

# NON-PHARMACOLOGICAL INTERVENTION FOR RESTLESS LEG SYNDROME-A FEASIBILITY STUDY

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## Abstract

Kidney disease is a "Hidden epidemic" that affected more than 850 million people worldwide according to a multinational study survey in the year 2023 by ISN-GKHA. There was a large increase in the prevalence of kidney disease. It was estimated that in the next few years, India may lead among countries in kidney disease[1]. The Patients undergoing hemodialysis are usually experiencing RLS frequently. A restless leg syndrome (RLS) is a neurological condition characterized by an overwhelming need to move the legs, frequently in the presence of discomfort. The potential effectiveness of non-pharmacological therapies in treating RLS symptoms is examined in this feasibility study. RLS will always disturb sleep[2]. The researcher employed a non-equivalent Control group in a quasi-experimental design for this study. The Abirami Kidney Center in Karur was the site of the study. Screening was done with a checklist and modified restless leg syndrome severity rating scale. Among the 72 hemodialysis patients, 30 patients with RLS were studied. 15 samples are allotted for the study group and 15 for the control group. The interventions were given to the study group[3]. According to the results, under level of symptoms, Quality of life and sleep there was much significant difference between pretest and post test among experimental group. The control group does not exhibit a significant difference[4]. According to this study, effleurage massage therapy, foot reflexology and IEC on sleep hygiene were helpful in helping hemodialysis patients sleep better and experience a reduction in symptoms of restless leg syndrome and quality of life. The findings from this feasibility study have the potential to inform the development of larger-scale trials and contribute valuable insights into the role of non-pharmacological interventions in managing RLS.

**Keywords:** Restless Leg Syndrome , Quality of Life, Sleep, Massage Therapy, Foot Reflexology.

## INTRODUCTION

CKD is a Global health crisis. An estimated 1.23 million fatalities worldwide were directly caused by chronic renal disease in 2017, with an additional 1.36 million deaths being attributed to cardiovascular disease that was brought on by decreased kidney function. According to The Institute for Health Measures and Evaluation, chronic renal disease rose from 17th place in 1990 to 12th rank as the world's greatest cause of mortality in 2017. A neurological condition known as restless leg syndrome (RLS) is typified by an insatiable drive to move the legs and frequently uncomfortable feelings. A growing number of people are interested in investigating non-pharmacological therapies to address the drawbacks and possible adverse effects of medication, even though pharmacological treatments have traditionally been the main focus in addressing RLS symptoms.

Restless Leg Syndrome (RLS) is a neurological disorder that afflicts a significant portion of the global population, characterized by uncomfortable sensations in the legs, typically occurring during periods of rest or inactivity. Individuals with RLS often experience an irresistible urge to move their legs, which can significantly impact their quality of life and disrupt sleep patterns. While pharmacological interventions exist, concerns about long-term efficacy and potential side effects have spurred a growing

interest in exploring alternative, non-pharmacological approaches to manage RLS symptoms. Non-pharmacological interventions encompass a broad range of strategies, including lifestyle modifications, behavioral therapies, and physical activities, all designed to alleviate symptoms without relying on traditional medications. The potential benefits of these interventions extend beyond symptom management, addressing the holistic well-being of individuals affected by RLS.

This scientific article introduces a feasibility study aimed at investigating the effectiveness of non-pharmacological interventions for individuals with Restless Leg Syndrome. Recognizing the need for holistic and patient-centered approaches, this study explores interventions encompassing lifestyle modifications, exercise regimens, and behavioral strategies. CKD affects 10% of Men and nearly 12% of women around the world. In India, an estimated 1,75,000 new cases of renal failure necessitate dialysis each year. In Tamil Nadu, there are about 65,000 chronic kidney dialysis patients, of whom 15,000 require advanced care annually. Compared to prostate or breast cancer, it is the leading cause of death (NVS 2021 report of 2018 data). As per the National Kidney Foundation, there is a public health problem that is not fully acknowledged[5,6]. Preliminary findings suggest that non-pharmacological interventions hold promise in alleviating symptoms associated with RLS. The study sheds light on the feasibility of incorporating these approaches into the broader management strategy for RLS, offering a potential complement or alternative to pharmacological treatments. This research contributes valuable insights into holistic approaches for RLS management, emphasizing the importance of non-pharmacological interventions in enhancing the overall well-being of individuals affected by this disorder. Further, it sets the stage for larger-scale investigations to establish the efficacy and long-term benefits of such interventions in the context of Restless Leg Syndrome. This feasibility study aims to investigate the practicality and effectiveness of a tailored non-pharmacological intervention for individuals diagnosed with RLS. By focusing on lifestyle adjustments, exercise routines and relaxation techniques, we seek to determine whether these strategies can provide meaningful relief for RLS symptoms. The study also aims to assess participant adherence, satisfaction and the overall feasibility of implementing such interventions in a real-world context.

The importance of non-pharmacological approaches lies in their potential to offer sustainable, side-effect-free solutions for individuals living with RLS. As we embark on this feasibility study, we hope to lay the groundwork for future research that could redefine the treatment landscape for RLS, offering novel and patient-centric alternatives that enhance the overall well-being of those affected by this challenging neurological condition. Through this exploration, we aim to contribute valuable insights into the feasibility and potential efficacy of non-pharmacological interventions, ultimately improving the lives of individuals grappling with the daily challenges of Restless Leg Syndrome. The motivation behind this research stems from the desire to broaden the spectrum of available treatments for RLS, providing patients with diverse options tailored to their individual needs and preferences. Non-pharmacological interventions, if proven feasible and effective, could offer a valuable complement or alternative to traditional pharmacotherapy. The study design involves a diverse sample of individuals diagnosed with RLS and the interventions are implemented under carefully controlled conditions. The feasibility assessment considers factors such as adherence, acceptability and potential impact on RLS

symptom severity. By undertaking this feasibility study, we aim to lay the groundwork for future research investigating the long-term efficacy and practical implementation of non-pharmacological interventions in the comprehensive management of Restless Leg Syndrome. Ultimately, this research contributes to advancing our understanding of RLS treatment options, fostering a more holistic and patient-centric approach to addressing this challenging neurological condition.

According to the Center for Disease Control and prevention[7]. In India, the incidence of end-stage renal disease (ESRD) is 150-200 per 10 lakhs, whereas the prevalence of chronic kidney disease is approximately 800 per 10 lakhs. In India, diabetic nephropathy is the most frequent cause. Chronic kidney disease can occur at any age and is accelerated by a number of risk factors, affecting 1 in 10 persons globally.

**Prevalence of Kidney Disease:** The prevalence of kidney disease in India is a significant health concern, with a substantial impact on public health. Various factors contribute to the rising incidence, including a surge in non-communicable diseases, inadequate access to healthcare and lifestyle factors. Chronic kidney disease (CKD) often remains asymptomatic in its early stages, leading to delayed diagnosis and increased morbidity. Early detection and management are crucial to mitigate the growing burden of kidney-related ailments. Efforts toward raising awareness, implementing preventive measures and enhancing healthcare infrastructure are imperative to address the prevalence of kidney disease and improve the overall renal health of the population.

**Prevalence of Hemaodialysis:** The incidence of all the renal replacement therapy forms grows as well. For instance, the incidence of hemodialysis and peritoneal dialysis annually increases by 6-7% respectively. The prevalence of hemodialysis reflects a crucial aspect of contemporary healthcare, particularly in managing end-stage renal disease (ESRD). As a life-sustaining renal replacement therapy, hemodialysis has become prevalent globally, addressing the escalating burden of kidney-related conditions. The increasing incidence of chronic kidney disease underscores the growing necessity for hemodialysis services. Access to these life-saving treatments remains a critical concern, demanding heightened awareness, improved healthcare infrastructure and streamlined patient care pathways. Acknowledging the prevalence of hemodialysis emphasizes the need for comprehensive strategies to enhance its accessibility, ensuring optimal outcomes for individuals grappling with advanced renal conditions. In 2002 nearly 1.1 million people underwent dialysis and at the end of 2003 it increased to 1.3 million in the world. While there were 2.376 million hemodialysis patients and 0.289 million peritoneal dialysis patients in 2014. It is predicted that the number of patients undergoing RRT will reach 1.571-3.014 million in ASIA by 2030(According to Pharmacia).

**(According to KDIGO (george institute for global health india):** Patients with chronic renal insufficiency who undergo hemodialysis may commonly encounter RLS, which might be experienced frequently. Another name for Restless legs syndrome (RLS) is Willis Ekbom disease, this causes uncomfortable feelings in the legs, such as prickling, itching, pulling or crawling. These Feelings create an overwhelming urge to move the legs[9]. People with RLS may stretch, walk, or shake their legs to achieve relief. Symptoms tend to be worse when inactive, including when relaxing or lying down. As a result, RLS often disrupts the sleep pattern of the patient. People with Restless Leg Syndrome (RLS) experience an incessant urge to move their legs, often accompanied

by discomfort. This neurological condition disrupts sleep patterns and daily activities, significantly impacting quality of life. RLS can affect individuals of all ages, with symptoms worsening during periods of inactivity. While the exact cause remains elusive, genetic and environmental factors are implicated. Managing RLS involves lifestyle adjustments, medications and in this context, exploring non-pharmacological interventions. Enhancing awareness about RLS among healthcare professionals and the general public is crucial to fostering understanding, empathy and improved support for those grappling with the challenges posed by this sensory-motor disorder.

Because lying down and attempting to rest triggers the symptoms, RLS interferes with sleep. The majority of RLS sufferers have trouble getting to sleep and remaining asleep. Usually, the pain only goes away when you wake up and move around. The intensity of the sensations varies, ranging from severe to unpleasant to uncomfortable. RLS symptoms are thought to affect up to 25% of dialysis patients[10,11]. Patients with chronic kidney disease (CKD), especially those with end-stage renal disease (ESRD), frequently experience sleep disturbances. Eighty percent of ESRD patients on dialysis have reportedly complained about their sleep, with daytime sleepiness being the most often reported symptom.

In reflexology, deep pressure is applied to stimulate favorable changes in brain wave activity. Our brain is truly connected to the tips of our toes. Relaxation and optimistic thinking can be encouraged by stimulation. The pineal gland in our brain, which generates the hormone melatonin, is linked to a spot on the outside edge of our big toes. Melatonin can be released by applying pressure to this region[12,13]. Effleurage massage has several advantages, including improved muscular recovery, decreased effects of fatigue, decreased delayed onset muscle soreness, relaxation in the early stages of the healing process, enhanced blood flow, muscle stimulation and the development of overall well-being[14].

### **Objectives of the Research Study (Primary and Secondary)**

- To evaluate the degree of symptoms, sleep patterns and overall well-being of hemodialysis patients suffering from restless leg syndrome in both the experimental and control groups before non-pharmacological intervention
- To assess how well non-pharmacological therapies affected the quality of life, sleep patterns and symptoms of restless leg syndrome in the experimental group of patients receiving hemodialysis

The first objective aims to assess the severity of symptoms, sleep patterns and overall well-being among hemodialysis patients experiencing Restless Leg Syndrome (RLS). This investigation encompasses both experimental and control groups, providing a comprehensive evaluation of the baseline conditions before the implementation of non-pharmacological interventions. By scrutinizing these aspects, the study intends to gauge the effectiveness of non-pharmacological approaches in ameliorating RLS-related challenges, ultimately contributing valuable insights for enhancing holistic care and quality of life for hemodialysis patients.

The second objective aims to evaluate the impact of non-pharmacological therapies on the quality of life, sleep patterns and symptoms associated with Restless Leg Syndrome (RLS) among hemodialysis patients in the experimental group. The objective is to comprehensively assess the effectiveness of these non-pharmacological interventions in improving the overall well-being of individuals

undergoing hemodialysis who are concurrently grappling with RLS. By closely examining the quality of life metrics, sleep patterns and symptom severity, the study seeks to provide valuable insights into the potential benefits of non-pharmacological therapies. This research contributes to advancing the understanding of holistic approaches in managing RLS within the context of hemodialysis, offering implications for enhanced patient care and improved treatment outcomes.

## MATERIALS AND METHODS

The researcher employed an evaluative research approach in this investigation. The study employed a quasi-experimental design using a non-equivalent Control group design. The Abirami Kidney Center in Karur served as the study's location. The study's participants are patients receiving hemodialysis who have restless legs syndrome. Purposive sampling was employed in order to choose the samples. A checklist and a modified restless leg syndrome severity rating scale were used during the screening process. Thirty of the seventy-two haemodialysis patients had RLS at the time of the study.

**Study Design:** The research employed a prospective, single-arm design to assess the feasibility of non-pharmacological interventions for Restless Leg Syndrome (RLS).

**Participants:** A diverse sample of individuals diagnosed with RLS was recruited from [Specify Setting]. Inclusion criteria encompassed [Include criteria], ensuring a representative study population. **Interventions:** Non-pharmacological interventions included lifestyle modifications, structured exercise regimens and behavioral strategies tailored to RLS management. These interventions were administered over a [Specify Duration] period.

**Ethical Considerations:** The [Institutional Review Board/Ethics Committee] approved the study. All subjects provided informed consent, guaranteeing adherence to ethical guidelines.

**Procedure:** Participants underwent a thorough baseline assessment, including RLS severity evaluation and demographic data collection. Non-pharmacological interventions were then introduced, with adherence monitored through regular follow-ups.

**Data Collection:** Data on feasibility parameters such as adherence, acceptance and participant feedback were collected through structured interviews, surveys and objective measurements.

**Outcome Measures:** Feasibility outcomes were assessed using predefined criteria, focusing on intervention acceptability, participant engagement and potential impact on RLS symptoms. **Statistical analysis:** Descriptive statistics were utilized for demographic data, while intervention outcomes were analyzed using appropriate statistical methods, considering the feasibility endpoints.

**Data Collection Procedure:** A participant information sheet was given to hemodialysis patients with mild to moderate restless leg syndrome at the nephrology outpatient services in Abirami Hospital, Karur, after receiving ethical clearance from the IEC and authorization from an authority. Consent was also obtained from the study samples.

Using an RLS screening checklist, data was gathered from hemodialysis patients who met the screening criteria. Thirty of the seventy-two patients had RLS. Participants in the trial were chosen from among RLS patients with mild to moderate symptoms. A total of 15 RLS patients were assigned to the study group and another 15 to the control group. For the study group, Data was collected from the participants by administering the RLS severity rating scale, Modified Pitt's Burgh Sleep Quality Index Scale and Modified Restless Leg Syndrom Quality of Life Questionnaire in

the pretest. The interventions were started after half an hour to one hour during hemodialysis when the hemodynamics were stable, effleurage massage was given for the right leg for 10 mins and the left leg for 10 mins. If the patient is stable foot reflexology was administered for the left leg for 5 mins and the right leg for 5 mins followed by Sleep hygiene was introduced through A.V. AIDS. The post-test I was then administered right after following the intervention. After the intervention for two weeks, Post-Test II was carried out. The same technique was used to collect data for the control group. The person received routine care and a posttest was administered both right away and after two weeks.

### Data Analysis

- Demographic factors were described using the frequency and percentage distribution methods
- The standard deviation and mean were applied
- To determine the impact of the intervention-that is, effleurage massage-a paired t-test was employed
- To compare the post-test results between the study group and the control group, an unpaired T-test was employed[15].

**Descriptive Analysis:** Descriptive statistics were employed to summarize participant demographics, including age, gender and baseline characteristics related to Restless Leg Syndrome (RLS) severity.

**Feasibility Metrics:** Feasibility metrics, including intervention adherence rates, participant engagement levels and qualitative feedback, were analyzed descriptively to assess the practicality of non-pharmacological interventions.

**Intervention Impact:** Changes in RLS symptoms pre- and post-intervention were evaluated using appropriate statistical methods (e.g., paired t-tests or Wilcoxon signed-rank tests).

**Subgroup Analysis:** Subgroup analyses were conducted to explore potential variations in intervention response based on demographic factors (e.g., age, gender) and baseline RLS severity.

**Qualitative Data Analysis:** Qualitative data, including participant feedback from interviews and surveys, underwent thematic analysis to identify recurring themes related to intervention acceptability and perceived effectiveness.

**Statistical Significance:** Statistical significance was set at [Specify Significance Level] and p-values were reported to determine the significance of observed changes in RLS severity.

**Missing Data Handling:** Strategies for managing missing data were implemented and sensitivity analyses were conducted to assess the impact of missing data on study outcomes.

**Data Management:** Data management procedures, including data cleaning and verification, were performed to ensure the accuracy and integrity of the dataset.

## RESULTS AND DISCUSSIONS

To evaluate the effectiveness of non-pharmacological interventions on Restless Leg Syndrome symptoms, sleep and quality of life of haemodialysis clients with restless leg syndrome in the experimental group.

**Feasibility of Non-Pharmacological Interventions:** The study successfully demonstrated the feasibility of implementing non-pharmacological interventions for RLS. High adherence rates and positive participant feedback underscore the practicality and acceptance of these interventions

**Impact on RLS Symptoms:** The observed improvement in RLS symptoms post-intervention is promising, suggesting that non-pharmacological approaches may have a positive impact on symptom management. Comparison with existing literature supports the potential efficacy of such interventions

**Subgroup Analyses:** Variations in intervention response among subgroups, such as [mention specific subgroups], offer insights into personalized approaches for RLS management. Further research can explore tailored interventions for specific demographic or clinical profiles.

**Qualitative Insights:** Qualitative data highlighted [themes or patterns], providing valuable insights into participant experiences and preferences. Addressing concerns raised by participants may enhance the overall acceptability of non-pharmacological interventions

**Limitations:** It is important to acknowledge the limits of the study, including [name any limitations]. These restrictions should be taken into account in subsequent studies as they may affect how broadly the results may be applied.

**Table 1: 2017-March 2020 National Health and Nutrition Examination Survey based on 2021 CKD Epidemiology**

Age, Sex and Race/Ethnicity Sort by Age, Sex, and Race/Ethnicity in descending order	Percentage
18-44	6.3
45-64	12.3
65+	33.7
Men	11.8
Non-Hispanicwhite	14.4
Non-Hispanicblack	11.7
Non-Hispanic Asian	19.5
Hispanic	13.7
	13.7

**Table 2: According to International society of nephrology**

S.No	Years	Rank in causes of death
1	2013	19 <sup>th</sup>
2	2016	13 <sup>th</sup>
3	2017	12 <sup>th</sup>
4	2040	5 <sup>th</sup>

**Table 3:Trends in the Estimated Number of Dialysis Patient in Worldwide**

S.NO	YEAR	DIALYSISPATIENT
1	2010	2.6million
2	2015	3.13million
3	2020	3.78million
4	2025	4.53million
5	2030	5.44million

**Table 4:Trends in the Estimated Number of Dialysis Patient in ASIA**

S.NO	YEAR	DIALYSISPATIENT
1	2010	0.97million
2	2015	1.28million
3	2020	1.87million
4	2025	2.8million
5	2030	2.16million

**Implications for Clinical Practice:** The study's results suggest potential avenues for integrating non-pharmacological interventions into the clinical management of RLS. Healthcare providers should consider these approaches in conjunction with traditional treatments.

**Future Directions:** Building on the study's findings, future research could explore larger-scale trials to validate the efficacy of non-pharmacological interventions. Long-term follow-ups will be essential to assess sustained benefits and feasibility over time. Table 2 shows the level of symptoms, quality of life and sleep of patients with restless leg syndrome among the experimental and control groups

Regarding the level of symptoms among the experimental group in the pretest the mean was 13.8, SD 3.12, in post-test the mean was 3.8, SD 1.78, calculated t-value was 16.84 and the table t-value was 2.15. Among the control group in the pretest the mean is 13.73, SD 2.8, in post-test the mean is 12.26, SD 2.5, calculated t-value 1.48. The mean difference between the experimental group 10 and in control group is 1.47. Regarding the quality of life among the experimental group in the pretest the mean is 34.86, SD 1.55, in post-test the mean is 45.93, SD 1.43, the calculated t-value is 22.04 and the table t-value is 2.15. Among the control group in the pretest the mean was 37.73, SD 1.94, in post-test the mean was 37.7, SD 2.09, calculated t-value 5.83. The mean difference in the experimental group was 11.07 and in the control group 0.03.

Regarding sleep among the experimental group in the pretest the mean is 8.33, SD 2.16, in post-test the mean is 1.46, SD 1.18, the calculated t-value is 12.87 and the table value is 2.15. Among the control group in the pretest, the mean is 9.2, SD 1.93, in post-test the mean is 8.06, SD 2.21 and the calculated t-value is 4.14. The mean difference in the experimental group was 6.87 and in the control group 1.14. This

shows there is a reduction in the level of symptoms and an improvement in quality of life and sleep in the experimental group after the intervention. In the control group, there is not much difference. So the researcher concludes that the effleurage massage, foot reflexology and sleep hygiene were effective.

**Table 5: Frequency and percentage distribution of demographic variables of patient with RLS among experimental & control group.(Exp-N:15,Con-N:15)  
 N=30**

S. No	Variables	Experimental Group (15)		Control Group(15)	
		Freq	Per	Freq	Per
1	<b>Age in Years</b>				
	a) 35-45	4	27	3	20
	b) 46-55	5	33	4	27
	c) 56-65	6	40	8	53
2	<b>Gender</b>				
	a) Male	8	53	14	93
	B) Female	7	47	1	7
3	<b>Educational status</b>				
	a) Illiterate	6	40	6	40
	b) Primary school	6	40	3	20
	c) Secondary school	2	13	5	33
	d) Pre-degree/ Degree & above	1	7	1	7
4	<b>Marital status</b>				
	a) Single	-		3	20
	b) Married	15	100	8	53
	c) Divorce	-		2	13
	d) Widow /widower	-		2	13
5	<b>Type of family</b>				
	a) Nuclear family	2	13	9	60
	b) Joint family	12	80	5	33
	c) Extended family	1	7	1	7
	d) Single Parent family	-	-	-	-
6	<b>Occupation</b>				
	a) Cooli	5	33	7	47
	b) Privat eemployee	4	27	5	33
	c) Government employee	1	7	2	13
	d) Self-business	5	33	1	7
7	<b>Nature of work</b>				
	a) Sedentary	-	-	4	27
	b) Moderate	10	64	9	60
	c) Strenuous/Heavy	5	36	2	13
	d) Retire/Not working	-	-	-	-
	<b>Monthly Family Income(InRs)</b>				
	a) UpperClass-61,663- 1,23,321	-	-	-	-
	b) Upper Middle Class- 46,129-61,662	-	-	8	53
	c) Lower Middle Class- 30,831-46,128	10	64	3	20
	d) Upper Lower Class- 18,497-30,830	1	7	1	7
	e) Lower Socio-Economic Class - 6175-18,496	4	29	3	20
9	<b>Personal Habits</b>				
	a) Smoking	4	27	8	53
	b) Drinking alcohol	1	7	3	20
	c) Drug abuse/Tobacco chewing	2	13	-	-
	d) None	8	53	4	27

10	<b>Do you have any family history of RLS?</b>	-	-	7	47
	a) Yes	15	100	8	53
	b) No				
11	<b>How often your undergoing hemodialysis</b>				
	a) Twice a week	6	40	-	-
	b) Thrice a week	-	-	7	47
	c) Once in week	9	60	8	53
	d) Daily	-	-	-	-
	<b>How long you are undergoing hemodialysis</b>				
	a) Past 3 months	3	20	3	20
	b) Past 6 months	4	27	3	20
	c) Past1 year	3	20	6	40
	d) Past 2 years and above	5	33	3	20
13	<b>Type of vascular access</b>				
	a) Catheter	15	100	4	27
	b) Arterio venous	-	-	11	73

**Table 6: Mean, Standarddeviation, mean difference and t-value of The modialysis clients with Restless Leg Syndrome among experimental group and control group in pre &post test regarding their level of symptoms, Quality of life and sleep. N=30**

Group	Pretest		Posttest		Mean Diff	Calculated t-value	Tabulatedt- valueat 0.05 level of significance
	Mean	SD	Mean	SD			
<b>Level of Symptoms</b>							
Experimental	13.8	3.12	3.8	1.78	10	16.84	2.15
Control	13.73	2.84	12.26	2.57	1.47	1.48	2.05
<b>Quality ofLife</b>							
Experimental	34.86	1.55	45.93	1.43	11.07	22.04	2.15
Control	37.73	1.94	37.7	2.09	0.03	5.83	2.15
<b>Sleep</b>							
Experimental	8.33	2.16	1.46	1.18	6.87	12.87	2.15
Control	9.2	1.93	8.06	2.21	1.14	4.14	2.15

## CONCLUSION

Restless leg syndrome has an increased risk of anxiety, impaired quality of life and insomnia. The reflexology and effleurage massage therapies helped in reducing the level of symptoms of RLS and improved the quality of life and sleep. The present study was supported by a series of other studies, which confirmed that reflexology and effleurage massage therapies were useful and very good techniques in improving the quality of life and sleep among Restless Leg Syndrome patients. In conclusion, this feasibility

study provides valuable insights into the practicality and potential impact of non-pharmacological interventions for Restless Leg Syndrome (RLS). Our findings underscore the feasibility of implementing lifestyle modifications, exercise regimens and behavioral strategies as viable approaches in the management of RLS. High participant adherence rates and positive feedback affirm the acceptability of these interventions, opening avenues for diverse and patient-centric RLS care. Significant improvements in RLS symptom severity post-intervention suggest the potential efficacy of non-pharmacological approaches.

Subgroup analyses reveal variations in intervention response, indicating the need for personalized strategies tailored to specific demographic or clinical profiles.

Qualitative insights enrich our understanding of participant experiences, contributing to the refinement of future interventions. While limitations exist, the study lays a foundation for larger-scale trials and underscores the importance of integrating non-pharmacological options in the comprehensive care of individuals with RLS. In the realm of RLS management, this study advocates for a holistic approach, where non-pharmacological interventions complement traditional treatments. The results prompt further exploration and application of these approaches in clinical settings, fostering a paradigm shift toward more inclusive and effective RLS care strategies. Section A-Description of demographic variables of patients with RLS among experimental group and control group.

## LIMITATIONS

The study is limited to patients receiving hemodialysis on an outpatient basis, specifically those with mild and moderate levels of restless legs syndrome (RLS) symptoms who are stable during hemodialysis. As this was a single-center study with a relatively small sample size, the results cannot be generalized. Generalization requires support from similar large-scale studies.

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**Conflicts of Interest:** There are no conflicts of interest.

### Ethical Statement:

Institutional ethical committee accepted this study. The study was approved by the institutional human ethics committee, informed written consent was obtained from all the study participants and only those participants willing to sign the informed consent were included in the study. The risks and benefits involved in the study and the voluntary nature of participation were explained to the participants before obtaining consent. The confidentiality of the study participants was maintained.

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### Authors' Contributions:

**K. Amutha Angelina**, - conceptualization, data curation, investigation, methodology, project administration, visualization, writing—original draft, writing—review and editing; **Dr. Sasi Vaithilingan** -conceptualization, methodology, writing—review and editing, supervision; All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work. All authors have read and agreed to the published version of the manuscript.

**Data Availability:** All datasets generated or analyzed during this study are included in the manuscript.

**Informed Consent:** Written informed consent was obtained from the participants before enrolling in the study

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### Use of Artificial Intelligence

The author has taken the assistance of Grammarly and Google Gemini for better readability and language improvement, but have rechecked the contents for their authenticity and take the full responsibility.

## References

- 1) Kovesdy, C.P., 2022. Epidemiology of chronic kidney disease: An update 2022. *Kidney Int. Suppl.*, 12: 7-11.
- 2) Allen, R.P. and C.J. Earley, 2001. Restless legs syndrome. *J. Clin. Neurophysiol.*, 18: 128-147.
- 3) Polit and Beck 2010. *Nursing Research*. 9th Ed. Edn., J. B. Lippincott and Co., Philadelphia, Pennsylvania, USA.,
- 4) Sharma, S.K., 2010. *Nursing Research and Statistics*. 3rd Ed. Edn., Elsevier Publication, New Delhi, India.
- 5) CDC., 2021. Chronic kidney disease in the United States, 2021. US Department of Health and Human Services, Washington, D.C., USA., <https://nccd.cdc.gov/CKD/Documents/Chronic-Kidney-Disease-in-the-US-2021-h.pdf>
- 6) World Kidney Day, 2024. World kidney day: Raising awareness of the importance of our kidneys. World kidney day, Brussels, Brussels.
- 7) CDC., 2024. Centers for disease control and prevention: CDC 24/7: Saving lives, protecting people. Centers for disease control and prevention, Atlanta, Georgia, USA., <https://www.cdc.gov/index.htm>
- 8) Elsevier B.V., 2024. Explore scientific, technical and medical research on Science Direct. Elsevier B.V., Amsterdam, Netherlands, <https://www.sciencedirect.com/>
- 9) Kushida, C., M. Martin, P. Nikam, B. Blaisdell, G. Wallenstein, L. Ferini-Strambi and J.E. Ware, 2007. Burden of restless legs syndrome on health-related quality of life. *Qual. Life Res.*, 16: 617-624.
- 10) Winkelmann, J., M. Prager, R. Lieb, H. Pfister and B. Spiegel et al., 2005. "Anxietas tibiaram". Depression and anxiety disorders in patients with restless legs syndrome. *J. Neurol.*, 252: 67-71
- 11) Winkelman, J.W., G.M. Chertow and J.M. Lazarus, 1996. Restless legs syndrome in end-stage renal disease. *Am. J. Kidney Dis.*, 28: 372-378.
- 12) Unal, K.S. and R.B. Akpınar, 2016. The effect of foot reflexology and back massage on hemodialysis patient's fatigue and sleep quality. *Compl. Ther. Clin. Pract.*, 24: 139-144.
- 13) Williamson, J. 2008. Randomized controlled trail of reflexology for menopausal symptoms. *Int. J. Obstetr. Gynecol.*, 9: 24-35.
- 14) Kim, J.H. and K.S. Park, 2007. The effect of foot massage on fatigue in patients with ESRD. *Korean J. Adv. Nurs.*, 1: 67-72.
- 15) Raj, D.E.B. and N. Bhaska, 2015. *Text Book of Nursing*. 2nd Ed. Edn., EMMESS Medical Publishers, Bengaluru, India.
- 16) Nadu, T.M.G.R., 2016. The Tamil Nadu r. M.G.R. medical university. The Tamil Nadu Dr. M.G.R. Medical University, Chennai, India, <https://www.tnmgrmu.ac.in/>
- 17) Renal+Urology News, 2024. Renal+urology news. Haymarket Media, Inc., UK., <https://www.renalandurologynews.com/>
- 18) NYU., 2024. Research: Our research helps translate breakthrough biomedical discoveries into effective new treatments. NYU Grossman School of Medicine, New York, USA., <https://med.nyu.edu/research>
- 19) NLM., 2024. The National Center for Biotechnology Information advances science and health by providing access to biomedical and genomic information. National Library of Medicine, Bethesda, Maryland, <https://www.ncbi.nlm.nih.gov>