ORIGINAL RESEARCH

Novel Exercises for Restless Legs Syndrome: A Randomized, Controlled Trial

Eloise G. Harrison, BPhysio(hons),
Jennifer L. Keating, PhD, GradDip ManipPT, BAppSc (Physio), and
Prue Morgan, PhD, MAppSc (research), BAppSc (Physio), Grad Dip Neuroscience

Background: Restless legs syndrome (RLS) is a sensorimotor disorder that can have a considerable negative impact on quality of life and sleep. Management is primarily pharmacological; nonpharmacological options are limited. The objective of the present study was to determine the effect of tension and trauma release exercises on RLS severity compared with discussion group controls.

Methods: Participants satisfied RLS diagnostic criteria, did not have acute mental health conditions, and reported being physically able to complete exercises. Eighteen participants (stratified by age and RLS severity) were randomly allocated with concealment to once-weekly sessions of trauma release exercises (n = 9), exercises to stretch and fatigue lower limb muscles and invoke therapeutic tremors, or control discussion groups (n = 9) for 6 weeks. Outcomes assessed at baseline and each week were International Restless Legs Syndrome Rating Scale scores, global RLS severity ratings (visual analog scale, 0 to 10), global stress ratings (visual analog scale, 0 to 10), Pittsburgh Insomnia Rating Scale scores and Major Depression Inventory scores.

Results: There were no significant between-group differences at baseline except for more severe global RLS scores for controls (*P* = .003). There were no significant between-group differences at week 6 on any outcome. Significant improvements across time were seen for both groups on all outcomes.

Conclusions: In this exploratory study, tension and trauma release exercises and attending discussion groups were associated with similar outcomes. Participants in both groups improved similarly across time. Future research might establish score stability across a prolonged baseline before commencing intervention. (J Am Board Fam Med 2018;31:783–794.)

Keywords: Exercise Therapy, Lower Extremity, Mental Health, Quality of Life, Restless Legs Syndrome, Visual Analog Scale.

Restless legs syndrome (RLS), also known as Willis-Ekbom disease, is a sensorimotor disorder characterized by an uncomfortable urge to move the legs.[1] The urge to move is usually accompanied by unpleasant sensations in the legs, which worsen in the evening or night and during rest or inactivity, and are relieved by movement.[2] RLS can have considerable negative impact on quality of life and sleep. People with RLS have a higher than typical prevalence of anxiety and/or depression, and approximately 50% to 85% experience troubling insomnia.[3] RLS has a prevalence of 5% to 15% in the general population,[3] however, is underdiagnosed[2] and often inadequately treated.[4] It is more common in women[5] and prevalence increases with age.[6] RLS may be primary (idiopathic), or secondary and associated with conditions such as iron deficiency anemia, pregnancy or end-stage renal disease.[2] As secondary RLS is addressed through management of the underlying condition, this study focused on idiopathic RLS. Periodic limb movements in sleep (PLMS) are repetitive movements of the lower extremities during sleep. Although PLMS is not specific to RLS and not an essential diagnostic crite-

rion for RLS, a high PLMS index (number of PLMS per hour of sleep) supports a diagnosis of RLS.[2]

Medications for RLS can have serious side effects such as augmentation. This worsening of symptoms[2] is associated with dopamine agonists[7] and levodopa.[8,9] Many people with RLS therefore seek alternate nonpharmacological options. However, high-quality guidelines published by Aurora et al[10] (AGREE assessment "recommended"[11]) concluded that there was insufficient evidence for nonpharmacological therapy. A recent review by the authors of eleven randomized trials[12–22] concluded that some nonpharmacological interventions including exercise and acupuncture seem beneficial for RLS symptoms; however, few studies were identified and the level of evidence was often not high. Given common unwanted side effects associated with pharmacological management, nonpharmacological treatment options may be valuable for symptom reduction.

Tension and trauma release exercises (TRE) invoke what protagonists refer to as "neurogenic tremors."[23] Although these exercises are promoted in Australia[24] and the United States,[25] reports of positive effects on RLS outcomes are anecdotal. Berceli and Maria[26] hypothesized that involuntary movements and tremors in the body may be part of the body's natural mechanism to relieve tension and restore homeostasis. TRE practitioners suggest that tremors, invoked by activities that fatigue muscles, behave to some extent like clonus. This clonus-like tremor seems to be under voluntary control, continuing until an attempt is made to overcome it. TRE practitioners report that tremors, once established, can increase in magnitude and "spread" to other parts of the body that have not undergone fatiguing exercises. The technique of allowing tremor is the focus of the TRE program. Berceli[23] proposed that the exercises release deep chronic tensions in the body. Proposed claims regarding the potential merit of TRE for RLS are built on the unsubstantiated hypothesis that RLS may be the result of chronic physiologic stress to the body. If the exercises release chronic tension, they may affect symptoms.

The primary objective of this exploratory trial was to investigate the effect of TRE on RLS severity compared with discussion group controls. Secondary aims were to compare TRE to control conditions on the outcomes of sleep quality, global stress, and depression. The null hypothesis was that there would be no difference in RLS severity scores for those allocated to intervention or control conditions.

Methods

Trial Design

The study was a randomized controlled trial comparing TRE to a control group for participants with RLS. The intervention involved participation in a weekly exercise group. The control condition involved attending a discussion group on the same days, at the same time, and for the same duration as the exercise group. Measurements of key outcomes were collected before each session for both groups. The study was reported using the CONSORT recommendations.[27] Institutional ethics approval was granted (Monash University Human Research Ethics Committee CF14/1931-2014000986). The trial was registered in the Australian New Zealand Clinical Trials Registry, ACTRN12615000011583.

Participants

Participants were included if they satisfied all 4 RLS diagnostic criteria,[2] did not have an acute mental health issue, and reported that they would be physically able to complete the exercises. The study took place at Monash University Peninsula Campus–Victoria from March to May 2015.

Recruitment

Participants were recruited using internet advertising on the Trauma Release Exercises Australia Web site, in the *Sleep Disorders Australia* newsletter, and through advertisements at Monash University and local physiotherapy and general practice clinics. To counter the potential for coercion, only administrative staff in clinics could invite participants to join the study. Interested participants were screened for eligibility by phone. Those who met inclusion criteria were advised that they would be randomly assigned to either immediate or a delayed intervention and informed regarding the nature of the intervention and control conditions, attendance requirements, and program location. They were also advised that if they were not allocated to the intervention group, they would be enrolled in a 6-week exercise program commencing after the 6-week trial. Those who remained interested were enrolled after providing written informed consent.

Table 1. Trauma Release Exercises (TRE) Procedure Summary

	Lead in Exercises	Floor Exercises
Duration	Approximately 30 minutes	Approximately 15 minutes
Purpose	Fatigue and stretch muscle groups in a sequence to assist invoking tremors	Cause adductor fatigue and invoke tremors
Exercises	In standing:	Isometric hip abductor exercises:
1	Ankle pronation/supination	"Butterfly position": Supine, feet together, hips held in abduction
2	Calf raises	As fatigue or tremor begins, knees are sequentially moved closer together for 2 minute sustained holds while tremor continues
3	A quadriceps exercise	Legs parallel with feet flat on the floor
4	Hamstring stretch	
5	A psoas exercise	
6	Wall squats	
Home exercise recommendation	At least once per week	At least twice per week

They were asked to continue as far as practicable with their current management.

Interventions

Trauma Release Exercises

The intervention consisted of an initial 3-hour introductory session, and a 1-hour session each week for the following 5 weeks (total 6 weeks). The program was designed to allow repeated reinforcement of the exercises and optimize exercise mastery, so participants could use the exercises in ongoing self management. Exercise instruction was delivered by a certified instructor. Participants were taught to invoke "self-induced therapeutic tremors" using structured progressive exercises. Table 1 summarizes the full procedure which has 2 parts: 1) preparatory, and 2) floor-based exercises. Participants were able to stop self-induced tremors by either straightening their legs to take the hip adductors off load, or consciously holding the limbs still. The process was fully self regulated and participants were educated to maintain comfort and control throughout. Participants could therefore self manage their fatigue and emotional levels. When participants were able to start and stop the self-induced tremors, they were encouraged to practice the exercises and invoke tremors at home. Participants were encouraged to use the floor-based exercises alone as needed when symptoms were acute.

Control Group

Participants in the control condition participated in discussion exploring the lived experience of RLS.

These sessions involved seated discussion and did not include active exercise. Discussions were led by an experienced facilitator and audio recorders captured the dialog. Session duration was matched to intervention group conditions. In the first week (3-hour session), participants were encouraged to talk about their condition in response to open questions. Discussion focused on participant experiences of the condition, and how they managed symptoms. Issues identified in week 1 were explored during subsequent sessions (5 × 1–hour duration). Qualitative analyses of discussion group data will be reported elsewhere.

Outcome Measures

Primary Outcome Measures

The primary outcome measure for RLS severity was the International Restless Legs Syndrome Rating Scale (IRLS), a 10-item questionnaire developed through expert evaluation of potential items. It has high internal consistency, interexaminer reliability, and test-retest reliability over a 2-to-4-week period,[28] and is considered the standard measure of RLS severity.[29]

Secondary Outcome Measures

RLS has also been associated with insomnia and psychological comorbidities such as depression and anxiety, possibly due to the influence of symptoms such as fatigue, sleep disturbance, and poor concentration.[3] Outcome measures for sleep, anxiety, and depression were therefore included. Two visual analog scales (0 to 10) were used, 1 for global RLS

severity and 1 for global stress level ratings, where 0 indicated no RLS symptoms or no stress and 10 indicated very severe symptoms. The Major Depression Inventory (MDI) is a self-rated inventory developed to measure depression. The MDI has been reported to have acceptable sensitivity and specificity.[30] The following MDI response options were used: all the time (4), most of the time (3), slightly more than half of the time (2), some of the time (1), at no time (0). No clear recommendations for assessing sleep related outcomes in RLS have been proposed.[31] The Pittsburgh Insomnia Rating Scale (PIRS) is a 65-item scale designed to assess severity of insomnia.[32] Sleep quality in this study was measured using the modified 20-item version (PIRS-20). The 20 items were selected to include daytime and night time items, and excluded the influence of items assessing symptoms of depression and anxiety.[33] It focused on sleep and wake symptoms as they occurred in the week before completion of the instrument. The PIRS-20 has been reported to be reliable (Cronbach's α, 0.95, =; test-retest reliability, 0.92).[33] Each week during the study, all participants were asked to report whether RLS symptoms were experienced in their arms, legs, or both.

Participants in the intervention group completed a weekly exercise diary to monitor home exercise adherence. Attendance data and adverse events of the intervention and control conditions were collected and recorded.

Participant Demographic Data
Data on participant characteristics were collected for both groups using an online survey 1 to 2 weeks before commencement of the study, and included age, gender, family history of RLS, medications, other therapies, comorbidities, and Human Activity Profile (HAP) scores. The HAP provided 2 measures of baseline physical activity. The Maximum Activity Score (MAS) is the number of the highest energy-expenditure item marked, and the Adjusted Activity Score is the MAS minus the total number of lower scoring items that the person has stopped doing.[34] IRLS scores were also collected at this time to stratify participants by severity of RLS during random allocation.

When Outcomes Were Assessed
Baseline measures were taken immediately before commencement of the intervention and control

sessions, and included IRLS scores, global RLS scores (0 to 10), global stress scores (0 to 10), PIRS scores and MDI scores (week 0). All outcomes were reassessed immediately before each exercise and discussion group session (weeks 1 to 5) and collected using an online survey if participants were not able to attend. Post-intervention data (week 6) were collected online.

Sample Size
Sample size was determined using power analysis for the outcome of IRLS scores (scale 0 to 40) based on results of similar studies where physical interventions for RLS were compared with control groups.[12,18,20] With a sample of 6 in each group the study would be powered (0.8) to detect a difference between means of 9/40 IRLS points when α was set at 0.05 using a 2-tailed t-test assuming a standard deviation of 5.9. Mean changes and variance estimates of this magnitude comparing baseline to postintervention scores are typical of those observed in similar studies.[12,18,20] Allowing for 20% attrition we aimed to recruit at least 8 people to each group (total n = 16).

Randomization
Sequence Generation, Concealment, and Allocation
Participants were stratified for RLS severity (IRLS score > 21, severe/very severe and < 20, mild/moderate RLS) and age (under 50 and over 50 years old) to limit the potential for confounding variables being assigned unequally to groups.[35] Participants were then randomly allocated to intervention or control groups using computer-generated blocks of 6 or 8 to limit the possibility of chance imbalances with small samples. After all participants had been enrolled, a research assistant completed the randomization procedures and provided the research team with sealed sequentially numbered envelopes. The research team then advised participants of allocation to the intervention or control group.

Statistical Methods
Data were analyzed using intention to treat. Missing data were imputed using the last observation carried forward method, where missing values were replaced by the last-known value before the participant was lost to followup.[36]

At baseline, χ^2 tests were used to compare groups for gender, family history, medications, and

Figure 1. Consort flowchart. TRE, trauma release exercises.
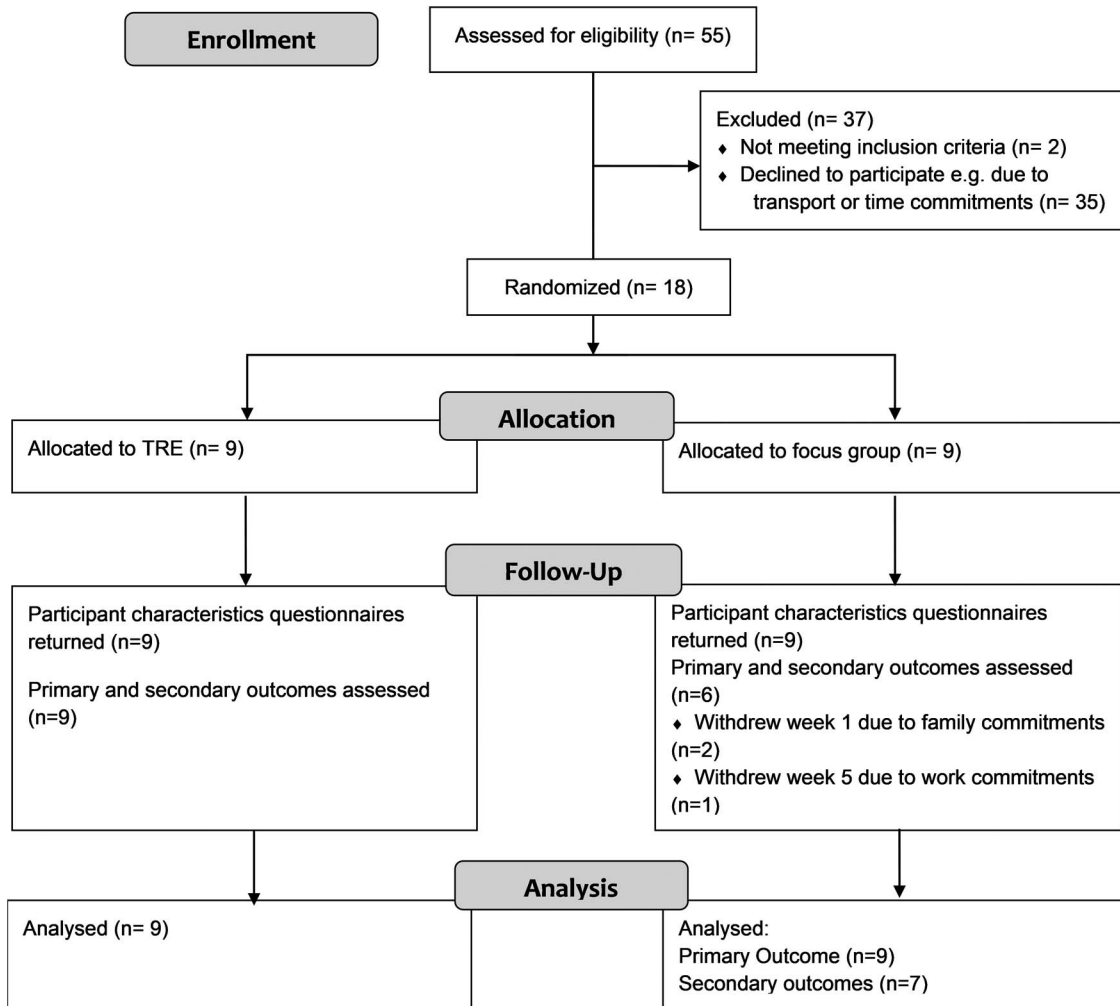
alternative therapies. Independent *t*-tests were used to compare age, duration of RLS, and HAP scores. Intervention and control groups were compared for primary and secondary outcomes at baseline using independent *t*-tests and post intervention (week 6) using ANCOVA[37] with baseline scores as covariates in the model ($\alpha = 0.05$). The magnitude of between-group differences was interpreted using the mean difference and its associated 95% CI.

Two-way ANOVAs (group × time), with repeated measures on time, were conducted to examine the effect of group, time, and group by time interactions on outcomes. Dunnett's correction for multiple comparisons was applied to maintain the family-wise error at an α of 0.05 when baseline values were compared with multiple follow-up assessments. Multiple comparisons were made to determine whether baseline scores differed significantly from measurements taken at each of the

subsequent 6 weeks using multiplicity adjusted *P* values.

Sample size analysis was conducted to determine the likely outcomes had the sample been larger.

Results

Figure 1 presents an overview of participant flow. Fifty-five participants expressed interest and were assessed for eligibility. Two participants were ineligible as they felt that they would not be physically able to complete the exercises. Eighteen participants were enrolled. As participants completed the online survey 1 to 2 weeks before commencement of the study, which included the IRLS but did not include secondary outcomes, only IRLS scores could be analyzed using imputation of missing data for the 2 participants who withdrew before week 1. All participants received intended treatment and

were analyzed for the primary and secondary outcomes. The trial ran from March to May 2015.

The intervention and control groups had attendance rates of 85% and 79%, respectively across the 6-week trial period. During the study, 62.5% of all participants experienced RLS symptoms in the legs only, while 37.5% of participants experienced symptoms in both the arms and the legs at some time during the study. On average, 65% of intervention group participants adhered to the recommended home exercise program. No participants withdrew due to harms. One participant in the intervention group experienced some emotional discomfort during the exercise program and was initially unable to control the tremoring. The participant was provided with individualized technique modification and debriefing, and was able to continue. No adverse events occurred in the control group.

Participant Characteristics
Participant characteristics are presented in Table 2. There were no significant between-group differences at baseline for any characteristic except for more women in the intervention group. Alternative therapies for RLS currently or previously used by participants included supplements such as magnesium, vitamins and fish oil, as well as yoga, chiropractic, massage, a homeopathic spray, and a low-FODMAP (low-fermentable oligosaccharides, disaccharides, and monosaccharides, and polyols) diet.[38]

Baseline Primary and Secondary Outcomes
Baseline data for primary and secondary outcomes are presented in Table 3. There were no significant between group differences at baseline on any outcome with the exception of global RLS (0 to 10) scores, with a significantly greater severity reported by control group participants.

Between-Group Analyses
Figure 2 presents intervention and control group scores over time for each outcome.

Data for primary and secondary outcomes at 6 weeks are presented in Table 4. No significant between group differences were identified on any outcome after the intervention. There were no significant group by time interaction effects for any outcome. There were significant effects attributable to time on all outcomes.

The primary outcome of IRLS scores for both groups changed during the 6 weeks of the study (mean [SD] change scores intervention, 6.9 [5.7]; control, 5 [4.6]). Sample size estimates using these statistics indicated that around 234 participants would be required for these small between-group differences to achieve significance if a future study replicated this work.

Discussion
To our knowledge, this is the first trial exploring the effects of TRE for RLS. There were minimal associated harms with the intervention. There were no significant differences between intervention or control groups at week 6 on any outcome, and no significant group by time interaction effects on any outcome. This was unlikely to be due to the effect of small sample size on uncertainty in estimates, because both final outcomes, and the way that scores changed across time, were similar for both groups. These findings held for both primary and secondary outcomes. Although a criticism of this study might be the small sample size, it represents a responsible preliminary analysis of the likely benefits of conducting a larger study, particularly in the light of the speculative nature of claims regarding effects of TRE.

Despite small numbers, the study did reveal significant effects attributable to time for all outcomes. The uniform behavior of the intervention and control groups across time was particularly interesting. If the effects across time were due to the intervention (exercise based), then the control condition (nonexercise based) seems to have had very similar effects on RLS severity, sleep quality, and depression. According to Ondo et al,[39] a 6-point change in IRLS score is clinically meaningful. In our study, 6 participants in the intervention group and 3 participants in the control group reported a change that could therefore be considered to be clinically meaningful. Important changes in symptoms were therefore not uniquely found in the intervention group.

Explanations for the similar changes across time in both groups include the possibility that participants changed the way they reported symptoms because they repeatedly completed the same assessment forms and gained familiarity with reporting procedures. The impact of assessment may have also changed participant perception of symptoms.[40]

Table 2. Participant Characteristics at Baseline

Baseline Data	Intervention (n = 9)	Control (n = 9)	P Value
Age (years)			
Mean	56.2	60.4	.45*
SD	9.1	12.5	
Duration of RLS (years)			
Mean	20.1	17.1	.7*
SD	18.1	11.9	
HAP (MAS)			
Mean	77.1	78.6	.78*
SD	7.0	11.2	
HAP (AAS)			
Mean	72.2	72.3	.99*
SD	9.3	15.2	
Gender			
Male			.02
n	1	6	
%	(11%)	(67%)	
Female			
n	8	3	
%	(89%)	(33%)	
Family history			
RLS			.26
n	3	1	
%	(33%)	(11%)	
Parkinson's disease			.53
n	2	1	
%	(22%)	(11%)	
Medications			
Yes			.11
n	4	1	
%	(44%)	(11%)	
No			
n	5	8	
%	(56%)	(89%)	
Other therapies			
Yes			.63
n	4	3	
%	(44%)	(33%)	
No			
n	5	6	
%	(56%)	(67%)	
Comorbidities	P1: Sciatica, OA ankle, 'Cold feet' P2: Anxiety, Depression, Shoulder injury P3: OA knees	P10: Depression, Fibromyalgia, Reflux P11: HT High cholesterol, High iron levels, Joint pain, Enlarged prostate P12: Asthma,	

Continued

Table 2. Continued

Baseline Data	Intervention (n = 9)	Control (n = 9)	P Value
		Fibromyalgia,	
		RSI arms/wrists,	
		Arthritis back, neck, foot,	
		Osteopenia,	
		Coeliac disease	

AAS, adjusted activity score; HAP, human activity profile; HT, hypertension; MAS, maximum activity score; OA, osteoarthritis; P1, P2, P3, etc., participant 1, 2, 3, etc.; RLS, restless legs syndrome; RSI, repetitive strain injury; SD, standard deviation.
*t tests, other p values derived from χ^2 tests.

Regression toward the mean[41] might also explain observed effects. People may have considered participation in research into RLS because their symptoms were unusually severe. A decrease in severity would be expected following the point in time when severity was particularly high, providing the appearance of improvement attributable to study conditions. Future trials investigating therapy for RLS might include a prolonged baseline phase with monitoring to identify when scores stabilize. This would improve confidence in the likely sources of changes in scores across time.

Alternatively, the effects across time for both groups may have been attributable to the effect of the group environment. It is possible that informal or formal sharing of experiences and strategies for managing RLS over the 8 face-to-face hours of the study reduced perception of the problem, or increased confidence in managing the condition, resulting in participants in both groups reporting ongoing improvement during the study. Benefits of group support have been reported for others with chronic illness,[42] particularly less well understood conditions such as chronic fatigue syndrome.[43] There may be considerable benefit to improving our understanding about whether group interaction plays a role in therapeutic effects for people with RLS. Not only are the specific effects of interest in supporting people with this condition, but the impact of group interaction needs to be partitioned in outcomes analysis in future trials of therapies. None of the eleven randomized controlled trials investigating nonpharmacological therapies for RLS[12–22] have provided insight into the potential effects of group therapy on symptoms, so this seems to be an important target for future attention.

Bias was minimized in this study by addressing key criteria argued as essential in high-quality randomized controlled trials.[44] Due to the nature of the intervention, participant and therapist blinding was not possible, and this meant that the self-reported outcome assessment was not blind.[44] Estimations of RLS duration cannot be considered

Table 3. Baseline IRLS, Global RLS, Global Stress, PIRS and MDI Scores for the Trauma Release Exercises (TRE) and Control Groups

Outcome	TRE (n = 9)		Control (n = 7)		P Value*	Difference Between Means	95% CI
	Mean	SD	Mean	SD			
Primary							
IRLS score (0 to 40)	18.1	7.5	20.9	3.2	.4	2.8	−3.4 to 8.9
Global RLS severity (VAS, 0 to 10)	3.8	1.6	6.4	1.1	.003	2.7	1.0 to 4.3
Secondary							
Global stress (VAS, 0 to 10)	4.7	2.9	5.1	3.1	.8	0.5	−3.0 to 3.9
PIRS-20 score (0 to 60)	26.2	10.3	21.9	14.1	.5	4.4	−18.3 to 9.6
MDI score (0 to 48)	11.1	6.2	9.6	5.5	.6	1.5	−8.4 to 5.3

IRLS, International Restless Legs Syndrome Rating Scale; MDI, Major Depression Inventory; PIRS-20, Pittsburgh Insomnia Rating Scale (20 item); VAS, Visual Analogue Scale; SD, standard deviation.

Figure 2. Baseline to post-intervention plot of International Restless Legs Syndrome Rating Scale (IRLS), global restless legs syndrome (RLS), global stress, Pittsburgh Insomnia Rating Scale (PIRS), and Major Depression Inventory (MDI) scores for trauma release exercises (TRE) and control groups. A, IRLS, scores over time. B, global RLS (Visual Analogue Scale [VAS], 0 to 10) over time. C, global stress (VAS, 0 to 10) scores over time. D, PIRS scores over time. E, MDI scores over time.
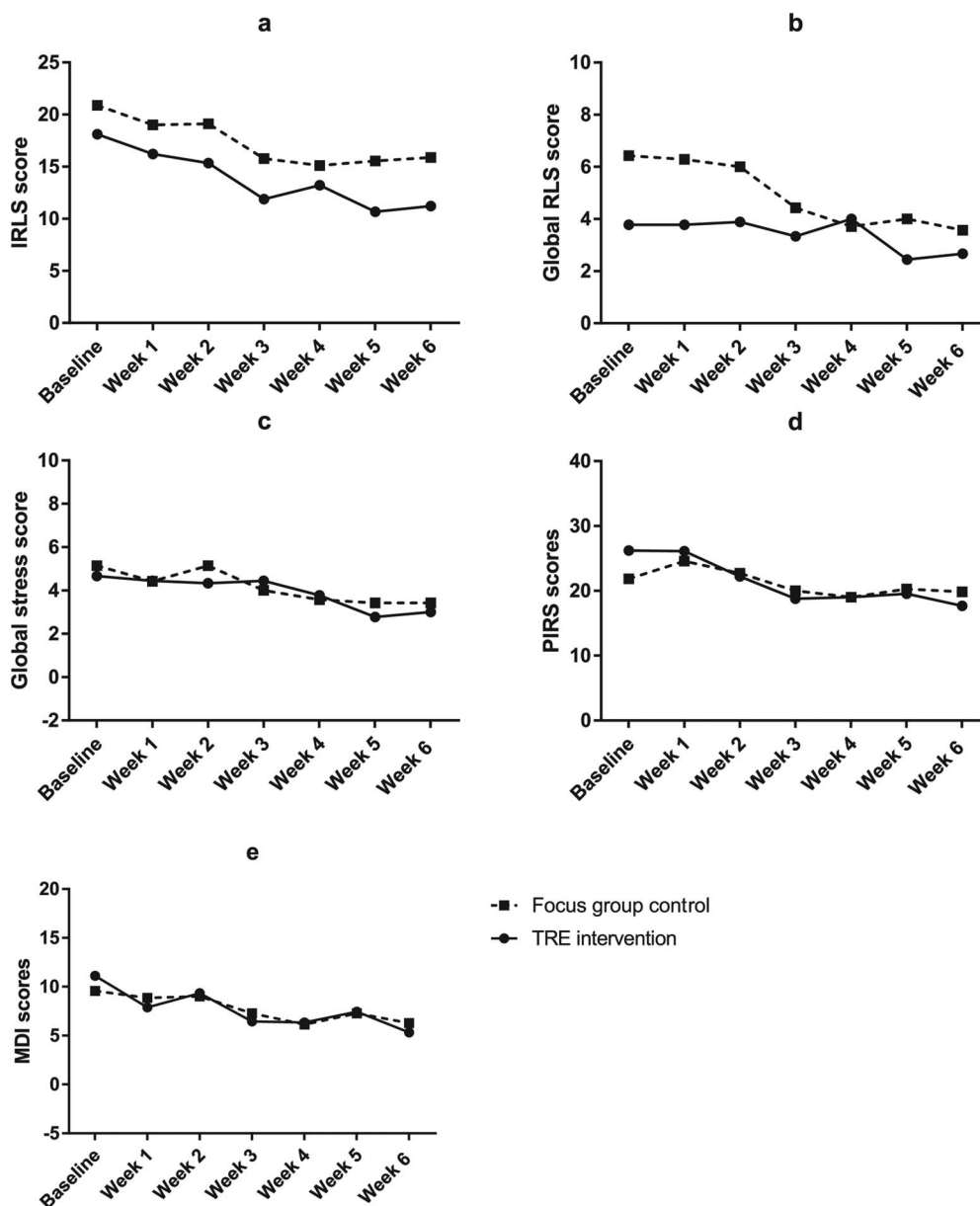
accurate given the poor recall of a number of participants, and therefore groups may have been different at baseline for duration of complaint. Generalizing these results to a different age group, RLS severity, or environment should be undertaken with caution.

Participants were stratified for RLS severity and age, however, not for gender, resulting in significant differences between groups for percentage of male and female participants. It is unlikely these differences affected RLS scores, as no evidence indicates gender-specific differences in clinical presentation of RLS.[45] Based on outcome measurements, there appeared to be a lot of variability in the presentation of RLS, and this should be considered in addition to effect sizes when considering sample size estimates. A SD of 5.85 for IRLS scores was used in the power estimates, and the baseline

Table 4. Post-Intervention IRLS, Global Restless Legs Syndrome (RLS), Global Stress, PIRS, and MDI Scores for the Trauma Release Exercises (TRE) and Control Groups

Outcome	TRE (n = 9)		Control (n = 7)		P Value*	Difference Between Means	95% CI
	Mean	SD	Mean	SD			
Primary							
IRLS score (0 to 40)	11.2	8.4	15.9	4.5	.36	4.7	−2.5 to 11.8
Global RLS severity (VAS 0 to 10)	2.7	2.4	3.6	1.6	.56	0.9	−1.5 to 3.3
Secondary							
Global stress (VAS, 0 to 10)	3	1.8	3.4	3.1	.85	0.4	−2.4 to 3.3
PIRS-20 score (0 to 60)	17.7	12.1	19.9	12.9	.31	2.2	−12.2 to 16.5
MDI score (0 to 48)	5.3	3.7	6.3	6.1	.55	1	−4.7 to 6.6

CI, confidential interval; IRLS, International Restless Legs Syndrome Rating Scale; MDI, Major Depression Inventory; PIRS-20, Pittsburgh Insomnia Rating Scale (20 item); SD, standard deviation; VAS, Visual Analogue Scale.
*P values adjusted using analysis of covariance for the main effect of group when baseline scores were added as covariates to the model.

SD in our combined sample was 5.95, suggesting that this was a reasonable parameter for sample size estimation. The last data point carried forward method for missing data may have introduced bias in analyzing data; however, conclusions did not differ when data were analyzed with and without imputed values.

Conclusions

Findings of this exploratory study provided preliminary data indicating that TRE and attending a series of discussion groups with other people with RLS were associated with similar outcomes. Both groups reported a reduction in RLS symptom severity and depression, and an improvement in sleep quality. The systematic reduction in RLS severity across the 6 weeks of the study highlights the need to collect baseline data over a prolonged period of time before intervening to counter the possible effects of regression to the mean and repeated assessment.

To see this article online, please go to: http://jabfm.org/content/31/5/783.full.

References

1. Garcia-Borreguero D, Kohnen R, Silber MH, et al. The long-term treatment of restless legs syndrome/Willis-Ekbom disease: Evidence-based guidelines and clinical consensus best practice guidance: A report from the International Restless Legs Syndrome Study Group. Sleep Med 2013;14:675–84.

2. Allen RP, Picchietti D, Hening WA, et al. Restless legs syndrome: Diagnostic criteria, special considerations, and epidemiology. A report from the Restless Legs Syndrome Diagnosis and Epidemiology Workshop at the National Institutes of Health. Sleep Med 2003;4:101–19.

3. Becker PM, Novak M. Diagnosis, comorbidities, and management of restless legs syndrome. Curr Med Res Opin 2014;30:1441–60.

4. Högl B, Kiechl S, Willeit J, et al. Restless legs syndrome: A community-based study of prevalence, severity, and risk factors. Neurology 2005;64:1920–4.

5. Berger K, Luedemann J, Trenkwalder C, et al. Sex and the risk of restless legs syndrome in the general population. Arch Intern Med 2004;164:196–202.

6. Bliwise DL. Periodic leg movements in sleep and restless legs syndrome: Considerations in geriatrics. Sleep Med Clin 2006;1:263–71.

7. Scholz H, Trenkwalder C, Kohnen R, et al. Dopamine agonists for the treatment of restless legs syndrome. Cochrane Database Syst Rev 2011;:CD006009.

8. Scholz H, Trenkwalder C, Kohnen R, et al. Levodopa for the treatment of restless legs syndrome. Cochrane Database Syst Rev 2011;:CD005504.

9. Allen RP, Earley CJ. Augmentation of the restless legs syndrome with carbidopa/levodopa. Sleep 1996;19:205–13.

10. Aurora RN, Kristo DA, Bista SR, et al. The treatment of restless legs syndrome and periodic limb movement disorder in adults—An update for 2012: Practice parameters with an evidence-based systematic review and meta-analyses: An American Acad-

emy of Sleep Medicine Clinical Practice Guideline. Sleep 2012;35:1039–62.

11. AGREE Collaboration. Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: The AGREE project. Qual Saf Health Care 2003;12:18–23.

12. Aukerman MM, Aukerman D, Bayard M, et al. Exercise and restless legs syndrome: A randomized controlled trial. J Am Board Fam Med 2006;19:487–93.

13. Altunrende B, Yildiz S, Cevik A, Yildiz N. Repetitive transcranial magnetic stimulation in restless legs syndrome: Preliminary results. Neurol Sci 2014;35: 1083–8.

14. Burbank F, Buchfuhrer M, Kopjar B. Sleep improvement for restless legs syndrome patients. Part 1: Pooled analysis of two prospective, double-blind, sham-controlled, multi-center, randomized clinical studies of the effects of vibrating pads on RLS symptoms. J Parkinsonism and Restless Legs Syndrome 2013;3:1–10.

15. Happe S, Evers S, Thiedemann C, et al. Whole body and local cryotherapy in restless legs syndrome: A randomized, single-blind, controlled parallel group pilot study. J Neurol Sci 2016;370:7–12.

16. Koo YS, Kim SM, Lee C, et al. Transcranial direct current stimulation on primary sensorimotor area has no effect in patients with drug-naïve restless legs syndrome: A proof-of-concept clinical trial. Sleep Med 2015;16:280–7.

17. Lettieri CJ, Eliasson AH. Pneumatic compression devices are an effective therapy for restless legs syndrome: A prospective, randomized, double-blinded, sham-controlled trial. Chest 2009;135: 74–80.

18. Mitchell UH, Myrer JW, Johnson AW, Hilton SC. Restless legs syndrome and near-infrared light: An alternative treatment option. Physiother Theory Pract 2011;27:345–51.

19. Mitchell UH, Johnson AW, Myrer B. Comparison of two infrared devices in their effectiveness in reducing symptoms associated with RLS. Physiother Theory Pract 2011;27:352–9.

20. Peters T, MacDonald R. Counterstrain manipulation in the treatment of restless legs syndrome: A pilot single-blind randomized controlled trial; the CARL Trial. Int Musculoskelet Med 2012;34:136–40.

21. Pan W, Wang M, Li M, et al. Actigraph evaluation of acupuncture for treating restless legs syndrome. Evid Based Complement Alternat Med 2015;2015: 343201.

22. Innes KE, Selfe TK. The effects of a gentle yoga program on sleep, mood, and blood pressure in older women with restless legs syndrome (RLS): A preliminary randomized controlled trial. Evid Based Complement Alternat Med 2012:294058.

23. Berceli D. Neurogenic tremors: A body-oriented treatment for trauma in large populations. Trauma und Gewalt 2010;4:148–56.

24. TRE Australia. Trauma Release Exercises, 2011. Available from: http://treaustralia.com.au. Accessed January 09, 2017.

25. TRE for all. Tension and trauma release exercises, 2018. Available from: https://traumaprevention.com. Accessed January 09, 2018.

26. Berceli D, Napoli M. A proposal for a mindfulness-based trauma prevention program for social work professionals. Complement Health Pract Rev 2006; 11:153–65.

27. Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials. BMJ 2010;340: c332.

28. Walters AS, LeBrocq C, Dhar A, et al. Validation of the International Restless Legs Syndrome Study Group Rating Scale for restless legs syndrome. Sleep Med 2003;4:121–32.

29. Walters AS, Frauscher B, Allen R, et al. Review of Severity Rating Scales for restless legs syndrome: Critique and recommendations. Mov Disord Clin Pract 2014;1:317–24.

30. Bech P, Rasmussen NA, Olsen LR, et al. The sensitivity and specificity of the Major Depression Inventory, using the Present State Examination as the index of diagnostic validity. J Affect Disord 2001; 66(2–3):159–64.

31. Walters AS, Frauscher B, Allen R, et al. Review of Quality of Life Instruments for the restless legs syndrome/Willis-Ekbom disease (RLS/WED): Critique and recommendations. J Clin Sleep Med 2014;10: 1351–7.

32. Moul DE, Pilkonis PA, Miewald JM, et al. Preliminary study of the test-retest reliability and concurrent validities of the Pittsburgh Insomnia Rating Scale (PIRS). Sleep 2002;25:A246–A7.

33. Sateia MJ, Buysse DJ. Insomnia: Diagnosis and treatment. London: UK: Informa Healthcare; 2010.

34. Davidson M, de Morton N. A systematic review of the Human Activity Profile. Clin Rehabil 2007;21: 151–62.

35. Kim J, Shin W. How to do random allocation (randomization). Clin Orthop Surg 2014;6:103–9.

36. Altman DG. Missing outcomes in randomized trials: Addressing the dilemma. Open Med 2009;3:e51–e53.

37. Vickers AJ, Altman DG. Statistics notes: Analysing controlled trials with baseline and follow up measurements. BMJ 2001;323:1123–4.

38. Ireton-Jones C. The low FODMAP diet: Fundamental therapy in the management of irritable bowel syndrome. Curr Opin Clin Nutr Metab Care 2017; 20:414–9.

39. Ondo W, Roth T, Grieger F, et al. Minimal clinically important improvement in IRLS total score in patients with restless legs syndrome: A post hoc analysis from a 6-month placebo-controlled US-

based study with rotigotine transdermal system (P02.059). Neurology 2013;80(7 Supplement).

40. McCambridge J, Witton J, Elbourne DR. Systematic review of the Hawthorne effect: New concepts are needed to study research participation effects. J Clin Epidemiol 2014;67:267–77.

41. Bland JM, Altman DG. Regression towards the mean. BMJ 1994;308:1499.

42. Davison KP, Pennebaker JW, Dickerson SS. Who talks? The social psychology of illness support groups. Am Psychol 2000;55:205–17.

43. Friedberg F, Leung DW, Quick J. Do support groups help people with chronic fatigue syndrome and fibromyalgia? A comparison of active and inactive members. J Rheumatol 2005;32:2416–20.

44. Maher CG, Sherrington C, Herbert RD, et al. Reliability of the PEDro scale for rating quality of randomized controlled trials. Phys Ther 2003;83: 713–21.

45. Gupta R, Ahmad S, Dhar M, et al. Clinical presentation of restless legs syndrome: Does the gender matter? Sleep Biol Rhythms 2014;12:180–6.