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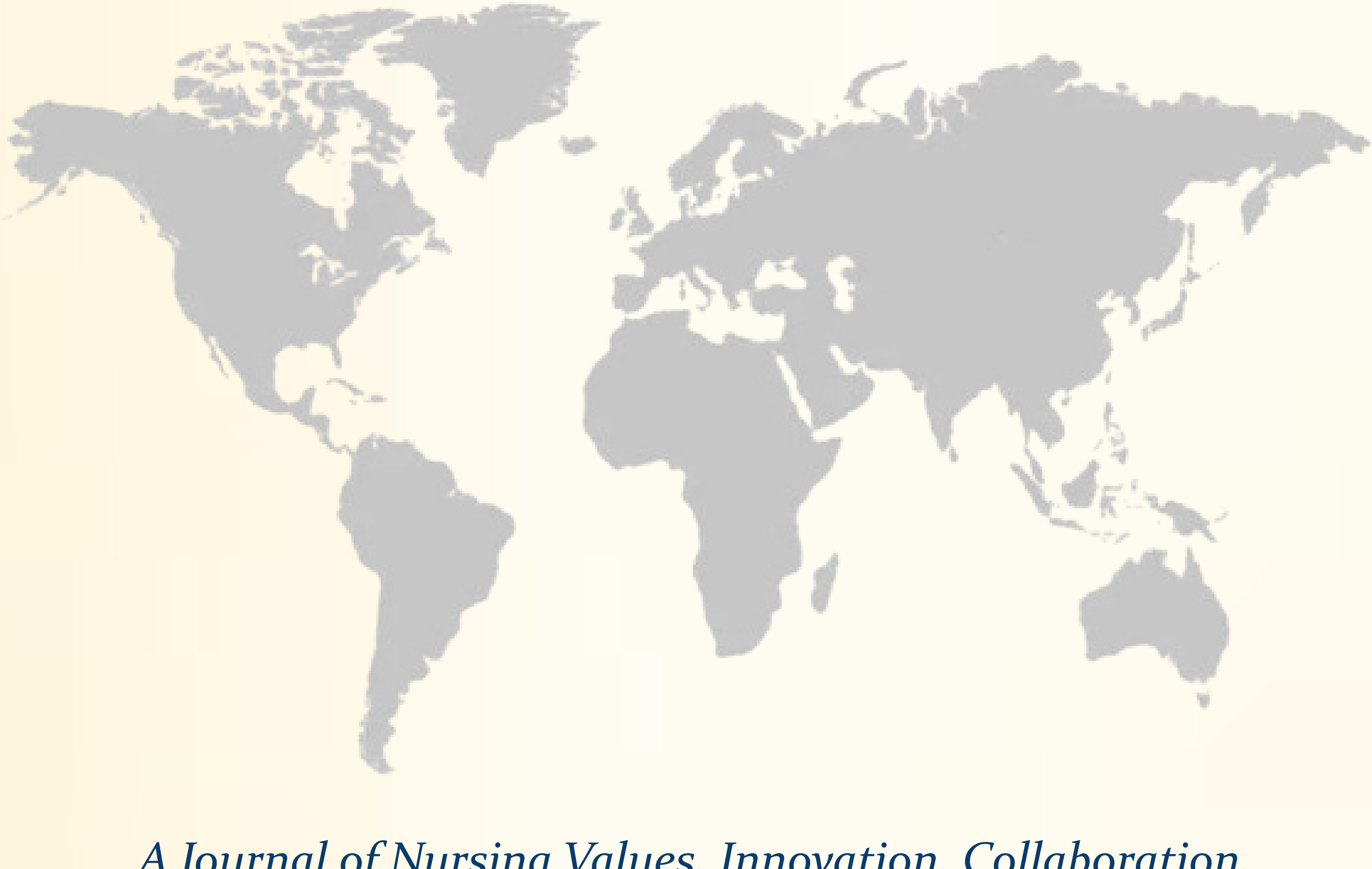

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Original Article

Effect of Intradialytic Resistance Exercise on Restless Legs Syndrome Among Hemodialysis Patients: A Pilot Randomized Controlled Trial

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Abstract

Background: Restless legs syndrome (RLS) is common and burdensome among patients undergoing hemodialysis (HD). Intradialytic exercise provides a pragmatic opportunity for symptom management; however, evidence on resistance exercise during HD remains limited.
Objective: This pilot study evaluated the effect of intradialytic resistance exercise on RLS severity in adults receiving maintenance HD.
Methods: A two-arm, parallel-group pilot randomized controlled trial was conducted in two HD units (January–April 2025). Adults on thrice-weekly HD for ≥3 months with at least moderate RLS (IRLS ≥11) were randomized 1:1 to intradialytic resistance exercise (IRE) or usual care. The IRE group performed supervised elastic-band exercises during the first 2 hours of HD, three times weekly for 8 weeks. Outcomes were assessed at baseline, week 4, and week 8. The primary outcome was the International Restless Legs Syndrome Scale (IRLS) score, analyzed using mixed-effects models.
Results: Forty-two participants were enrolled (IRE n=21; control n=21), with 90.5% completing the study. A significant group×time interaction was observed ($p<0.001$). At week 8, the IRE group demonstrated a clinically meaningful reduction in IRLS compared with controls (mean difference −8.4; 95% CI −11.7 to −5.0; Cohen's d=1.11). Adherence was high and no serious adverse events occurred.
Conclusions: An 8-week intradialytic resistance exercise program was feasible, safe, and effective in significantly reducing RLS severity among HD patients. Larger trials are warranted to confirm long-term benefits and implementation potential.

Keywords: restless legs syndrome; hemodialysis; intradialytic exercise; resistance training; symptom management; quasi-experimental study

INTRODUCTION

Restless legs syndrome (RLS) is a highly prevalent and distressing neurological disorder characterized by an uncontrollable urge to move the legs, especially during periods of rest or inactivity. It frequently affects individuals with chronic kidney disease (CKD), particularly those undergoing maintenance hemodialysis (HD). A recent meta-analysis by Zhou (1) reported that approximately 27.2% of HD patients experience RLS, a prevalence significantly higher than that observed in the general adult population, which ranges from 3% to 10%. RLS among HD patients is strongly associated with poor sleep quality, daytime fatigue, anxiety, depression, and impaired quality of life (QOL) (2). Furthermore, the chronic discomfort and disrupted sleep caused by RLS can negatively impact adherence to dialysis sessions and overall treatment satisfaction.

The pathophysiology of RLS in patients with CKD is multifactorial, involving dopaminergic dysfunction, brain iron deficiency, and peripheral nerve alterations aggravated by uremic toxins and chronic inflammation (3). Iron deficiency anemia, secondary hyperparathyroidism, and reduced dopamine receptor sensitivity in the central nervous system have all been implicated in the development of RLS among individuals on HD. Pharmacological management using dopaminergic agents, α2-δ ligands, or opioids may alleviate symptoms; however, their long-term use is limited by adverse effects, augmentation, and drug accumulation in renal impairment. Consequently, non-pharmacologic interventions, particularly exercise therapy, have emerged as promising complementary strategies to manage RLS in HD populations (4)

Intradialytic exercise (IDE) physical activity performed during dialysis sessions has been recognized as a feasible and safe intervention to improve multiple outcomes in HD patients, including cardiovascular health, sleep, fatigue, and mental well-being (5). Lee et al. (2024) found that both IDE and home-based exercise (HBE) improved cardiorespiratory fitness and QOL, emphasizing the practicality of exercise performed during dialysis.

With respect to RLS, recent studies have reported that regular physical exercise, particularly stretching and aerobic programs, significantly reduces symptom severity and improves sleep quality. Fauzi and Triaswati (2) demonstrated that eight weeks of intradialytic stretching training significantly decreased International Restless Legs Syndrome (IRLS) scores and improved sleep quality among Indonesian HD patients. Similarly Ismail (4), in a systematic review, concluded that aerobic and stretching exercises were effective in reducing RLS symptoms and fatigue levels among HD patients.

However, while IDE has proven benefits, the type, duration, and intensity of exercise that yield optimal symptom relief remain unclear. Previous research has mainly emphasized aerobic or flexibility exercises, with limited focus on resistance exercise modalities (6,7). As resistance exercise provides unique physiological and neuromuscular adaptations, such as enhanced muscle perfusion, increased oxygen utilization, and improved lower limb strength, it may be particularly beneficial for relieving the uncomfortable sensations and periodic limb movements associated with RLS (8).

Resistance exercise is an accessible, low-cost, and effective strategy that can be safely integrated into dialysis routines using elastic bands or ankle weights (8). Evidence shows that resistance training during dialysis improves muscle strength, sleep quality, and overall QOL among HD patients (9). The physiological mechanisms underlying its benefits include improved blood flow to lower limbs, increased endorphin release, reduced inflammation, and modulation of dopaminergic pathways all of which may reduce RLS symptoms (5). Nevertheless, most existing exercise interventions addressing RLS in HD populations have primarily adopted stretching or aerobic protocols. Only a few have examined the independent effects of intradialytic resistance exercise on IRLS severity as a primary outcome. Hence, despite its promising theoretical benefits, empirical evidence supporting resistance-based IDE for RLS reduction remains sparse.

Despite increasing evidence for the general effectiveness of exercise in HD, there is a notable gap regarding the specific role of intradialytic resistance exercise in reducing RLS severity. Most prior studies focused on flexibility or aerobic programs, while trials using resistance training have measured outcomes such as sleep quality or fatigue without evaluating IRLS scores. Systematic reviews (10) have highlighted substantial heterogeneity in exercise protocols, small sample sizes, and a lack of modality-specific evidence, calling for pilot trials to test resistance-based IDE protocols targeting RLS as a primary endpoint.

Addressing this evidence gap is timely and clinically relevant because resistance exercise can be easily implemented in dialysis centers using minimal equipment, offering a scalable, low-cost intervention to improve patient comfort and QOL. This pilot study aimed to evaluate the effect of intradialytic resistance exercise on RLS severity among adults undergoing maintenance hemodialysis. It was hypothesized that a structured resistance exercise program conducted during dialysis sessions would lead to a significant reduction in IRLS scores and demonstrate feasibility for larger, controlled clinical trials.

METHODS

Study design

We conducted a two-arm, parallel-group, pilot randomized controlled trial to evaluate the effect of intradialytic resistance exercise (IRE) on restless legs syndrome (RLS) severity among adults receiving maintenance hemodialysis (HD). Repeated measurements were obtained at baseline (T0), week 4 (T1), and week 8 (T2). A pilot RCT is appropriate for feasibility and preliminary efficacy estimation and supports modeling of longitudinal change with mixed-effects approaches in small samples (11,12). Randomization (1:1) used concealed, computer-generated permuted blocks (sizes 4 and 6) stratified by sex to minimize imbalance. Outcome assessors were masked to group assignment.

Sample

Participants were recruited consecutively from two HD units in West Java, Indonesia (three weekly sessions, 4 h/session). Eligibility was assessed by a nephrologist and trained research nurses. Inclusion criteria were (i) age 18–75 years; (ii) on thrice-weekly HD for ≥3 months; (iii) RLS diagnosis based on International Restless Legs Syndrome Study Group (IRLSSG) essential criteria; (iv) baseline International RLS Severity Scale (IRLS) score ≥11 (at least moderate severity). Exclusion criteria were unstable cardiovascular disease (e.g., recent myocardial infarction within 3 months), uncontrolled hypertension (pre-HD SBP > 180 mmHg or DBP > 110 mmHg), active infection, severe anemia (Hb < 7 g/dL), pregnancy, lower-limb ulcer or amputation precluding exercise, cognitive impairment precluding consent, or physician-advised exercise restriction.

For this pilot trial we targeted a sample sufficient to (a) assess feasibility (recruitment ≥ 60%, adherence ≥ 70%) and (b) provide preliminary effect estimates. A priori, using G*Power 3.1 for a repeated-measures ANOVA (within–between interaction; 2 groups × 3 time points), with medium effect size f=0.25f=0.25f=0.25, α = 0.05, power = 0.80, correlation among repeated measures = 0.50, and ε = 1, yields N = 34 (17/group). Allowing 20% attrition, the target was N = 42 (21/group) (Kang, 2021; Serdar et al., 2020). This size is consistent with guidance for small-N longitudinal (13). Consecutive sampling during routine HD sessions was used until the target was met, then randomized as above.

Intervention procedure

Participants in the IRE arm performed supervised, low-to-moderate intensity elastic-band resistance exercises during the first 2 hours of HD, three times per week, for 8 weeks. Exercises targeted major lower- and upper-limb muscle groups not affected by the fistula arm, using color-coded bands (light to moderate resistance). Each session comprised: 5-min warm-up; two sets of 10–15 repetitions for 6–8 movements (ankle plantar/dorsiflexion, knee extension/flexion, hip abduction/adduction, shoulder flexion/abduction), 60–90 s rest between sets; and 5-min cool-down. Intensity was titrated to Borg RPE 11–13 while maintaining HD safety parameters (14,15). Adverse events and intradialytic blood pressure/heart rate were monitored each session.

Control participants received standard HD care (no structured exercise) plus printed advice on sleep hygiene and general physical activity per unit policy; they were offered the exercise handout after study completion.

Instruments

The International RLS Severity Scale (IRLS) is a 10-item, 5-point Likert questionnaire (total 0–40; higher =worse), covering symptom intensity/frequency and impact (16,17). Severity bands: 0–10 mild, 11–20 moderate, 21–30 severe, 31–40 very severe. The IRLS shows excellent reliability and responsiveness: ICC 0.87 (test–retest), inter-rater ICC 0.93–0.97, and α = 0.93–0.95. We used the self-administered IRLS (sIRLS) Bahasa Indonesia version produced via forward–back translation and content validation in Indonesian adults, which demonstrated satisfactory content validity and internal consistency (18). The IRLS minimally important difference is discussed by the IRLSSG as a threshold for clinical success in trials; recent methodology papers reinforce the use of anchor-based MIDs when available (19)

Procedure

The study protocol received ethical approval from the institutional review board (IRB) of STIKes Abdi Nusantara. Unit directors provided site permissions. Eligible patients received oral and written information; written informed consent was obtained prior to any procedures. Baseline assessments (IRLS, PSQI, covariates) were conducted pre-HD on a non-exercise day by blinded assessors. Randomization occurred after baseline. IRE sessions were delivered by physiotherapists/nurses trained in intradialytic exercise safety. Attendance and adverse events were logged each session. Mid-intervention (week 4) and post-intervention (week 8) outcomes were collected by masked assessors. At study end, participants completed a brief acceptability survey (5-point Likert items on comfort, perceived benefit, willingness to continue) and open-ended feedback to inform refinement (Lee et al., 2024). Participants in both arms continued their usual medications; any medication changes relevant to RLS.

Data management and quality assurance

Paper forms were double-entered into a REDCap database with programmed range checks. Missing items on IRLS/PSQI followed instrument guidance; otherwise, missingness patterns were examined and addressed analytically. Adherence was defined a priori as attending ≥70% of prescribed sessions.

Statistical analysis

Analyses followed intention-to-treat, with sensitivity per-protocol analyses (≥70% adherence). Descriptive statistics summarized baseline characteristics; between-group differences at baseline used t-tests/χ^2 as appropriate. The primary analysis modeled IRLS total scores across T0–T2 using a mixed-effects model for repeated measures (MMRM) with fixed effects for group (IRE vs control), time (categorical), and group×time, adjusting for prespecified covariates (age, sex, HD vintage, ferritin). Participant-specific random intercepts captured within-person correlation; an unstructured covariance was the default, with alternative structures (compound symmetry, AR) compared by AIC. Robust standard errors were used when residual assumptions were questionable.

Safety monitoring

Vital signs were monitored at 30-min intervals during HD per unit protocol; exercise was paused for symptomatic hypotension, leg cramps, chest pain, or technician concern. All adverse events were recorded and reviewed weekly by the clinical lead.

RESULTS

Participant characteristics

A total of 42 hemodialysis (HD) patients were enrolled between January and April 2025; all met eligibility criteria and were randomized equally to the intradialytic resistance-exercise (IRE) group (n = 21) and the control group (n = 21). Four participants (two per group) withdrew before week 8 because of relocation or hospitalization, yielding a completion rate of 90.5%. Baseline demographic and clinical characteristics were comparable between groups (Table 1). Mean age was 52.4 ± 10.3 years, and 57% were male. The median HD vintage was **5** years (IQR 3–7). There were no baseline differences in hemoglobin, ferritin, or dialysis adequacy (Kt/V) ($p > 0.05$).

Table 1. Baseline Demographic and Clinical Characteristics of Participants (N = 42)

Characteristic	IRE Group (n = 21)	Control Group (n = 21)	*p-Value*
Age (years), mean ± SD	52.6 ± 10.8	52.2 ± 9.9	0.91
Sex, n (%)			
Male	12 (57.1)	12 (57.1)	1.00
Female	9 (42.9)	9 (42.9)	
Education, n (%)			
≤ High school	11 (52.4)	12 (57.1)	0.75
> High school	10 (47.6)	9 (42.9)	
Employment, n (%)			
Employed	8 (38.1)	9 (42.9)	0.76
Unemployed/retired	13 (61.9)	12 (57.1)	
HD vintage (years), median [IQR]	5 [3–7]	5 [3–8]	0.84
Dialysis frequency (per week)	3	3	—
Hemoglobin (g/dL), mean ± SD	10.6 ± 1.1	10.4 ± 1.2	0.64
Ferritin (ng/mL), median [IQR]	305 [212–446]	298 [205–430]	0.87
Kt/V, mean ± SD	1.43 ± 0.21	1.39 ± 0.18	0.52
Comorbid diabetes, n (%)	7 (33.3)	8 (38.1)	0.74
Baseline IRLS score, mean ± SD	25.7 ± 4.2	26.3 ± 4.0	0.64
Baseline PSQI global, mean ± SD	10.6 ± 2.3	10.2 ± 2.1	0.67

Table 2. Comparison of Mean IRLS Scores Between Groups Across Study Time Points

Time	IRE Mean ± SE	Control Mean ± SE	Between-group Δ (95% CI)	*p-value*	Cohen's d
Baseline	25.7 ± 0.9	26.3 ± 0.8	−0.6 (−2.3 to 1.1)	0.52	0.07
Week 4	19.2 ± 1.0	24.8 ± 1.1	−5.6 (−8.5 to −2.7)	0.001	0.83
Week 8	14.5 ± 1.1	22.9 ± 1.3	−8.4 (−11.7 to −5.0)	< 0.001	1.11

Adherence and safety

Participants in the IRE arm attended a median of 93% (range 81–100%) of prescribed sessions, exceeding the predefined adherence criterion (≥ 70%). No exercise-related adverse events occurred. Transient mild leg cramps (n = 3, 14.3%) resolved with rest and did not require medical intervention.

Primary outcome: RLS severity (IRLS scores)

At baseline, the mean ± SD International Restless Legs Syndrome (IRLS) total score was 25.7 ± 4.2 in the IRE group and 26.3 ± 4.0 in controls ($p = 0.64$), indicating severe symptoms in both groups. The linear mixed-effects model for repeated measures (MMRM) revealed a significant group × time interaction ($F = 9.34$, $p < 0.001$), indicating greater improvement over time in the IRE group.

DISCUSSION

This two-arm, parallel-group pilot randomized controlled trial found that an 8-week intradialytic resistance-exercise (IRE) program produced a large reduction in RLS severity among hemodialysis (HD) patients compared with usual care. The adjusted between-group difference in International RLS (IRLS) scores at week 8 (Δ = −8.4 points; $p < .001$; Cohen's $d = 1.11$) indicates a clinically meaningful effect, supported by high adherence (median 93%) and favorable participant feedback. These findings strengthen the case for integrating structured resistance exercise into routine dialysis care for symptomatic relief.

Our results align with and extend the growing evidence that exercise reduces RLS burden in HD. A randomized trial from Indonesia showed that intradialytic stretching significantly reduced IRLS scores and improved sleep quality over eight weeks (2). A 2024 systematic review further concluded that aerobic and stretching regimens consistently attenuate RLS severity and improve related outcomes (4). Our study adds modalities-specific evidence by demonstrating that resistance exercise alone, delivered intradialytically with elastic bands, can achieve robust symptom reductions.

Beyond RLS symptoms, the broader HD exercise literature shows that intradialytic programs are feasible and can improve patient-centered outcomes, though results vary by modality, dose, and patient characteristics. The multicenter PEDAL RCT found that a six-month intradialytic aerobic program did not yield clinically important improvements in HRQoL in a deconditioned cohort, underscoring that not all exercise prescriptions are equally effective across outcomes. By contrast, more recent syntheses and trials report benefits of intradialytic training for physical function, sarcopenia indices, and fatigue (14,15). Our data complement these findings by targeting RLS severity as a primary outcome and isolating resistance work as the active component, which may be mechanistically relevant for RLS through improvements in lower-limb perfusion, muscle oxygen utilization, and neuromodulatory effects associated with strength exercise.

The magnitude of improvement observed here compares favorably with prior intradialytic exercise reports in HD. For example, stretching-based protocols typically report moderate IRLS reductions, whereas our resistance-based regimen yielded a large effect size at 8 weeks. In addition, the acceptability profile in our sample (95% willingness to continue; no serious adverse events) mirrors contemporary programmatic experiences in dialysis units, where supervised, in-chair protocols during the first half of dialysis optimize adherence and safety. Finally, our results sit within the broader epidemiologic context that RLS is common in HD with pooled prevalence estimates around one in four patients globally highlighting the need for scalable symptom management strategies (20,21). Given resource constraints in many HD centers, low-cost elastic-band resistance routines are attractive for implementation.

Clinical implications

Resistance exercises using elastic bands can be delivered during the first two hours of HD, supervised by nurses/physiotherapists, without disrupting routine care or vascular-access precautions, facilitating high adherence and patient safety. For patients with RLS, where pharmacologic options may be limited by augmentation or renal dosing which is IRE represents a low-risk adjunct that can meaningfully reduce symptom burden, potentially improving sleep quality, comfort during HD, and overall well-being. Elastic-band programs require minimal equipment and staff training, making them suitable for resource-limited units and compatible with multidisciplinary symptom-management pathways (22).

Study limitations

Several limitations warrant consideration. First, although randomization and assessor masking were implemented, this was a pilot trial with a modest sample size, limiting precision of effect estimates and generalizability. Second, the sample size was modest and the follow-up limited to 8 weeks; durability of benefits and dose–response relationships require confirmation in longer, adequately powered trials. Third, outcomes relied on self-reported instruments (IRLS; PSQI), which, despite established validity and sensitivity to change, may be influenced by expectation or reporting bias; future work should incorporate objective sleep metrics and neurophysiological or vascular endpoints to probe mechanisms. Fourth, blinding participants to a behavioral intervention is not feasible; however, we mitigated bias with masked outcome assessors and standardized measurement intervals.

CONCLUSION

In summary, an 8-week intradialytic resistance-exercise program was feasible, well accepted, and produced large reductions in RLS severity among HD patients compared with usual care. These findings, in the context of supportive literature on intradialytic exercise, position resistance training as a practical, scalable, and non-pharmacologic option for RLS management in dialysis units. Multicenter trials with longer follow-up, mechanistic endpoints, and economic evaluations are warranted to confirm efficacy, understand underlying pathways, and support widespread adoption.

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Author Contributions
AF: Conceptualization, study design, methodology, data collection, intervention supervision, data analysis, interpretation of results, manuscript drafting, and final approval.
FA: Methodology consultation, statistical analysis guidance, critical manuscript revision, and final approval.

Conflict of Interest
The authors declare that there is no conflict of interest regarding the publication of this article.

Data Availability Statement
The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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