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Efficacy of an Eight-Week Yoga Intervention on Symptoms of Restless Legs Syndrome (RLS): A Pilot Study

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Abstract

Background: Restless legs syndrome (RLS) is a common and highly burdensome sleep disorder. While relaxation therapies, including yoga, are often recommended for RLS management, rigorous supporting research is sparse. The goal of this preliminary study was to assess the effects of yoga on RLS symptoms and related outcomes in women with RLS.

Methods: Participants were 13 nonsmoking women with moderate to severe RLS, who did not have diabetes, sleep apnea, or other serious concomitant chronic conditions, and who were not pregnant. The intervention was a gentle, 8-week Iyengar yoga program. Core outcomes assessed pre- and post-treatment were RLS symptoms and symptom severity (International RLS Scale [IRLS] and RLS ordinal scale), sleep quality (Medical Outcomes Study Sleep Scale), mood (Profile of Mood States), and perceived stress (Perceived Stress Scale). Participants also completed yoga logs and a brief exit questionnaire regarding their experience with the study.

Results: Ten (10) women, aged 32–66 years, completed the study. Participants attended an average 13.4 ± 0.5 (of 16 possible) classes, and completed a mean of 4.1 ± 0.3 (of 5 possible) homework sessions/week. At follow-up, participants demonstrated striking reductions in RLS symptoms and symptom severity, with symptoms decreasing to minimal/mild in all but 1 woman and no participant scoring in the severe range by week 8. Effect sizes (Cohen's *d*) were large: 1.6 for IRLS total, and 2.2 for RLS ordinal scale. IRLS scores declined significantly with increasing minutes of homework practice per session ($r = 0.70$, $p = 0.025$) and total homework minutes ($r = 0.64$, $p < 0.05$), suggesting a possible dose–response relation. Participants also showed significant improvements in sleep, perceived stress, and mood (all $p's \leq 0.02$), with effect sizes ranging from 1.0 to 1.6.

Conclusions: These preliminary findings suggest that yoga may be effective in attenuating RLS symptoms and symptom severity, reducing perceived stress, and improving sleep and mood in women with RLS.

Introduction

Restless legs syndrome (RLS) is a potentially disabling sleep and sensorimotor disorder that affects an estimated average of 19.5% of U.S. and European primary care patients,[1] and up to 45% or more of adults with certain chronic disorders.[2] RLS prevalence is higher in women than in men, and increases with age.[1] Recognition of RLS as an important clinical condition is growing, in part aided by standardized diagnostic criteria developed by international expert consensus in 1995[3] and revised in 2002.[4] RLS is characterized by a compelling urge to move the legs that is usually accompanied by unpleasant, often painful sensations in the legs, begins or worsens during periods of inactivity, is more pronounced during the evening and night-time hours, and is at least partially relieved by movement.[4] RLS can lead to reductions in quality of life comparable to or worse than those reported in Parkinson's disease, stroke, and other serious chronic disorders.[5–8] RLS has also been linked to profound impairment in sleep and mood, and is associated with significant economic and societal burden.[5,7,8] Clearly, the high prevalence and associated health and financial burden of RLS render cost-effective management of this disorder a public health priority.[7]

The etiology of RLS remains poorly understood.[9–11] While defects in dopamine function and iron metabolism have long been considered key factors in RLS pathogenesis,[12–15] evidence remains inconclusive.[9,16–18] An emerging body of research suggests that autonomic and metabolic dysfunction may also play an important role.[2,19] Recent community-based studies suggest that RLS may also be linked, in a

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bidirectional manner, to cardiovascular disease (CVD), stroke, and key components of the metabolic syndrome,[2,9,10,20] associations that may be mediated in part by the adverse effects of RLS on sleep and mood.[7,21]

With no cure for RLS currently available, existing treatments focus on symptom reduction. Unfortunately, the commonly prescribed treatments for RLS, which include dopaminergic agents, opioids, benzodiazepines, and anticonvulsants, can produce serious side effects.[7,22] In addition, these medications are not effective in all patients, and even for those who do respond, benefits may decline over time.[23,24] While clinical guidelines recommend nonpharmacologic approaches such as lifestyle changes and stress reduction practices for patients with RLS, recommendations remain nonspecific and rigorous supportive research is still sparse.[19]

Yoga, an ancient mind–body discipline that continues to gain popularity throughout the Western industrialized world as both a recreational and therapeutic modality,[25,26] may offer particular promise for those suffering from RLS. Data from a growing number of controlled trials suggest that yoga can enhance mood[27–30] and sleep,[29,31,32] as well as decrease blood pressure[33] and improve glucose tolerance,[33–35] lipid profiles,[33,36,37] body composition,[33,37] and autonomic function,[34,36,37] factors associated with both RLS and CVD risk.[2,9,10,20] However, while mind–body therapies, including yoga, are often recommended for patients with RLS,[38,39] no clinical trials have yet examined the effects of yoga on RLS symptoms. In this preliminary pre–post study, investigation was made on the effects of a gentle yoga program on RLS symptoms and symptom severity, and on the associated outcomes of sleep, mood, and perceived stress in women with RLS.

Methods

Participants

Eligible participants were community-dwelling women aged 18 and older who met all four International Restless Legs Syndrome Study Group (IRLSSG) criteria, and who suffered RLS symptoms at least 5 times/month, had not changed dosage of any opiates, sedative hypnotics, anticonvulsants, adrenolytic agents, or benzodiazepines within the previous 3 months, had not practiced yoga for at least 1 year, and were willing to forgo any other new therapies for RLS for the duration of the study; those who were taking dopaminergic agents were excluded due to the high rates of symptom augmentation associated with these medications.[40] Also excluded were women who had uncontrolled hypertension, had been diagnosed with diabetes or diabetic neuropathy, kidney disease, heart failure, cancer, or other serious concomitant disorders, or had any orthopedic, neurological, or other condition that might affect assessments or preclude their safe completion of an 8-week yoga program. Women were recruited using a combination of print advertisements, flyers, and brochures. Eligibility criteria were reviewed with all potential participants via telephone, along with the study protocol, timing, and class schedules. Those indicating that they were eligible, willing, and available to participate were then scheduled for a consent visit and baseline assessment.

To confirm that potential participants met the four IRLSSG diagnostic criteria for RLS,[4] each woman was asked whether she experienced an urge to move the legs, often with uncomfortable (e.g., "creepy-crawly", painful, tingling) sensations in the legs, and whether these feelings began or worsened when lying or sitting, were worse in the evening/night, and were relieved at least in part by movement (e.g., wiggling feet, moving legs, or walking). Participants were also queried regarding frequency of RLS symptoms. Those participants endorsing all four diagnostic criteria and reporting symptoms at least 5 times per month were considered to meet RLS diagnostic criteria; none of those enrolled in the study indicated the presence of cramping or other potential RLS mimics. The study was approved by the West Virginia University Institutional Review Board, and all participants provided informed consent prior to final eligibility screening and study enrollment. Of a total 105 initial inquiries by potential participants, 32 met study eligibility criteria; of these, 13 women were available to participate in the fall yoga program and were enrolled in the current trial.

Outcome assessment

Participants underwent an assessment at baseline and following the 8-week intervention period; all assessments were conducted by an experienced clinician. Detailed baseline information was gathered on medical history, demographic characteristics, and lifestyle factors. The primary outcome for this study was RLS symptomatology, measured using the International RLS Rating Scale (IRLS), a 10-item scale that includes questions related to frequency, intensity, and impact.[41] Considered the criterion standard for measuring RLS symptoms,[42,43] this instrument is recommended for use in RLS clinical trials by the European RLS Study Group (EURLSSG)[44] and other RLS experts,[20] and is widely used both in the United States and internationally.[1,2] Also assessed were the effects of yoga on RLS symptom severity using the IRLS severity subscale[45] (considered relatively robust to placebo effects[44]), and the single-item RLS ordinal scale.[46,47]

Secondary outcomes included sleep quality, mood, perceived stress, blood pressure, and heart rate. Sleep quality was assessed using the 12-item Medical Outcomes Study Sleep Scale[48]; mood was evaluated using the 65-item Profile of Mood States (POMS)[49] and stress was measured using the 10-item Perceived Stress Scale.[50] These well-established scales have been shown to be sensitive to short-term behavioral interventions, and have been validated in a wide range of populations, including patients with RLS.[51–60] Blood pressure and heart rate were measured with subjects in a seated position following a 5-minute rest period; using the OMRON HEM-780 automatic blood pressure monitor, measurements were taken 3 times and averaged for a final score.

To measure expectations of benefit, a brief treatment credibility questionnaire was administered to all participants at baseline. In addition, all subjects were asked to complete a short, anonymous exit questionnaire, modeled after that used in the authors' previous trials.[61]

Intervention

Participants completed a gentle 8-week Iyengar yoga program specifically designed for women with RLS and based on that successfully used in the authors' previous

randomized controlled trial in older women with RLS.[19] Participants attended two 90-minute classes per week and were asked to complete at least 30 minutes of home practice on nonclass days. Class size was limited to ensure adequate instructor attention; no class contained more than 7 participants. To facilitate her home practice, each participant was given a comprehensive homework manual illustrating the yoga home practice routines, along with a yoga mat and strap. A list of poses included in the yoga program is provided in Table 1. Poses were modified and props (e.g., blankets, chairs, and straps) were used as needed to allow participants to perform the sequences easily and safely. Each session began with a simple yogic centering and relaxation exercise and ended with a 10–15-minute guided supine relaxation practice (*Savasana*). Upon study completion, all participants were given modest compensation for their time and travel expenses.

Adherence and adverse events

Yoga class attendance was recorded by the instructor on standardized check sheets. Participants also completed a daily log after each home practice session, indicating the number of minutes practiced, as well as any comments regarding the session. Homework logs were turned in to the instructor at the first group class each week. Logs and attendance records were collected weekly.

Adverse events were tracked via weekly review of participant yoga logs. At the beginning of each class, the yoga instructor also queried participants discretely regarding any potential problems; these were likewise recorded. In addition, participants were encouraged to contact study investigators and/or staff if they had any questions or concerns.

Table 1. Poses Included in the Yoga Program

Mountain pose (*Tadasana, Tadasana* with arm variations)
Fierce pose (*Utkatasana*)
Tree pose (*Vrksasana*)
Extended hands and feet pose (*Utthita hasta padasana*)
Standing wide apart legs pose (*Prasarita padottanasana*)
Warrior I & II (*Virabhadrasana I & II*)
Half forward bend (*Ardha uttanasana*)
Triangle pose (*Utthita trikonasana*)
Reverse triangle pose (*Parivrtta trikonasana*)
Extended Marichi's pose (*Utthita marichyasana I & III*)
Extended arms and legs pose I & II (*Utthita hasta padangusthasana I & II*)
Downward facing dog pose (*Adho mukha svanasana*)
Eagle pose (*Garudasana*)
Hero pose (*Virasana*)
Staff pose (*Dandasana*)
Spinal twist pose (*Bharadvajasana* and *Marichyasana III*)
Seated wide-angle pose (*Upavista konasana* and *parsva upavista konasana*)
Seated bound-angle pose (*Baddha konasana*)
Extended legs up the wall pose (*Urdhva prasarita padasana*)
Lying down holding big toe pose I & II (*Supta padangusthasana I & II*)
Supported-bridge pose (*Setu bandha sarvangasana*)
Reclined crossed-legs back-arch pose (*Supta swastikasana*)
Reclined mountain pose (*Supta tadasana*)
Lying down bound-angle pose (*Supta baddha konasana*)
Corpse pose (*Savasana*)

Statistical analysis

Data were analyzed using IBM SPSS Statistics v. 20. Differences between those who did versus those who did not complete the study were evaluated using χ^2 (for categorical variables), independent samples *t*-tests (for continuous variables with a normal distribution), or Mann-Whitney *U* tests (for ordinal variables or continuous variables with evidence of skewing). Within-group changes (pre- to postintervention) were initially evaluated using paired *t*-tests (continuous variables), or Wilcoxon signed-rank test (ordinal or continuous variables with evidence of skewing). Change over time adjusted for treatment expectancy and other baseline factors was assessed using repeated-measures analysis of variance (multivariate tests); distributions of all dependent variables were examined to ensure that the assumptions of normality and sphericity were met and that variables were transformed as necessary. Effect sizes were calculated using Cohen's *d*. The relationships between improvement in RLS symptoms and changes in sleep, mood, and perceived stress were assessed using Pearson Product-Moment Correlation.

Results

Of the 13 eligible women enrolled in the study, 92% were white (Table 2). All of the women reported RLS symptoms at least 2 days/week, with 6 reporting symptoms ≥4 days/week. Three (3) women, all white, withdrew in the first 2 weeks of the study due to acute illness ($N=2$) or work schedule change ($N=1$). Relative to completers, dropouts were significantly younger, less likely to be married, or to report a history of pregnancy (p's <0.05), but were otherwise similar in baseline demographic, lifestyle, and anthropometric characteristics, RLS symptomatology, and medical history (Table 2); dropouts were also similar to completers in baseline sleep quality and mood profiles ($p>0.7$, data not shown).

Of the 10 women completing the study, their ages ranged from 32 to 66 years (mean = 49.5 ± 3.9), and most were overweight, with a mean BMI of 29.6 ± 2.3 (range 19.5–46.7). Eight (8; 80%) consumed caffeine in moderation, and 6 (60%) reported exercising at least twice/week. While the women were healthy overall, 8 reported an immediate family history of hyperlipidemia or hypertension, and 7 indicated a family history of diabetes or CVD. All women reported RLS symptoms in the moderate to severe range; 5 of the 10 women reported RLS symptoms ≥4 days/week, and 5 indicated severe symptoms (Table 2).

Participants completing the study attended an average of 13.4 ± 0.5 (of 16 possible) classes and completed an average of 4.1 ± 0.3 (of 5 possible) homework sessions/week, with a mean 30.4 ± 2.3 minutes/session. All indicated high satisfaction with the yoga program overall and reported multiple benefits on their yoga logs and/or exit questionnaires, including the following: enhanced energy and well-being ($N=9$); RLS symptom relief ($N=8$); reduced stress and increased feelings of tranquility and relaxation ($N=6$); improved sleep ($N=5$); increased strength, flexibility, and fitness ($N=5$); reduced pain and improved physical function ($N=3$); and greater body awareness ($N=2$). Two (2) participants also indicated improvements in other health conditions. All indicated that they were likely ($N=5$) or very likely ($N=5$) to continue yoga practice. While several participants

Table 2. Baseline Characteristics of Participants Completing the Study Versus Those Not Completing the Study ($N = 13$ Total Women with Restless Legs Syndrome)

	Total		*Dropouts*		*Completers*		
	Freq/ mean	*Percent/ SE*	*Freq/ mean*	*Percent/ SE*	*Freq/ mean*	*Percent/ SE*	p
Demographic and lifestyle characteristics							
Age in years (mean, SE)	43.8	4.21	25	1.00	49.50	3.911	0.007
<35	4	30.77%	3	100.00%	1	10.00%	
35–50 years	3	23.08%	0	0.00%	3	30.00%	
>50 years	6	46.15%	0	0.00%	6	60.00%	
Race/ethnicity							NS
Non-Hispanic white	12	92.31%	3	100.00%	9	90.00%	
African American	1	7.69%	0	0.00%	1	10.00%	
Education							NS
<4 years college	2	15.38%	0	0.00%	2	20.00%	
≥4 years college	11	84.62%	3	100.00%	8	80.00%	
Employed	12	92.31%	3	100.00%	9	90.00%	NS
Married/cohabiting	10	76.92%	1	33.33%	9	90.00%	0.05
Consume caffeine							NS
Yes (1–3 caffeinated beverages/d)	10	76.92%	2	66.67%	8	80.00%	
No	3	23.08%	1	33.33%	2	20.00%	
Consume alcohol							NS
Yes (1–3 drinks/week)	6	46.15%	2	66.67%	4	40.00%	
No	7	53.85%	1	33.33%	6	60.00%	
Current smoker	0	0.00%	0	0.00%	0	0.00%	
Ever smoked							NS
Yes	6	46.15%	2	66.67%	4	40.00%	
No	7	53.85%	1	33.33%	6	60.00%	
Regular exercise program							NS
Yes (2–7×/week)	8	61.54%	2	66.67%	6	60.00%	
No	5	38.46%	1	33.33%	4	40.00%	
Health history							
Live births							
0	7	53.85%	3	100.00%	4	40.00%	NS
1	3	23.08%	0	0.00%	3	30.00%	
≥2	3	23.08%	0	0.00%	3	30.00%	
Pregnancies							
0	5	38.46%	3	100.00%	2	20.00%	0.002
1	3	23.08%	0	0.00%	3	30.00%	
≥2	5	38.46%	0	0.00%	5	50.00%	
Physician diagnosed:							
Anemia	1	7.69%	1	33.33%	0	0.00%	
Hyperlipidemia	3	23.08%	0	0.00%	3	30.00%	
Hypertension	1	7.69%	0	0.00%	1	10.00%	
Asthma	3	23.08%	0	0.00%	3	30.00%	
Osteoarthritis/rheumatoid arthritis	0	0.00%	0	0.00%	0	0.00%	NS
Family history of:							
Heart disease	5	38.46%	2	66.67%	3	30.00%	NS
Diabetes	6	46.15%	2	66.67%	4	40.00%	NS
Stroke	4	30.77%	1	33.33%	3	30.00%	NS
Hypertension and/or hyperlipidemia	11	84.62%	3	100.00%	8	80.00%	NS
RLS	2	15.38%	1	33.33%	1	10.00%	NS
RLS symptoms (mean, SE)	2.46	.144	2.33	0.33000	2.50	0.167	NS
2–3×/week	7	53.85%	2	66.67%	5	50.00%	
≥4×/week	6	46.15%	1	33.33%	5	50.00%	
IRLS score (mean, SE)	21.15	1.54	21.33	0.67	21.10	2.01	NS
Moderate (11–20)	6	46.15%	1	33.33%	5	50.00%	
Severe (21–30)	7	53.85%	2	66.67%	5	50.00%	
IRLS severity scale			4.70	0.423	4.67	0.333	NS
Moderate (3–4)	5	38.46%	1	33.33%	4	40.00%	
Severe (5–6)	8	61.54%	2	66.67%	6	60.00%	
Body–mass index (mean, SE)	30.29	1.89	32.46	3.35	29.64	2.28	NS
<25	3	23.08%	1	33.33%	2	20.00%	
25–29 (overweight)	5	38.46%	0	0.00%	5	50.00%	
≥30 (obese)	5	38.46%	2	20.00%	3	30.00%	

Freq, frequency; NS, nonsignificant ($p > 0.5$); SE, standard error of the mean; RLS, restless legs syndrome; IRLS, International RLS Scale.

indicated mild muscle soreness in the first few weeks, no participants reported significant pain, discomfort, or other adverse events in association with the yoga program.

Improvement in RLS symptoms and symptom severity was striking, with participants showing significant declines in both total and subscale scores (Table 3). Participants demonstrated a mean 49% (±11.9) decline in RLS symptoms overall ($p=0.01$), and an average 62% (±8.9) reduction in overall symptom severity (RLS, $p=0.0006$), with symptoms decreasing to minimal/mild in all but 1 woman by week 8. Effect sizes (Cohen's d) were also large[62] (1.6. 1.8, and 2.2, for changes in total IRLS score, IRLS severity subscale, and overall symptom severity, respectively) (Table 3). IRLS scores also declined significantly with increasing minutes of homework practice per session ($r=0.70$, $p=0.025$) and total homework minutes ($r=0.64$. $p<0.05$), suggesting a possible causal, dose–response relation between yoga practice and RLS symptom improvement.

As illustrated in Table 3, participants also showed significant improvement in sleep both overall ($p\leq0.0004$) and in several specific domains, including sleep disturbance ($p=0.001$), sleep adequacy ($p=0.003$), and daytime somnolence ($p=0.0007$). Similarly, participants demonstrated significant declines in perceived stress ($p<0.02$) and significant or marginally significant improvements in all domains of mood; these included tension–anxiety ($p=0.008$), anger–hostility ($p=0.04$), fatigue ($p=0.005$), vigor ($p=0.07$), confusion ($p=0.06$), and depression ($p<0.05$). Participants demonstrated no appreciable changes in either blood pressure or heart rate. Adjustment for treatment expectancy scores did not alter these findings, with the observed improvements in RLS symptoms and symptom severity, perceived stress, sleep disturbance, and mood all remaining highly significant ($p\leq0.01$).

The reduction in IRLS scores over time was significantly correlated with improvement in sleep quality, both overall ($r=0.8$, $p<0.008$) and in the domains of sleep disturbance ($r=0.68$, $p=0.03$) and sleep adequacy ($r=-0.71$, $p=0.02$). Likewise, decline in IRLS scores was correlated with reductions in perceived stress ($r=0.62$, $p=0.05$) and in mood

Table 3. Change Over Time in RLS Symptoms, Symptom Severity, Sleep, Mood, and Related Indices After a Gentle, Eight-Week Iyengar Yoga Program ($N=10$ Women with RLS)

	Pre-treatment		*Post-treatment*			
	Mean/N	*SE*/%	*Mean*/N	*SE*/%	p	*Effect size*[a]
Restless legs symptoms and severity						
IRLS symptom total	21.10	2.01	10.80	2.86	0.01	1.62
Symptom severity subscale	14.40	1.27	7.10	1.79	0.009	1.82
Symptom impact subscale	4.40	0.79	2.20	0.80	0.05	0.88
RLS severity scale	4.70	0.42	1.80	0.49	0.0006	2.16
RLS severity scale category					0.001	
None–mild (0–2): *N* (%)	0	0.00%	9	90.00%		
Moderate (3–4): *N* (%)	4	40.00%	1	10.00%		
Severe (5–6): *N* (%)	6	60.00%	0	0.00%		
Sleep (Medical Outcomes Scale)						
Sleep Problems Index I	48.33	4.41	32.50	5.16	0.0004	1.27
Sleep Problems Index II	55.00	4.22	33.33	5.51	0.0003	1.62
Sleep disturbance	53.25	7.87	26.25	8.61	0.001	1.09
Snoring	36.00	11.08	32.00	8.54	0.44	0.11
Sleep short of breath or headache	20.00	8.43	8.00	4.42	0.14	0.45
Sleep adequacy scale	19.00	4.58	43.00	4.48	0.003	−1.66
Somnolence scale	46.00	5.39	27.33	6.16	0.0007	1.09
Sleep duration (hours)	6.20	0.13	6.40	0.16	0.18	−0.47
Optimal sleep hours						
<7 hours: *N* (%)	8	80.00%	6	60.00%	0.32	
7+ hours: *N* (%)	2	20.00%	4	40.00%		
Mood (Profile of Mood States)						
Total Mood Score	26.90	9.04	−0.20	3.77	0.01	0.95
Tension–Anxiety	6.90	2.09	1.30	1.08	0.008	0.85
Anger–Hostility	8.00	1.81	4.00	0.71	0.04	0.70
Vigor	13.80	1.88	17.70	2.13	0.07	−0.66
Fatigue	13.10	1.33	8.20	1.09	0.005	1.17
Confusion	4.80	1.65	1.50	0.89	0.06	0.63
Depression	7.90	2.57	2.50	0.64	0.047	0.66
Perceived stress scale total	17.70	1.98	11.50	0.97	0.018	0.99
Blood pressure						
Systolic blood pressure	124.33	5.24	124.33	9.31	1.00	0.00
Diastolic blood pressure	83.89	2.09	82.64	2.52	0.45	0.02
Heart rate	73.83	2.59	74.33	2.59	0.57	−0.01

[a]Cohen's *d*.
SE, standard error; IRLS, International RLS Scale.

($r = 0.60$, $p = 0.07$). These findings suggest that decline in RLS symptoms is strongly associated with beneficial changes in sleep quality, mood, and stress.

Discussion

Apart from the authors' recent nested RCT,[19] this is the first trial to examine the potential benefits of yoga for persons with RLS, and the first study to assess the efficacy of this popular mind–body therapy for reducing RLS symptoms and symptom severity. Findings of this pilot study suggest that yoga can significantly alleviate RLS symptoms, improve sleep and mood, and reduce perceived stress in women with moderate to severe RLS. Effect sizes were large, and all but 1 woman tested in the minimal-to-mild RLS symptom range following the 8-week yoga program, indicating a high response rate to this nonpharmacologic therapy. Notably, improvements in RLS symptoms, sleep quality, and mood observed following the 8-week yoga program in this study were comparable to those reported in recent pharmaceutical trials in patients with RLS.[63–67] In addition, no adverse events were reported, retention and compliance were very good overall, and participant satisfaction with the program was high. Collectively, these findings suggest that yoga may offer a safe and viable complement or alternative to pharmacologic treatment for patients with this burdensome disorder. Given the promising results of this small pilot study, larger controlled trials are warranted to further investigate the efficacy of yoga for the management of RLS.

Consistent with the findings of this preliminary trial, an RCT in 23 community-dwelling adults and a U.S. nonrandomized controlled trial of 14 patients undergoing dialysis reported significant declines in RLS symptoms in those assigned to a 12–16 week exercise program relative to those receiving usual care, with pre–post effect sizes ranging from 1.3[46] to 1.6.[68] A single-arm study of 25 outpatients with psychosocial impairment due to RLS also reported significant, although more modest improvements in RLS symptoms and symptom severity following 8 weeks of cognitive behavioral therapy (CBT) (effect sizes 1.0–1.05).[69] Likewise, the significant improvements in sleep quality, mood, and perceived stress observed in this pilot study are comparable to those demonstrated in the authors' recent RCT regarding the effects of yoga in sedentary postmenopausal women with RLS.[19] The present findings are also consistent with improvements in sleep and mood reported in dialysis patients with RLS following a 16-week exercise program[68] and with the albeit more modest changes noted in patients with RLS patients with psychosocial impairment following 8 weeks of CBT.[69] In contrast to an earlier study conducted by the present authors in older inactive women with RLS, there were no changes in blood pressure observed in this study, perhaps reflecting the differing profiles of the two study populations. Relative to those in the authors' previous RCT,[19] participants in the current study were younger (58.9 ± 2.9 versus 49.5 ± 3.9), had lower baseline blood pressure (systolic blood pressure 141.9 ± 4.7. versus 124.3 ± 5.2 mm Hg), lower prevalence of hypertension (45.0% versus 7.8%), and were more likely to be active (0% versus 60%) (all p's < 0.01); thus, floor effects are possible, and may help explain discrepancies in the present findings.

Mechanisms underlying the improvements observed in this study remain speculative. However, as detailed in the authors' recent article, yoga may benefit those suffering from RLS via several possible inter-related pathways.[19] For example, yoga may attenuate RLS symptoms and symptom burden by reducing sympathoadrenal and hypothalamic-pituitary-adrenal axis activation, restoring parasympathetic/sympathetic balance, and improving cardiometabolic function, factors recently linked to RLS etiology and progression and associated, in a reciprocal manner, with sleep impairment, stress, and mood disturbance.[2,70–72] In addition, data from recent neuroimaging and neurophysiological studies[73–76] suggest that yogic practices may, by selectively activating specific neurochemical systems implicated in RLS, likewise promote beneficial changes in autonomic, neuroendocrine, and metabolic function, and in mood, sleep, and pain processing, changes that may, in turn, contribute to reduced RLS symptoms and symptom burden.[19]

Strengths and limitations

Strengths of this study include the community-based design, relatively high participant retention, and overall excellent adherence. All women tested in the moderate to severe range, with symptom scores comparable to those of participants in other RLS intervention trials.[77–80] In addition to RLS symptom change, change in sleep quality and mood were also assessed, since these are both recommended endpoints for clinical trials of RLS.[7]

This pilot study also has several limitations. Sample sizes were small, substantially limiting power and generalizability. However, participants nonetheless demonstrated significant and striking improvement in RLS symptoms and symptom severity, as well as in other clinically important outcomes. The study population was limited to overall healthy women and comprised predominantly non-Hispanic white adults; therefore, findings may not be generalizable to men or to clinical, minority, or other populations. Diagnosis of RLS was based on self-report, and some diagnostic error is thus possible. However, the requirement that participants meet all four essential criteria, coupled with comprehensive screening to exclude possible mimics, renders this possibility less likely. Perhaps most important, the study lacked a control group, and participants could not be masked to treatment, raising the possibility that the present findings could be due in part to a placebo effect. While the IRLS overall is considered vulnerable to placebo effects, the IRLS severity subscale, which showed a significant and substantial decline in this study, is thought to be less sensitive.[44] In addition, adjustment for treatment expectations did not materially alter findings, suggesting that this factor did not explain the observed improvements in any of the clinical endpoints assessed. Likewise, observed effect sizes were considerably larger than would be expected with placebo in this population,[81] and improvements in RLS symptoms were strongly and positively correlated with the frequency and duration of yoga home practice, suggesting a potential causal association between yoga practice and decline in RLS symptom severity.

Conclusions

These preliminary findings suggest that yoga may offer a safe and effective intervention for reducing RLS symptoms

and symptom severity, sleep and mood disturbance, and perceived stress in women with RLS. Larger, controlled trials are needed to confirm these benefits in this and other adult populations with RLS and to evaluate potential underlying mechanisms.

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Disclosure Statement

No competing financial interests exist.

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