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Effect of continuous progressive resistance training during hemodialysis on body composition, physical function and quality of life in end-stage renal disease patients: a randomized controlled trial

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Abstract

Objective: This study aimed to investigate the effect of continuous progressive resistance training on body composition, functional capacity and self-reported quality of life in end-stage renal disease patients.
Design: A randomized controlled trial.
Subjects: The study included 52 hemodialysis patients (aged 55.7 ± 14.03 years) randomized into exercise (progressive resistance training (PRT), $n = 28$) or control (CON, $n = 24$) groups.
Intervention: Patients randomized into the PRT group received prescribed strength exercises in two sets of 15–20 repetitions, in a repetition maximum training zone regime, thrice a week for 12 weeks, during hemodialysis. Patients randomized into the CON group received a sham-exercise with active mobilization of the arms and legs without load and progression.
Main outcome measure: Body composition using dual-energy X-ray absorptiometry (DXA), strength using handgrip dynamometry (HGS), repeated sit-to-stand test (STT), 6-minute walk test, flexibility and the SF-36 questionnaire (quality of life (QoL)) were assessed at baseline and at 12 weeks.
Results: Leg lean mass ($P = 0.04$, effect size (ES) of 0.56), bone mineral content ($P = 0.02$, ES of 0.65), leg strength in STT repetitions ($P = 0.01$, ES of 0.66) and flexibility ($P < 0.01$, ES of 1.03) were significantly

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improved in the PRT group compared to the CON group. Walking capacity, HGS and QoL were not different between the groups.

Conclusion: 12 weeks of PRT with a repetition maximum training zone regime provided significant load to increase leg lean mass and STT performance as well as bone mineral content, compared to the CON, which continued to deteriorate. There was lack of efficacy on walking test, HGS and QoL.

Keywords

Renal failure, hemodialysis, strength training, physical capacity, exercise

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Introduction

Individuals with chronic kidney disease undergoing hemodialysis have a complex syndrome comprised metabolic abnormalities which contribute to muscle wasting.[1] The prevalence of low muscle mass reported in a recent study ranged from 8% to 32% in patients receiving hemodialysis.[2] In addition, patients undergoing hemodialysis present a loss of functional capacity and a reduction in physical activity,[3,4] and consequently low quality of life and a low survival rate.[5]

In this context, resistance training has been successfully recommended as a method of gaining lean mass, strength and physical functioning in frail elderly persons and those with chronic diseases, including patients with cardiovascular and kidney diseases.[6,7] However, the effectiveness of intradialytic resistance training in hemodialysis patients is still uncertain. Although studies have demonstrated an improvement in maximal strength, results in functional capacity tests such as walking capacity and the sit-to-stand test remain controversial.[8–11] While some researchers have identified significant muscle hypertrophy[8,11,12] with resistance exercises, others observed no significant change in lean mass.[13–15]

Although the reason for the lack of anabolic response to resistance exercise in hemodialysis patients is unclear, the management of resistance training protocols, such as overload progression, may play an important role.[16] The aim of this study was, therefore, to determine whether a continuous progressive resistance training, ensuring progression, could improve body composition, physical function and quality of life in patients receiving regular hemodialysis.

Methods

The present clinical trial was designed to investigate the effect of 12 weeks of progressive resistance training versus 12 weeks of sham-exercise attention control. The sample was selected from the Hemodialysis Center of the Bauru Hospital, Brazil from April 2013 to January 2015. A qualified researcher screened all patients admitted to the hemodialysis center. The eligibility criteria included: older than 18 years, time since starting hemodialysis of more than three months, without acute or chronic medical conditions that would preclude exercise or the collection of the outcome measure data, with the permission of the attending nephrologist, independent ambulation for >50 m with or without an assistive device, cognition and willingness to be randomly assigned into groups and to undergo the study protocols. All patients provided written free and informed consent for their participation in the study. The procedures used in this study met ethics in human research criteria in accordance with resolution number 466/2012 of the Brazilian Ministry of Health Written and was approved by the local Ethics Committee: FIB (CAAE:02564112.2.0000.5423), Bauru-SP, Brazil. The protocol for this study is registered with the Clinical Trials Registry (NCT02621918).

All participants attended two measurement sessions: one on entry into the study (baseline and prior to randomization) and one after the 12-week-period (posttest). The assessors were physical education and physical therapist professional's not blinded to group allocation at both time points. Allocation into progressive resistance exercise intervention or control group used a simple random sampling using SPSS (approximately 50%/50% of all the cases).[17] Group allocation was set by random allocation in SPSS: progressive resistance training group (1) and control group (2). A value of 1 indicates case assignment to progressive resistance training group while a value of 2 indicates case assignment to control group. A researcher not involved in recruitment or assessment generated the randomization and group allocation.

Primary outcome body composition was assessed by dual-energy X-ray absorptiometry (DXA). Body composition variables included in this study were total mass, total fat mass, lean body mass and bone mass contend using a total body scan, with HOLOGIC Discovery Wi equipment (Hologic Inc., Waltham, MA, USA). Regional analysis was used to assess leg lean mass, arm lean mass and trunk lean mass.[18] Secondary outcomes physical capacity and strength were assessed by the 6-minute walking test,[19] 30-seconds sit-to-stand test[20] and handgrip strength,[21] and leg and back flexibility was measured by the sit and reach test using a Wells bench.[22] Quality of life assessment was analyzed using the Medical Outcomes Study 36-item Short-Form Health Survey (SF-36),[23] and mental and physical dimensions were analyzed separately. All data were collected at the University Laboratory.

Intervention

In total, 11 exercises were used for progressive resistance training (Supplementary Figure 1) and were carried out with the appropriate amount of resistance to allow the patients to complete 15–20 repetitions (repetition maximum training zone regime), performed in two sets. Resistance was progressively increased during the study to maintain these ranges of repetitions per set. For each set, the training subjects performed repetitions until momentary failure occurred. If the subject performed repetitions beyond the prescribed training zone, the weight was sufficiently increased to return the number of repetitions to within the maximum repetition training zone.[16]

The approximate total workout time in each session was 40–50 minutes, divided into two time segments (immediately prior and during hemodialysis session). Rest between sets and exercises were managed according to the necessity of the patients. The familiarization exercises were held over two weeks (six sessions) prior to training with no/low loads and volumes set at two sets of 10 repetitions. After the exercises, passive stretching of the lower limbs was performed to facilitate recovery.

The control group received a very low intensity exercise without load and progression, composed by active mobilization of the arms and legs, circumduction of the cervical and scapular girdle, and a breathing exercise with no loads in two sets of three to five repetitions only and no stretching exercises. Sham-exercise did not exceed 5–10 minutes in duration.

In both groups, the upper limb exercises were performed in the waiting room before the hemodialysis session and the lower limb exercises were performed during the hemodialysis session, three times per week. A certified Clinical Exercise Physiologist supervised all exercise sessions.

Analyses

All available data were included in an intention-to-treat analysis regardless of patient compliance to the intervention. Data from patients who were unavailable for follow-up assessments at week 12 were carried forward from baseline values. Before analysis, all data were statistically inspected for normality. The baseline characteristics of the groups were compared with the Student's *t*-test where appropriate, and the Chi-square test was used for proportion data. Training progression was analyzed by volume of training (repetition × load), and weeks were compared by one-way analysis of variance (ANOVA) for repeated measures. Changes were calculated cross the groups as $\Delta = \text{Posttest} - \text{Pretest}$, then the independent *t*-test or Mann–Whitney *U* test were used on the changes in the scores. Clinical significance was evaluated via effect size (g) calculated

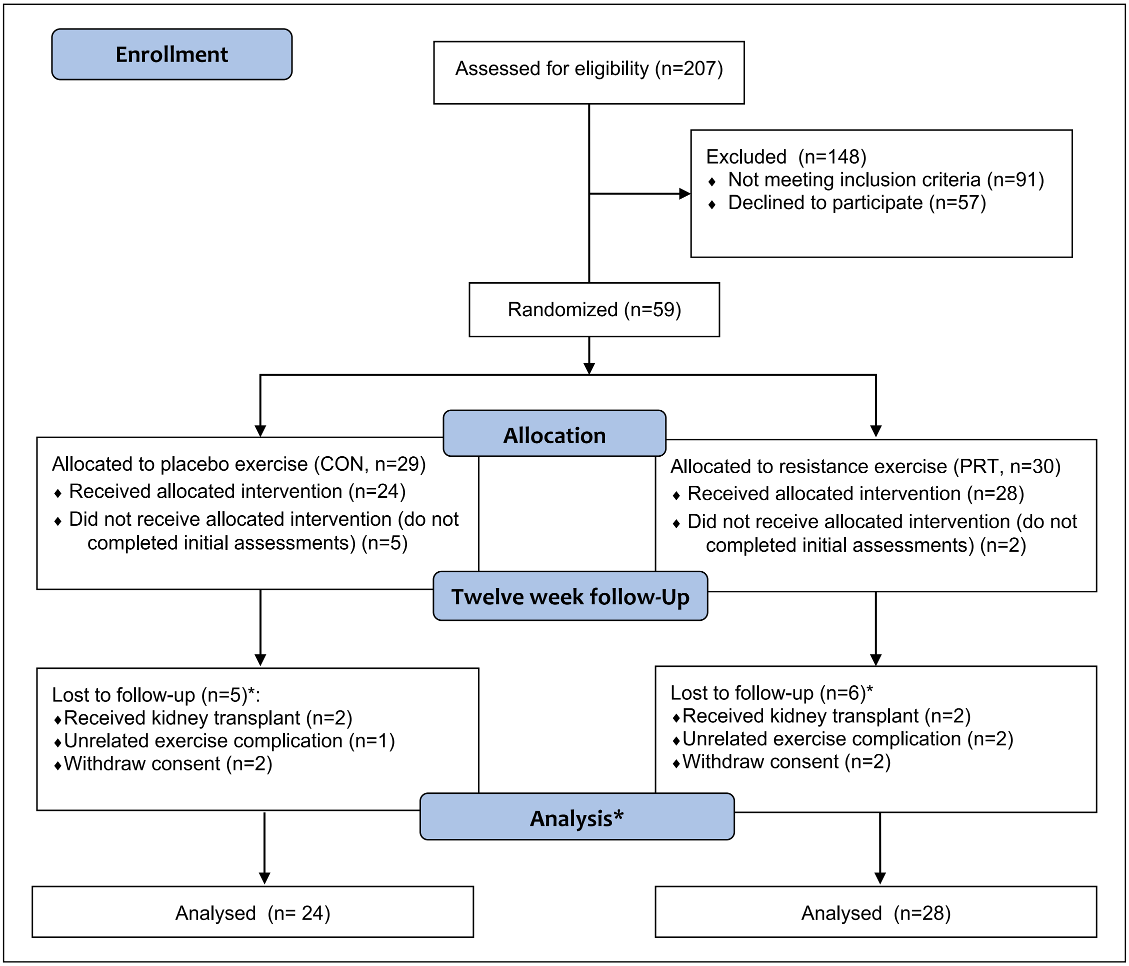

Figure 1. CONSORT diagram.
*Intention to treat analysis, baseline data carried forward for six in resistance exercise participants and five in control participant lost to follow-up.

based on Hedge's *g* formula and was interpreted as small (0.3), medium (0.5) or large (0.8). Results were considered to be statistically significant when *P*-values were ≤0.05. All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS version 17.0) statistical software (SPSS Inc., Chicago, IL, USA).

Results

The recruitment flow diagram is shown in Figure 1. A total of 207 patients were screened between 2013 and 2015, of whom 59 were randomly assigned. Seven randomized patients did not complete the baseline evaluations for reasons unrelated to the study and were not included in the final analysis. The characteristics of the study population are shown in Table 1. Overall, the cohort was composed of 35 men and 17 women; the average age of the study participants was 55.7 ± 14.03 years with a range of 26–81. There were no significant differences in baseline patient characteristics across the study groups.

The progressive resistance training group attended 66.9 ± 17.6% (minimum of 25.0% and

Table 1. Main baseline characteristics.

	CON group ($N=24$)	PRT group ($N=28$)	P-value
Age (years)	57.10 ± 16.20	54.49 ± 11.97	0.509[a]
Hemodialysis vintage (years)	2.35 ± 1.66	1.54 ± 1.26	0.057[a]
Etiology of kidney failure, *n* (%)			
Diabetes	9 (50)	9 (50)	–
Hypertension	6 (50.0)	6 (50.0)	
Diabetes and hypertension	2 (28.6)	5 (71.4)	
Glomerular diseases	6 (50)	6 (50)	
Unknown	1 (33.3)	2 (66.7)	
Gender, *n* (%)			
Men	15 (42.9)	20 (57.1)	0.494[b]
Women	9 (52.9)	8 (47.1)	
Skin color, *n* (%)			
White	19 (51.4)	18 (48.6)	0.238[b]
Black	5 (33.3)	10 (66.7)	
Biochemical			
K_t/V	1.48 ± 0.33	1.45 ± 0.32	0.815[a]
Sodium (mEq/L)	138.48 ± 2.63	138.50 ± 2.78	0.977[a]
Potassium (mEq/L)	4.97 ± 0.84	4.90 ± 0.61	0.719[a]
Hemoglobin (g/dL)	11.50 ± 1.32	11.38 ± 1.17	0.730[a]
Glucose (mg/dL)	93.87 ± 57.59	103.46 ± 49.49	0.525[a]
Phosphate (mg/dL)	5.30 ± 1.95	4.60 ± 1.44	0.144[a]
Creatinine (mg/dL)	9.66 ± 2.21	9.71 ± 2.40	0.935[a]
Calcium (mg/dL)	8.96 ± 0.55	8.83 ± 0.61	0.427[a]

CON: control; PRT: progressive resistance training.
Values are mean ± SD or *n* (%).
[a]Independent *t*-test.
[b]Chi-square test.

maximum of 91.7%) of the training sessions for the upper extremities (prior to hemodialysis sessions) and 83.2 ± 9.2% (minimum of 63.0 and maximum of 94.4%) of training sessions for other exercises (during hemodialysis). The main reasons for the lower adherence to exercises performed before hemodialysis were a lack of time, due to delays in patient transportation and hypertension combined with intradialytic overload due to body fluid, with some of the patients reporting feeling well enough to start exercising after 30 minutes of hemodialysis therapy. Over the course of the 12 weeks period, increased workload was observed (workload multiplied by number of repetitions) for the upper (abdominal, chest, biceps and upper back) and lower exercises (quadriceps, hip, gluteus, adductor and abductor, calf and tibialis), with significant differences from weeks ($P < 0.001$) (Table 2).

The primary outcomes investigated are presented in Table 3. Total lean body mass and total fat mass did not change significantly between the groups after the 12-week intervention; however, when lean body mass was analyzed by body region, leg lean mass differed significantly between the groups with a moderate effect size of 0.56 (95% confidence interval (CI) 0.0; 1.11), decreasing in the control group while increasing in the exercise group. Similarly, bone mineral content improved to a statistically significant degree in the exercise group versus the control group (effect size of 0.65 (95% CI 0.09; 1.21)), while the control group exhibited a decrease in bone mass.

Table 2. Workout load improvement for upper exercises and lower exercises.

	First week	Fourth week	Eighth week	Twelfth week	*P*
Upper exercises	96.73 ± 48.87	121.1 ± 52.77	143.5 ± 60.63	156.9 ± 70.89	<0.001
Lower exercises	173.8 ± 60.47	244.5 ± 75.44	298.8 ± 84.33	336.7 ± 95.29	<0.001

Upper exercises: abdominal, chest, biceps and upper back; lower exercises: quadriceps, hip, gluteus, adductor and abductor, calf and tibialis. Workout load = load × repetition.

Table 3. Summary and comparison of body composition and nutritional status.

Variables	CON group (*n* = 24)		PRT group (*n* = 28)		*P*-value
	Baseline	Follow-up	Baseline	Follow-up	
BMI (kg/m²)	25.54 ± 3.95	25.51 ± 4.03	26.36 ± 4.48	26.61 ± 4.44	0.752
BMC (kg)[a]	2.03 ± 0.54	2.01 ± 0.50	2.01 ± 0.53	2.03 ± 0.57	0.019
Total LBM (kg)	43.48 ± 8.02	44.04 ± 8.23	46.55 ± 9.03	47.55 ± 9.49*	0.277
Trunk lean mass (kg)	22.43 ± 4.16	22.98 ± 4.49	23.90 ± 4.92	24.40 ± 5.00	0.768
Arm lean mass (kg)	4.45 ± 1.11	4.56 ± 1.17	5.03 ± 1.33	5.10 ± 1.35	0.417
Leg lean mass (kg)[a]	13.34 ± 2.73	13.25 ± 2.59	14.36 ± 2.95	14.78 ± 3.27*	0.045
Total fat mass (kg)	23.15 ± 8.98	21.92 ± 8.81*	23.81 ± 9.21	23.10 ± 8.40	0.619
Total mass (kg)	68.13 ± 12.81	67.44 ± 12.53	71.87 ± 13.94	72.18 ± 13.54	0.277

CON: Control; PRT: progressive resistance training; BMI: body mass index; BMC: bone mineral content; LBM: lean body mass. Data reported as mean ± SD.
[a]Student's *t*-test.
P-value reported for between group comparison; *significant difference for within group comparison.

The secondary outcomes are presented in Table 4. A medium effect size of 0.66 (95% CI 0.10; 1.22) was found for the increase in the leg strength in 30 second sit-to-stand test repetitions, a difference which was statistically significantly between the groups. The exercise group also demonstrated statistically significantly improved flexibility (effect size of 1.03 (95% CI 0.45; 1.61)) while this measure decreased in the controls. No other secondary outcomes were significantly changed between the two groups.

Discussion

Twelve weeks of resistance exercise during hemodialysis session, also known as intradialytic exercise, was associated with improvement in muscle mass, strength and bone mineral content. However, unexpectedly, progressive resistance exercise was not efficacious at improving functional capacity, handgrip strength and self-reported quality of life in this cohort of patients.

The improvement in leg lean mass in exercise group are in contrast to previous studies that failed to identify leg muscle hypertrophy through 12-week resistance exercise intervention.[13–15] While it is dubious that the incorporation of progressive overload, an necessary attribute to elicit an anabolic effect, has been adhered to in previous studies in intradialytic exercise, this study proposed a continuous progression of overload resistance training, while the use of the "repetition maximum training zone" in our protocol provided significant and constant overload over the weeks of the study. In same way, a pilot study supports our results showing that an adequate overload (weekly) on lower limbs in hemodialysis patients elicited to high anabolic response.[10]

Even though upper body exercises were prescribed in this study, no statistically significant changes were observed in upper body composition and handgrip strength. This may be due to low training volume because only three small muscle groups were exercised in the upper body (biceps,

Table 4. Summary and comparison of functional capacity, respiratory muscle strength and self-reported quality of life.

Variables	CON group (n = 24)		PRT group (n = 28)		P-value
	Baseline	Follow-up	Baseline	Follow-up	
6MWT (m)	452.65 ± 169.19	469.42 ± 162.93	506.13 ± 130.34	526.45 ± 126.15*	0.277
STT (rep)	10.88 ± 3.04	11.79 ± 2.93	11.79 ± 3.47	15.18 ± 6.07*	0.015
HGS (kg/strength)	59.21 ± 20.66	58.52 ± 18.19	65.71 ± 23.27	66.61 ± 22.22	0.213
Flexibility (cm)	17.83 ± 9.64	17.44 ± 9.73	15.51 ± 10.91	19.77 ± 10.70*	0.001
QoL physical (score)	67.33 ± 19.07	74.43 ± 18.07*	65.52 ± 21.61	72.02 ± 20.36	0.861
QoL mental (score)	71.86 ± 20.54	76.08 ± 19.15	75.33 ± 21.65	78.02 ± 16.44	0.926

CON: control; PRT: progressive resistance training; 6MWT: 6-minute walk test; STT: 30 second sit-to-stand test; HGS: handgrip strength (both hands); SBP: systolic blood pressure; DBP: diastolic blood pressure; QoL physical: physical summary of quality of life; QoL mental: metal summary of quality of life; rep: repetition.
Data reported as mean ± SD.
P-value reported for between group comparison; *significant difference for within group comparison.

back and shoulder) and/or due to low adherence in upper limb training. In this study, exercise for upper limbs was performed just before hemodialysis session and, the main obstacle reported was the short time available to perform the predialysis exercises due to the time commitments of the patients and consequently their wish to start and subsequently finish their dialysis as early as possible.

The use of exercises for the upper limbs in this population is, therefore, a major challenge as arteriovenous fistulas in the upper limbs accomplish vascular access in most patients, which does not allow patients to exercise both arms during hemodialysis. In the literature, few studies have prescribed exercises for the upper limbs,[11,14,24] and their findings have been inconsistent. Therefore, more studies are needed to assess the efficacy, safety and feasibility of upper limb exercises prior or during hemodialysis sessions.

This study showed an increase in the number of repetitions in the sit to stand test, which could be related to an increase in the strength gains of the lower limbs,[20] as resistance exercise has proven to be effective among this population.[8–11,24,25] Noteworthy, it is interesting that the results of the sit-to-stand test contradict the gains identified by dynamometry in most studies involving resistance training.[8–11] An explanation is that while other studies provided a low repetition protocol (8–10 repetitions), which elicited maxim strength, in comparison, this study could be considered high repetition training (15–20 repetitions), which may elicit resistance strength.

Furthermore, an important finding in our results was the increase in bone mineral content as a result of progressive resistance training. While one study, in contrast, found a loss of bone content in patients who exercised (aerobic, resistive, or mixed),[13] a recent study demonstrated gains bone alkaline phosphatase, over 24 weeks of resistance exercise,[26] corroborating our results.

The importance of these findings are profound as chronic renal failure patients have a higher risk of fall-related accidents compared to the age matched general population,[27] and consequently, a high risk of fractures and related deaths. Encouragingly, this study shows that 12 weeks of exercise using a continuous progressive training can help maintain a positive bone mineral balance, preventing further deterioration of bone mass. In combination with improvements in lower body muscle strength, it is possible to improve overall balance and therefore reduce fall-related accidents. However, more research controlling for other risk factors such as the parathyroid hormone is needed to further support such preliminary data.

Resistance exercise had no effect on meters walked in 6-minute walking test, furthermore to date no study has identified a significant improvement in walking test for the strength training group compared to non-exercise groups in. In contrast, studies using aerobic exercise alone or in combination with resistance training identified an improvement in the walk test, as well as in the VO_{2max}.[28–30] Despite its association with the strength of the lower limbs, improvements in the distance covered in the 6-minute walking test reflect positive changes in cardiopulmonary capacity.[31] While improving leg strength, resistance training adaptations do not involve the cardiorespiratory pathways, suggesting that even for a debilitated population such as end-stage renal disease patients, resistance training only is not enough to fully rehabilitate individuals, especially those who need to improve cardiovascular capacity. As expected, studies involving resistance exercise training have not assessed VO_2 capacity as an outcome.

Literature reviews unanimously shows that exercise improves self-reported quality of life, in patients undergoing hemodialysis.[8,12,32] Conversely, this study found no statistical difference between groups. However, unlike the majority of studies in this area, this study included the use of a very low intensity exercise in the control group, which may reduce the confounding effect of motivation and socialization of a supervised exercise program. Similarly, also using a placebo exercise in control group, others studies[9,10,33] did not find significant differences in quality of life between exercise and control group in hemodialysis patients.

In this way, a recent meta-analysis has shown that the use of a very low intensity exercise as a placebo intervention in experimental designs of exercise training suggests that the placebo effect is approximately half of the observed psychological benefits of exercise training.[34] Therefore, the true effect of resistance exercise per se on quality-of-life outcomes observed in hemodialysis patients might be smaller than those suggested in previous studies that have ignored the potential placebo effect. It is crucial that future randomized trials should be designed to assess the magnitude of the placebo effect in exercise treatments by including an intervention, placebo and control group.[34]

Some important limitations and strengths of this study need to be recognized. For example, an important limitation was the fact that we were unable to blind participants and evaluators regarding group allocation and behavior change, which could influence outcome measures. In addition, the leg muscle mass assessment was based on compartmental analysis using DXA images and not on more specific approaches such as magnetic resonance imaging, computed tomography, or ultrasounds. Finally, this study did not assess muscle strength using a direct approach such as a leg dynamometer. In contrast, the significant strength of this study is the fact that our protocol proposes a continuous progression of overload training in strength training in hemodialysis patients, using easy materials such as free weights and rubber bands, which may deliver the continuous neuromuscular stimulus which is indispensable to the occurrence of improvements.[35] This study also included a sham-exercise control group, which reduces the confounding effect of motivation and socialization of a supervised exercise program. In addition, even though this study could benefit from a larger sample group of patients, analysis revealed that it possesses sufficient power to detect statistically significant differences between the two groups.

In conclusion, while resistance training using the repetition maximum training regime carried out on hemodialysis session seems to be a safe and effective method of increasing leg lean mass and strength, flexibility and bone mineral content in hemodialysis patients, in comparison with a placebo exercise control group, there was lack of efficacy on walking test, handgrip strength, and quality of life. Nevertheless, more randomized clinical trials evaluating the effect of progressive resistance exercise on health outcomes are necessary.

Clinical messages

- Intradialytic resistance exercise training of sufficient volume and progression, using free weight and elastic band can improve lower body strength and muscle mass.
- Intradialytic resistance exercise training did not alter walking functional capacity.
- True effect of resistance exercise per se on quality of life outcomes observed in hemodialysis patients must be studied from the view of potential placebo effects.

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Supplement material

Supplementary Material is available for this article online.

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