57 patients, proved that At all of the time points, there were no statistically significant differences among the groups in terms of pain levels.

CONCLUSION

The current study concluded that, even though; both interventions (vibration therapy and massage therapy) are considered as non-pharmacological interventions; being of low cost, easy to apply and safe to improve RLS symptoms, the massage therapy was found to be more effective in decreasing RLS severity than vibration therapy.

RECOMMENDATIONS

In the light of the current study finding, the following recommendation is suggested:

- It is suggested to apply both vibration and massage therapy for the patients with RLS in the early course of the disease, so that the patients have a maximum benefit.
- Provide audio – visual educational films for patients with RLS in hemodialysis units, which include easy, interesting and simplified information to explain how to cope with RLS symptoms.
- Presence of specialized physiotherapy room with specialized physiotherapy nurse to help such patients.
- Further studies regarding vibration therapy and massage therapy to be conducted, to evaluate their difference from other CAM methods in controlling and managing RLS.

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