



# Effects of Alternative Therapies on Pain, Anxiety, Quality of Sleep, Activities of Daily Livings (ADLS) And Quality of Life in Patients with Restless Legs Syndrome (RLS): A Randomized Controlled Trial

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## KEYWORDS

Alternative Therapies, Patients with Restless

## ABSTRACT:

Restless legs syndrome (RLS), also referred to as a Willis-Ekbom disease (WED), is a neurological illness that equally affects women and men<sup>1</sup>. RLS is a set of sensory and motor symptoms that are triggered by rest (e.g. lying down or sitting), either when one is trying to go to sleep or during periods of peaceful wakefulness. The symptoms worsen in the evening and early hours of the night during the day or night cycle. RLS is still diagnosed clinically using subjective complaints. Thus, the subsequent four symptoms were created and determined as minimum criteria for RLS diagnosis by the IRLSSG<sup>2,3</sup>. In the general community, RLS affects 5% to 15% of people, yet it is commonly misdiagnosed and untreated. It is more common in women and rises with age. RLS may be primary (idiopathic) or secondary, and it may be linked to illnesses including end-stage renal disease, pregnancy, or iron-deficiency anemia<sup>1,4</sup>. Sleep initiation and maintenance were found to be severely impacted by unpleasant sensations in individuals with RLS<sup>5</sup>. Sleep disturbance is caused by PLMS, which can be found in eighty to ninety percent of RLS patients. A series of flexion movement at the ankle, knee, and hip is distinguished of PLMS (PLMS, periodic leg movements of Sleep) which are repetitive leg jerks. They happen while sleeping, especially in the first and second NREM phases, as well as while relaxing awake (PLMW, periodic leg movements during awake). PLMS has been related with cortical arousal and awaking, insomnia, and excessive drowsiness during day<sup>6</sup>. The prolonged recurrence of these symptoms severely reduced the sleep quality of people with RLS, perhaps leading to the onset of anxiety and depression<sup>7</sup>. Improper sleep cycles among RLS sufferers could affect their health, productivity, and social activities<sup>5</sup>. However irregular sleep patterns and sensory issues during the day may have an impact on ADLs, QoL and even cause cognitive impairment. RLS has been responsible for daytime exhaustion, excessive sleepiness, increased physical and mental health issues, and symptoms of anxiety and sadness<sup>6</sup>.

## INTRODUCTION

Restless legs syndrome (RLS), also referred to as a Willis-Ekbom disease (WED), is a neurological illness that equally affects women and men<sup>1</sup>. RLS is a set of sensory and motor symptoms that are triggered by rest (e.g. lying down or sitting), either when one is trying to go to sleep or during periods of peaceful wakefulness. The symptoms worsen in the evening and early hours of the night during the day or night cycle. RLS is still diagnosed clinically using subjective complaints. Thus, the subsequent four symptoms were created and

determined as minimum criteria for RLS diagnosis by the IRLSSG<sup>2,3</sup>. In the general community, RLS affects 5% to 15% of people, yet it is commonly misdiagnosed and untreated. It is more common in women and rises with age. RLS may be primary (idiopathic) or secondary, and it may be linked to illnesses including end-stage renal disease, pregnancy, or iron-deficiency anemia<sup>1,4</sup>. Sleep initiation and maintenance were found to be severely impacted by unpleasant sensations in individuals with RLS<sup>5</sup>. Sleep disturbance is caused by PLMS, which can be found in eighty to ninety percent of RLS patients. A



series of flexion movement at the ankle, knee, and hip is distinguished of PLMS (PLMS, periodic leg movements of Sleep) which are repetitive leg jerks. They happen while sleeping, especially in the first and second NREM phases, as well as while relaxing awake (PLMW, periodic leg movements during awake). PLMS has been related with cortical arousal and awaking, insomnia, and excessive drowsiness during day<sup>6</sup>. The prolonged recurrence of these symptoms severely reduced the sleep quality of people with RLS, perhaps leading to the onset of anxiety and depression<sup>7</sup>. Improper sleep cycles among RLS sufferers could affect their health, productivity, and social activities<sup>5</sup>. However irregular sleep patterns and sensory issues during the day may have an impact on ADLs, QoL and even cause cognitive impairment. RLS has been responsible for daytime exhaustion, excessive sleepiness, increased physical and mental health issues, and symptoms of anxiety and sadness<sup>6</sup>.

Both pharmaceutical and non-pharmaceutical treatments are used to treat this illness. Dopaminergic therapy which includes levodopa or dopamine receptor agonists like pramipexol ropinirole pergolide or cabergoline is the suggested course of treatment for RLS in the general population. The usefulness of these drugs in treating patients with renal failure and the common adverse effects of levodopa however are poorly understood. It is therefore urgently necessary to implement a non-pharmacological alternative treatment<sup>8,9</sup>.

This study had offer a more comprehensive view of therapy strategies for managing the clinical signs of RLS. The International Restless Legs Syndrome Study Group states that in order to identify therapeutic approaches and serve as an indicator of pathologic processes in RLS, neurological and muscle aspects are objectively monitored and evaluated. The primary objective was to investigate the effects of physiotherapy (Relax Revive Technique) with affirmation, yoga (Utkatasana) with affirmation, and their combination approach to controlling conditions on pain, anxiety and sleep quality. The secondary objectives were effects of above approaches to control ADLs and quality of life.

## MATERIALS & METHODS

### Design & Ethics

The study design was a pre-post experimental study. This type of study design used in scientific research for measured or observed both before and after the intervention or treatment. The first ethical approval was approved by the ethical committee, FAHS, MRIIRS (Ref.No. MRIIRS/SAHS/PT/2023-24/N-002). Even this study protocol was registered in clinical trial registration at <https://www.ctri.nic.in/>, registration date of 5<sup>th</sup> April, 2024 identifier: CTRI/2024/04/065293. The study used a convenient sampling method. It was done by using coin and toss method in every time suffered.

### Participants and eligibility criteria

IRLSSG patients were chosen via Google Forms to evaluate patients with misdiagnosed idiopathic RLS. Total 42 of participants were allocated in the research. Participants eligible for the study were required to meet the following conditions: They had to be between the ages of 20 and 45 years old and newly diagnosed with Restless Legs Syndrome (RLS) based on the IRLSSG scale, showing mild to moderate severity. Participants were also required to have been experiencing pain for more than three months, with a Visual Analog Scale (VAS) score ranging between 3 and 8. Both male and female participants were included, provided they had not been treated with any medication for their condition. Additional inclusion criteria required participants to report disturbed sleep and exhibit a poorer quality of life, as indicated by a lower score on the SF-36 questionnaire. Participants were excluded from the study if they were diagnosed with psychosomatic or psychotic disorders, had any history of sensory loss, or had recently experienced musculoskeletal or neurological impairments or neuromuscular diseases. Individuals with no medical complaints related to conditions like high blood pressure, diabetes, renal failure, the presence of a cardiac pacemaker, pregnancy, or any other significant physiological problems were also excluded. Abnormal findings on Nerve Conduction Studies (NCS) or Electromyography (EMG) also led to exclusion.

### Sample size calculation

The sample size was determined by using G\*Power - 3.1.9.7. The resultant impact size was 0.25. With an effect size of 0.25( $\alpha= 0.05$ ), and power of =0. 80%, it was



concluded that 42 people were needed in total. The effect size was derived from a previous study by Eloise G. Harrison et al. in 2018, where the mean of the outcome variable “restless leg syndrome (IRLSSG)” was used<sup>1</sup>.

### Treatment allocation and randomization

In this study, 42 participants voluntarily took part after receiving detailed explanations and providing informed consent. Assessment tools include IRLSSG<sup>10</sup>, VAS<sup>11</sup>, PSQI<sup>12</sup>, GAD-7<sup>13</sup> and SF-36<sup>14</sup>. The participants were randomly selected into three experimental groups: Group-A: Physiotherapy (Relax Revive Technique) with self-affirmation, Group-B: Yoga (Utkatasan) with self-affirmation, Group-C: Physiotherapy (Relax Revive Technique) with self-affirmation and Yoga (Utkatasan) with affirmation both applied on alternate days. A total of 36 subjects participated in baseline testing as 6 of participants declined to further participate in training protocol. Therefore, the final data were collected on 36

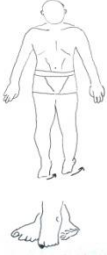
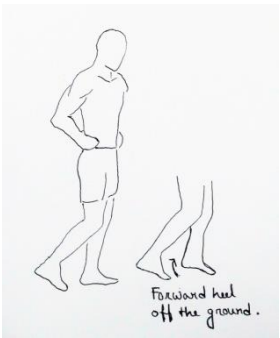
subjects, 12 each in all three groups. There were no injuries resulting from either training program.

### Baseline and outcome measures

The study duration is six weeks, with data collection at baseline and post-treatment. The study’s primary outcome measures were VAS scale for Pain severity<sup>11</sup>, GAD-7 for anxiousness<sup>15,16</sup>, and PSQI for sleeping quality<sup>17</sup>. Secondary outcome measures include the ability to perform ADLs and QoL. These outcomes were assessed via SF-36 questionnaire. PF-Physical functioning, role limitations resulting from PF-physical problems, role limitations resulting from EM-emotional problems, energy and fatigue, ED-emotional difficulties, SF-social functioning, bodily pain and general health perception are all evaluated by the SF-36 questionnaire (GH)<sup>6,14</sup>. These assessments were conducted before and after the course of the intervention to determine the changes in the selected physical attributes.

## Intervention

### Relax Revive Technique (4times/week)

Week 1-2				
Exercises	Events in standing	Procedure	Timeline	Exercise (Stick Diagram)
Position 1	Ankle pronation/supination	Roll to side of your feet, stretch your ankles and going for side to side in rhythm.	Hold each position for 3 sec and do 8 times/each side.	
Position 2	Calf raises	<p><b>For Left leg:</b></p> <p>Left leg forward and right leg backward on toe (use for balance); weight should be in the front foot. Then lift your front heel off the ground.</p> <p><b>For Right leg:</b></p> <p>Right leg forward and left leg backward on toe (use for balance); weight should be in</p>	Hold each position for 7 sec. and do 8 times/ each side.	



		the front foot. Then lift your front heel off the ground.		
Position 3	Semi Squats	<p><b>For left leg:</b></p> <p>Left leg forward and right leg backward like toe stand; then sitting the hips back (like sitting into a chair and put weight in your left leg).</p> <p><b>For right leg:</b></p> <p>Right leg forward and left leg backward like toe stand; then sitting the hips back (like sitting into a chair and put weight in your right leg).</p>	Hold each position for 7 sec. and do 8 times/ each side.	
Week 3-4				
Exercises	Events in standing	Procedure	Timeline	Exercise (Stick Diagram)
Position 1	Ankle pronation/supination	Roll to side of your feet, stretch your ankles and going for side to side in rhythm.	Hold each position for 3 sec and do 8 times/each side.	
Position 2	Semi Squats	<p><b>For left leg:</b></p> <p>Left leg forward and right leg backward like toe stand; then sitting the hips back (like sitting into a chair and put weight in your left leg).</p> <p><b>For right leg:</b></p> <p>Right leg forward and left leg backward like toe stand; then sitting the hips back (like sitting into a chair and put weight in your right leg).</p>	Hold each position for 7 sec. and do 8 times/ each side.	
		Your feet wide of shoulder width. Bend your knees like		



Position 3	Squats with trunk rotation	<p>sitting in chair.</p> <p>Rotate your trunk to your right leg and put your both hand over right knee.</p> <p>Then come back to center.</p> <p>Again rotate trunk to your left and put your both hand over left knee.</p> <p>Then come back to center.</p> <p>Then back upright posture.</p>	Hold each position for 3 sec. and do 8 repetitions.	
Week 5-6				
Exercises	Events in standing	Procedure	Timeline	Exercise (Stick Diagram)
Position 1	Ankle pronation/supination	Roll to side of your feet, stretch your ankles and going for side to side in rhythm.	Hold each position for 3 sec and do 8 times/each side.	
Position 2	Squats with trunk rotation	<p>Your feet wide of shoulder width. Bend your knees like sitting in chair.</p> <p>Rotate your trunk to your right leg and put your both hand over right knee.</p> <p>Then come back to center.</p> <p>Again rotate trunk to your left and put your both hand over left knee.</p> <p>Then come back to center. Then back upright posture.</p>	Hold each position for 3 sec. and do 8 repetitions.	
Position 3	Squats	Your feet wide of shoulder width. Bend your knees like sitting in chair. Hand should	Hold each position for 5 sec. and do 8	



		<p>parallel to ground.</p> <p>Hips should parallel to the ground. Hold this position on count of 5.</p> <p>Move up an inch. Hold this position on count of 5.</p> <p>Again move up an inch and put hands in lower back and look up. Hold this position on count of 5.</p>	<p>repetitions.</p>	
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Table 1: Relax Revive Technique

### Yoga Training Protocol<sup>18</sup> (4times/week)

The subjects were instructed to put feet parallel. They executed the chair pose(Utkatasana) as described below:

POSITION	Position No 1	Position No 2	Position No 3	Position No 4	Position No 5	Position No 6	Position No 7	Position No 8	Position No 9
COMMAND	STAND	ARMS UP	HOLD	BEND KNEES	HOLD	KNEES UP	HOLD	ARMS DOWN	STAND
TIME LINE	1 <sup>th</sup> second	5 <sup>th</sup> second	8 <sup>th</sup> second	13 <sup>th</sup> second	15 <sup>th</sup> second	26 <sup>th</sup> second	30 <sup>th</sup> second	35 <sup>th</sup> second	38 <sup>th</sup> -40 <sup>th</sup> second
EVENT DESCRIPTION	Stand straight heel on the ground for 5 sec	Maintain heel on position and raise Both arms overhead palm facing each other in 3 sec	Hold position for 5 sec	Bend knees down and hip are lowered and thigh become parallel to the ground in 3 sec	Hold the position for 10 sec	Raise your knee or come back to position 2 in 4 sec	Hold the position for 4 sec	Lowering arms down in 3 sec	Stand straight for 2sec

Table 2: Yoga Training protocol



### Self-affirmations Techniques used in audio recording and visual cues<sup>19</sup>(4 times/week)

- 1) I am strong, and I am aware of my strength.
- 2) It is very easy for me to relax my body.
- 3) I choose to be healthy and to protect my health.

### Statistical Analysis

The collected data was statistically analysed using Python version 9.11.4. The study variables' properties were summarised using descriptive statistics such as mean and standard deviation (SD). The Shapiro-Wilk test was used to determine whether the data had a normal distribution, and it did not. To calculate within-group gender distribution, the Chi-Square test was employed to investigate the relationship between therapy groups and the patient's gender. The Kruskal Wallis test was used to investigate variations in patient age among the three treatments groups at the baseline and to check difference between the three treatment groups for the time variables (pre and post). To see the effects of the intervention over time, repeated measures Wilcoxon was used, considering the factors of time (pre and post) within the treatment groups (Group-A, Group-B and Group-C). All statistical tests in the thesis were carried out at appropriate significance level of p-value ( $< 0.05$ ).

### RESULT

A total of 36 subjects participated who were comprised of 30.8% female and 40.0% male in group A, where 38.5% female and 40.0% male in group B, and 30.8% female and 20.0% male in group C, met probable the criteria of RLS, and a comparison on gender distribution(Chi-Square test ( $\pi^2$ ) shown in Table 3 As per the below table 3 it was interpret that the distribution of male and female were not equal as  $p > 0.05$ .

As per table 3 p value was greater than the level of significance, indicating that the ages of patients did not significantly differed across the three treatment groups. The VAS, PSQI, and GAD-7, SF-36 results were significant value  $p < 0.05$  which is less than the level of significance in within group analysis. (table 4 & 5)(fig: 1&2). The relationship between the three treatment groups possible factor that may affect the RLS was examined using Kruskal wallis test (table 6). There was a positive significance in the parameter of VAS score, GAD-7 where  $p(<0.05)$ , but lower significant effect in parameters of PSQI and SF-36.

Table3: Baseline characteristics of patients in Group-A, Group-B and Group-C and homogeneity

Variable	Treatment Group (n)			$\pi^2$ -value*	P- Value*
Gender	Group A	Group B	Group C		
Female	8	10	8	1.10769	0.57473
Male	4	2	4		
Age	Group A Mean±SD	Group B Mean±SD	Group C Mean±SD	t- Value*	P- Value*
	25.41±5.45	24.16±6.64	26±4	3.6286	0.1630

$\pi^2$  = Chi-Square test; t= non-parametric statistical test, kruskal-wallis test; p= Significance value



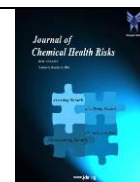
Table 4 Within group analysis of VAS, PSQI &amp; GAD-7

VAS				
Treatment Groups	Time	Mean±SD*	t*- Value	p value
group A	pre	5.83± 1.03	78	0.0002
	post	2.33±1.15		
group B	pre	5.17±1.19	15	0.0197
	post	4.5±1.51		
group C	pre	5.83±0.93	78	0.0002
	post	2.58±1.38		
PSQI				
Group A	pre	9.42± 2.78	64	0.0028
	post	6.42±1.24		
Group B	pre	10.08±2.43	74	0.0017
	post	6.42±1.88		
Group C	pre	11.75±2.60	77	0.0005
	post	6.42±1.50		
GAD-7				
group A	pre	9.83± 3.33	66	0.0015
	post	3.83±1.59		
group B	pre	11.17±3.71	78	0.0002
	post	4.17±1.40		
group C	pre	13.17±2.98	78	0.0002
	post	6.083±3.34		

t= non-parametric statistical test, Wilcoxon test, p= Significance value; SD= Standard deviation

Table 5: Within group analysis of SF-36

ITEM 1(Physical functioning)				
Treatment Groups	Time	Mean±SD*	t*- Value	p value
group A	pre	64.58± 23.59	0	0.0025
	post	92.08±8.91		
group B	pre	66.67±10.77	0	0.0002



	post	87.5±5.84		
group C	pre	57.29±18.62	0	0.0015
	post	93.33±7.49		
ITEM 2 (Role limitations due to physical health)				
group A	pre	45.83± 42.42	0	0.0035
	post	91.67±16.28		
group B	pre	27.08±22.51	0	0.0053
	post	64.58±22.51		
group C	pre	33.33±30.77	0	0.0023
	post	81.25±18.84		
ITEM 3 (Role limitations due to emotional problems)				
group A	pre	27.78± 34.33	0	0.0015
	post	94.44±12.97		
group B	pre	24.99±25.13	1	0.0004
	post	88.89±16.41		
group C	pre	24.99±32.17	3	0.0012
	post	83.33±22.47		
ITEM 4 (energy/ fatigue)				
group A	pre	51.25± 12.81	0	0.0002
	post	80.41±8.65		
group B	pre	45.83±10.40	1	0.0002
	post	72.08±14.53		
group C	pre	34.58±16.85	3	0.0002
	post	75±17.33		
ITEM 5 (emotional well-being)				
group A	pre	73± 13.00	10.5	0.0219
	post	80±8		
group B	pre	58±9.26	0	0.0002
	post	76.67±9.16		
group C	pre	53.33±24.02	0	0.0025
	post	80.67±11.67		
ITEM 6 (social functioning)				

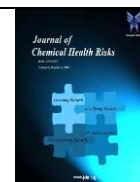


group A	pre	43.33± 23.22	0	0.0015
	post	75±15.99		
group B	pre	42.71±15.50	0	0.0002
	post	70.83±15.38		
group C	pre	33.33±24.03	1.5	0.0005
	post	72.92±16.71		
ITEM 7 (Pain)				
group A	pre	42.5± 21.29	0	0.0015
	post	80.83±13.95		
group B	pre	37.08±9.33	0	0.0036
	post	53.75±16.29		
group C	pre	37.71±17.24	0	0.0002
	post	76.67±18.54		
ITEM 8 (General health)				
group A	pre	45.83± 21.62	4	0.0081
	post	67.08±11.57		
group B	pre	39.17±13.29	0	0.0002
	post	64.58±13.05		
group C	pre	34.58±12.87	0	0.0002
	post	73.75±10.89		

t= non-parametric statistical test, Wilcoxon test; p= Significance value; SD= Standard deviation

**Table 6:** Between group analysis among three groups with parameters of VAS, PSQI, GAD-7 & SF-36

Parameter	Treatment groups			t*- Value	p-Value
	group A Mean±SD	group B Mean±SD	group C Mean±SD		
AGE	25.42 ± 5.70	24.17 ± 6.94	26.00 ± 4.18	3.628576	0.162954
PRE VAS SCORE	5.83 ± 1.03	5.17 ± 1.19	5.83 ± 0.94	2.747079	0.253209
POST VAS SCORE	2.33 ± 1.15	4.50 ± 1.51	2.58 ± 1.38	12.68077	0.001764*
PRE PSQI	9.42 ± 2.78	10.08 ± 2.43	11.75 ± 2.60	6.104278	0.047258*
POST PSQI	6.42 ± 1.24	6.42 ± 1.88	6.42 ± 1.51	0.250704	0.882186
PRE GAD	9.83 ± 3.33	11.17 ± 3.71	13.17 ± 2.98	5.805592	0.05487



POST GAD	3.83 ± 1.59	4.17 ± 1.40	6.08 ± 3.34	4.954885	0.083958
Item_1_pre SF_36	64.58 ± 23.59	66.67 ± 10.77	57.29 ± 18.62	2.973624	0.226092
Item_2_pre SF_36	45.83 ± 42.42	27.08 ± 22.51	33.33 ± 30.77	1.058138	0.589153
Item_3_pre SF_36	27.78 ± 34.33	25.00 ± 25.13	25.00 ± 32.18	0.05836	0.971242
Item_4_pre SF_36	51.25 ± 12.81	45.83 ± 10.41	34.58 ± 16.85	5.948263	0.051092
Item_5_pre SF_36	73.00 ± 13.00	58.00 ± 9.26	53.33 ± 24.02	9.22953	0.009905*
Item_6_pre SF_36	43.33 ± 23.22	42.71 ± 15.50	33.33 ± 24.03	1.254409	0.534083
Item_7_pre SF_36	42.50 ± 21.29	37.08 ± 9.93	37.71 ± 17.24	0.917413	0.632101
Item_8_pre SF_36	45.83 ± 21.62	39.17 ± 13.29	34.58 ± 12.87	3.39744	0.182918
Item_1_post SF_36	92.08 ± 8.91	87.50 ± 5.84	93.33 ± 7.49	3.349316	0.187372
Item_2_post SF_36	91.67 ± 16.28	64.58 ± 22.51	81.25 ± 18.84	9.279092	0.009662*
Item_3_post SF_36	94.44 ± 12.97	88.89 ± 16.41	83.33 ± 22.47	1.988345	0.37003
Item_4_post SF_36	80.42 ± 8.65	72.08 ± 14.53	75.00 ± 17.32	2.127239	0.345204
Item_5_post SF_36	80.00 ± 8.00	76.67 ± 9.16	80.67 ± 11.67	1.082336	0.582068
Item_6_post SF_36	75.00 ± 15.99	70.83 ± 15.39	72.92 ± 16.71	0.382651	0.825864
Item_7_post SF_36	80.83 ± 13.95	53.75 ± 16.29	76.67 ± 18.54	12.090415	0.002369*
Item_8_post SF_36	67.08 ± 11.57	64.58 ± 13.05	73.75 ± 10.90	4.941231	0.084533

t= non-parametric statistical test, Wilcoxon test, p= Significance value  $p^* < 0.05$ ; SD= Standard deviation

## DISCUSSION

The current study sought to evaluate if a training protocol consisting solely of physiotherapy with affirmation (group A) or yoga with affirmation (group B) might

effectively reduce pain and anxiety, better sleep quality, increasing ADLs, and enhancing QoL. An additional objective of this research had been to find out whether the combination of two training regimens- physiotherapy



with affirmation and yoga with affirmation (group C), could be beneficial in decreasing anxiety and discomfort, improving sleep patterns, increasing ADLs, and enhancing QoL.

There have been numerous studies that support the fact that both physiotherapy treatment and yoga training could reduce RLS symptoms<sup>1,8</sup>. Previous literature had proven that self-affirmation could reduce postoperative anxiety and perceived discomforts regarding pain, dyspnea, palpitation, and fatigue Yildirim et al. (2023)<sup>19</sup>, but this self-affirmation was not undertaken in any RLS treatment. This study was the first to experimentally show the use of both treatment protocols—physiotherapy with self-affirmation and yoga with self-affirmation—as well as the combination of both treatment protocols in the management of pain, anxiety, disturbed sleep, along with improved performance of everyday activities and overall quality of life for individuals with RLS(fig:1&2).

Physiotherapy intervention was influenced by the neural system, in which pressure applied to a specific portion of the skin triggers neuronal reflexes and transmits them to the brain. On the other hand, reflexes stimulate the nerve's chemical system, balance enzymes, and regulate endocrine activity. It has been stated that exercises decreased the sleep disturbances<sup>20</sup>. Exercises were one of the oldest movement therapy approaches, improving muscular circulation and facilitating the delivery of nutrients to cells. Because inadequate circulation exacerbates the development of restless leg syndrome indicators and activity changes this state, exercises can help reduce the severity of this syndrome<sup>21</sup>. Therefore in current study physiotherapy with self-affirmation, a new treatment algorithm for treating PLMS, sleep disturbance and mood disorders by reduced anxiety symptoms (fig:1).

On the other hand, Kim E. ines et al. (2020) reported that by lowering sympathoadrenal and hypothalamic-pituitary levels yoga decreased RLS symptoms and burden. RLS aetiology and development along with sleep impairment have been linked to the activation of the adrenal axis restoration of parasympathetic/sympathetic balance and enhancement of cardio-metabolic function. Yoga could improve autonomic, neuroendocrine, and metabolic function, as well as sleep and mood, potentially reducing RLS symptoms<sup>8</sup>. In the present study the combination of both treatment protocols physiotherapy with self-affirmation and yoga with self-affirmation used to reduce

the effects of RLS, by stimulate parasympathetic nervous system by evokes the circulations that decrease the neuromuscular pain symptoms, periodic limb movements, improved the sleep quality, and thus reduce day time exhaustion, improve the quality of life(fig:1&2).

## CONCLUSION

Finally, the current study found that a six-week intervention between the three treatment groups, which include physiotherapy with affirmation, yoga with affirmation, and a combination of both groups, physiotherapy with affirmation and yoga with affirmation, had considerable favourable benefits. All three groups reported a reduction in pain, and anxiety, and improved sleep quality across the six weeks of the study in RLS patients. These positive changes had a notable effect on daily life and overall QoL. Physiotherapy with self-affirmation particularly helped to reduce pain, discomfort, and unpleasant sensations. The findings showed that self-affirmation combined with yoga poses significantly improved the psychiatric symptoms of anxiety and lower quality of life that were linked to idiopathic RLS.

We accept some limitation. The six-week period of the intervention may not adequately reflect the long-term effect. The study did not determine which of the three treatment groups worked best for overall improvement in RLS symptom severity. Further research is needed to validate the results in larger and more diverse populations in order to establish a substantial difference in all three groups. Longer intervention durations should also be considered, as well as any other confounding variables.

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## Ethical approval:

All procedures performed in the present study involving human participants were in accordance with the ethical standards of the Institutional Ethics committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The present study was



approved by the ethical committee, FAHS, MRIIRS (Ref.No. MRIIRS/SAHS/PT/2023-24/N-002),

India prior to the conduct of the study procedure. Even this study protocol was registered in clinical trial registration at <https://www.ctri.nic.in/>, registration date of 5<sup>th</sup> April, 2024 identifier: CTRI/2024/04/065293.

The exercise protocol (RELAX REVIVE TECHNIQUE) for patients with restless legs syndrome was copyrighted in Copyright Office, Government Of India, registration date of 27<sup>th</sup> May, 2024 registration number: L-148095/2024.

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**Abbreviations:**

RLS: Restless Legs Syndrome

PLMS: Periodic Leg Movements of Sleep

PLMW: Periodic Leg Movements during awake

GAD: General Anxiety Disorder

RRT: Relax Revive Technique

TRE: Tension and Trauma Releasing Exercises

ADLS: Activity of Daily Living

QoL: Quality of Life

IRLSSG: International Restless Legs Syndrome Study Group

VAS: Visual Analogue Scale

PSQI: Pittsburgh Sleep Quality Index

SF-36: Generalized Health Assessment

**REFERENCES**

- Harrison EG, Keating JL, Morgan P. Novel exercises for Restless Legs syndrome: A randomized, controlled trial. *J Am Board Fam Med.* 2018;31(5):783-794. doi:10.3122/jabfm.2018.05.180065
- Press D. JPRLS-37451-Restless-Legs-Syndrome. Published online 2012:49-57.
- Glasauer FE. Scienti@c Review Restless Legs Syndrome. *Spinal Cord.* 2001;39:39-125.
- Özsimsek A, Koyuncuoglu HR. Electrophysiological findings of Turkish patients with restless legs syndrome. *Neuropsychiatr Dis Treat.* 2017;13:2005-2010. doi:10.2147/NDT.S132903
- Joseph N, Suresh S, Prasad S, Malwee SM, Brittas A, Gupta V. Study on restless leg syndrome and its relationship with quality of sleep among the general population of Mangalore, India. *Egypt J Neurol Psychiatry Neurosurg.* 2022;58(1). doi:10.1186/s41983-022-00544-z
- Zucconi M, Manconi M. Sleep and quality of life in restless legs syndrome. *Sleep Qual Life Clin Med.* Published online 2008:101-106. doi:10.1007/978-1-60327-343-5\_11
- An T, Sun H, Yuan L, Wu X, Lu B. Associations of anxiety and depression with restless leg syndrome: a systematic review and meta-analysis. *Front Neurol.* 2024;15(March):1-13. doi:10.3389/fneur.2024.1366839
- Innes KE, Selfe TK, Montgomery C, et al. Effects of a 12-week yoga versus a 12-week educational film intervention on symptoms of restless legs syndrome and related outcomes: An exploratory randomized controlled trial. *J Clin Sleep Med.* 2020;16(1):107-119. doi:10.5664/JCSM.8134
- Innes KE, Selfe TK, Agarwal P, Williams K, Flack KL. Efficacy of an eight-week yoga intervention on symptoms of restless legs syndrome (RLS): A pilot study. *J Altern Complement Med.* 2013;19(6):527-535. doi:10.1089/acm.2012.0330
- Restless I, Syndrome L, Group S, Scale R. International Restless Legs Syndrome Study Group Rating Scale 44. Published online 2012:195-202. doi:10.1007/978-1-4419-9893-4
- Anderson JC, Fritz ML, Benson JM, Tracy BL. Nerve decompression and restless legs syndrome: A retrospective analysis. *Front Neurol.* 2017;8(JUL):1-8. doi:10.3389/fneur.2017.00287
- Pittsburgh sleep quality index instructions: :1-4.



13. GAD-7 Anxiety Scoring GAD-7 Anxiety Severity. Published online 1999:21. doi:10.3390/jcm10040664
14. Abetz L, Vallow SM, Kirsch J, Allen RP, Washburn T, Earley CJ. Validation of the Restless Legs Syndrome Quality of Life questionnaire. *Value Heal.* 2005;8(2):157-167. doi:10.1111/j.1524-4733.2005.03010.x
15. Rutter LA, Brown TA. Journal of Psychopathology and Behavioral Assessment. 2017;39(1):140-146. doi:10.1007/s10862-016-9571-9.Psychometric
16. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A brief measure for assessing generalized anxiety disorder: The GAD-7. *Arch Intern Med.* 2006;166(10):1092-1097. doi:10.1001/archinte.166.10.1092
17. Nowowiejska J, Baran A, Lewoc M, Grabowska P, Kaminski TW, Flisiak I. The assessment of risk and predictors of sleep disorders in patients with psoriasis—a questionnaire-based cross-sectional analysis. *J Clin Med.* 2021;10(4):1-16.
18. Mandal S. The Effects of Yoga ( Asana ) on Human Lower Limb Muscles. 2011;7109(September):263-266.
19. Yildirim M, Akbal S, Turkoglu M. The effect of self-affirmation on anxiety and perceived discomfort in patients who have undergone open-heart surgery. A randomized controlled trial. *Appl Nurs Res.* 2023;72(May):151687. doi:10.1016/j.apnr.2023.151687
20. Çoban Ö. Effects of Different Exercise Programs on Symptoms , Sleep , and Quality of Life in Patients with Primary Restless Legs Syndrome. 2023;10(May):1349-1359. doi:10.1002/mdc3.13833
21. Xu X min, Liu Y, Jia S yu, Dong M xue, Cao D, Wei Y dong. Complementary and Alternative Therapies for Restless Leg Syndrome: An Evidence-Based Systematic Review. *Sleep Med Rev.* Published online 2017. doi:10.1016/j.smrv.2017.06.003