

## Original Articles

# Effects of an intradialytic resistance training programme on physical function: a prospective stepped-wedge randomized controlled trial

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### ABSTRACT

**Background.** Intradialytic exercise programmes are important because of the deterioration in physical function that occurs in people receiving haemodialysis. Unfortunately, exercise programmes are rarely sustained in haemodialysis clinics. The aim of this study was to determine the efficacy of a sustainable resistance exercise programme on the physical function of people receiving haemodialysis.

**Methods.** A total of 171 participants from 15 community satellite haemodialysis clinics performed progressive resistance training using resistance elastic bands in a seated position during the first hour of haemodialysis treatment. We used a stepped-wedge design of three groups, each containing five randomly allocated cluster units allocated to an intervention of 12, 24 or 36 weeks. The primary outcome measure was objective physical function measured by the 30-s sit-to-stand (STS) test, the 8-foot timed up and go (TUG) test and the four-square step test. Secondary outcome measures included quality of life, involvement in community activity, blood pressure and self-reported falls.

**Results.** Exercise training led to significant improvements in physical function as measured by STS and TUG. There was a significant average downward change ( $\beta = -1.59$ ,  $P < 0.01$ ) before the intervention and a significant upward change after the

intervention ( $\beta = 0.38$ ,  $P < 0.01$ ) for the 30-s STS with a similar pattern noted for the TUG.

**Conclusion.** Intradialytic resistance training can improve the physical function of people receiving dialysis.

**Keywords:** exercise therapy, randomized controlled trial, renal dialysis, resistance training

### INTRODUCTION

People receiving haemodialysis are older [1], more frail [2] and have decreased physical function [3, 4] compared with the general population. Functional deterioration occurs long before dialysis commences in people with chronic kidney disease, with an associated reduction in physical activity [5]. Once a person commences haemodialysis, factors such as sitting for long periods of time connected to the dialysis machine and post-dialysis fatigue exacerbate this poor physical function [6]. Currently, programmes addressing this physical function deterioration are not common in haemodialysis clinics [7], but there is evidence that exercise programmes can have positive effects for people on dialysis. A Cochrane meta-analysis of 32 studies including only parallel group randomized controlled trial (RCT) designed studies indicated that exercising for >30 min three times per week for people with end-stage

kidney disease (ESKD) improved physical fitness, physical function, blood pressure and health-related quality of life (QoL) [8]. In particular, resistance training has demonstrated positive effects on muscle strength, physical function, biochemical parameters and QoL [9]. Resistance training also improves restless legs syndrome and sleep quality in people with ESKD [10] and elicits a normal anabolic and strength response when compared with healthy controls [11].

For people receiving dialysis, the most convenient time to perform exercise is during the dialysis treatment [12]. Intradialytic exercise interventions have demonstrated improvements in physical function, cardiac function [13], strength, QoL [14] and hospitalization rates [15]. A recent meta-analysis of intradialytic exercise in 24 controlled studies concluded that there were improvements in urea clearance, aerobic capacity and the physical QoL [16]. Despite these positive findings, there are few dialysis clinics that have been able to sustain ongoing exercise programmes [7].

The major barrier to intradialytic exercise is the lack of staff expertise to prescribe, encourage and monitor exercise programmes [12, 17]. Therefore, exercise programmes need to be performed intradialytically and need to be enhanced by qualified exercise professionals [18–21]. Thus, the aim of this study was to determine the effect of a sustainable progressive resistance training programme delivered by qualified exercise professionals on the physical function of people receiving haemodialysis compared with no intervention.

## METHODS

The protocol for this study has been reported previously [21] and therefore only a summary will be described in this article. Participants were recruited from 15 satellite dialysis centres located in one Australian metropolitan city. Inclusion criteria consisted of ESKD, receiving haemodialysis for >3 months, age  $\geq 18$  years, able to understand English and no lower limb amputation. Exclusion criteria included any hospitalization in the month prior to study commencement. The study was approved by all five intervention health network ethics committees overseeing the 15 dialysis centres and the Deakin University Human Research ethics committee.

### Study design

A stepped-wedge cluster RCT design was used, which allowed randomization to occur while still being able to provide all participants the opportunity to undertake a period of intervention [21]. Randomization occurred at the clinic level, where each clinic was a cluster. There were five clusters (clinics) in each of the three groups: the first group received 36 weeks of exercise training, the second group were followed for 12 weeks before receiving 24 weeks of exercise and the third group were followed for 24 weeks before receiving 12 weeks of exercise (see Figure 1). The study design was reviewed by the Australian New Zealand Clinical Trials Registry, approved and registered as ACTRN12612001223820.

One researcher (C.O.) conducted the recruitment by first providing a verbal explanation of the study. Potential participants

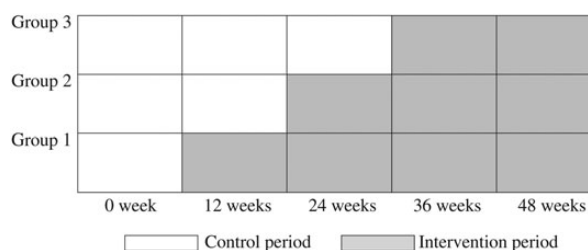


FIGURE 1: Study stepped wedge design.

who met the inclusion criteria were invited to take the information home to read and discuss with care partners and family. If they elected to participate, they returned their signed consent form to a protected return box at each clinic.

The randomization of clinics was performed by a research assistant not involved in intervention, data collection, analysis or evaluation. A Microsoft Office Excel computer-generated random number system was used. Each cluster (dialysis clinic) was randomly prescribed a number, and the five clinics with the five lowest numbers were designated into Group 1 (receiving 36 weeks of the exercise intervention), numbers 6–10 were allocated to Group 2 (receiving 24 weeks of the exercise intervention) and the final five clinics were allocated to Group 3 (receiving 12 weeks of the exercise intervention). Allocation was concealed at the time of participant consent; however, the participants and clinic staff were made aware of their group at the commencement of the intervention. Due to the nature of the intervention, blinding of intervention groups to the clinic staff and dialysis patient participants was not possible.

### Intervention

Accredited exercise physiologists (AEPs) were appointed to each haemodialysis clinic 6 h per week per clinic for the duration of the intervention. Each participant was assessed by an AEP who developed an individualized and progressive exercise programme. A typical programme consisted of six lower and upper body resistance exercises using thick-coloured elastic bands commonly used in physical therapy resistance programmes. The exercises were performed during the first hour of haemodialysis treatment. When participants were able to perform two sets of 15–20 repetitions for each exercise, the resistance exercises were made progressively harder using different colour-graded elastic bands. Participants were encouraged to perform each exercise as rapidly as possible to optimize movement speed and muscle power.

The resistance exercises incorporated into the programme included leg abduction, plantar flexion, dorsiflexion, straight-leg/bent-knee raise, knee extension and knee flexion. All resistance exercises were performed in a seated position, so the participant maintained a comfortable position while still receiving haemodialysis treatment. Participants received one supervised session per week and were encouraged to perform the exercises during the two haemodialysis treatments per week where the AEP was not present.

### Data collection

There were five data collection points: baseline and every 12 weeks over a 48-week period (Table 1).

**Table 1. Baseline demographic and biochemical characteristics across three groups**

Demographics	Group 1 (n = 51)	Group 2 (n = 61)	Group 3 (n = 59)	Total (n = 171)
Gender, %				
Male	60.8	60.7	66.1	62.6
Female	39.2	39.3	33.9	37.4
Dates in clinic, %				
MWF	70.6	80.3	67.8	73.1
TTS	29.4	19.7	32.2	26.9
Shift, %				
Morning	47.1	52.5	52.5	50.9
Afternoon	52.9	47.5	47.5	49.1
Hospital, %				
Public	68.6	83.6	81.4	78.4
Private	31.4	16.4	18.6	21.6
Age (years)	65.6 (10.4)	68.7 (14.1)	69.6 (12.4)	68.1 (12.6)
Months on dialysis, median (IQR)	37 (20.3–56.5)	53 (27.5–118.0)	47 (27.0–98.0)	44 (26.0–85.5)
DEA (ratio)	1.01 (2.32)	0.99 (2.97)	0.52 (1.48)	0.83 (2.35)
Mean arterial pressure (mm/hg)	90.5 (14.9)	94.1 (13.9)	103.9 (72.7)	96.5 (44.6)
Albumin (g/L)	36.3 (3.8)	34.7 (4.7)	34.7 (3.2)	35.2 (4.0)
Urea reduction ratio	77.09 (4.61)	75.41 (4.64)	76.47 (6.89)	76.28 (5.54)
Phosphate (mmol/L)	1.64 (0.38)	1.57 (0.45)	1.51 (0.42)	1.57 (0.42)
Weight (kg)	81.1 (18.7)	73.0 (18.2)	75.2 (17.8)	76.1 (18.4)
Potassium (mmol/L)	5.1 (0.7)	5.0 (0.6)	5.0 (0.6)	5.1 (0.7)
Urea (mmol/L)	19.8 (5.2)	19.5 (5.0)	20.1 (5.2)	19.8 (5.1)
Creatinine (µmol/L)	678 (194)	667 (174)	712 (205)	686 (191)
Haemoglobin (g/L)	114.3 (9.3)	111.9 (11.3)	111.4 (12.6)	112.4 (11.2)

Values given as mean (SD) unless stated otherwise. SD, standard deviation; MWF, Monday, Wednesday, Friday; TTS, Tuesday, Thursday, Saturday; IQR, interquartile range.

### Outcome measures

Objective physical function was the primary outcome measure using three separate tests: the 30-s sit-to-stand (STS) test, the 8-foot timed up and go (TUG) test and the four-square step test (FSST). The tests followed the protocols developed by Rikli and Jones [22] and Dite and Temple [23], are non-invasive tests and can be conducted with minimal equipment in the haemodialysis clinic. STS has been reported as a strength test appropriate for older adults and frailer, clinical populations [24] such as dialysis patients. All three physical function tests have been validated for use with older people and people with chronic disease [22, 23]. Objective physical function tests were conducted before the participant's mid-week haemodialysis treatment every 12 weeks from the start date by a research assistant who was blinded to the intervention group randomization.

Secondary measures included QoL, community activity involvement, dialysis exercise adequacy (DEA), falls and falls confidence, biochemical measures, blood pressure and morbidity. QoL was measured at baseline, at the commencement of the intervention and at the completion of the intervention using the validated Kidney Dialysis Quality of Life (KDQOL) index, a valid and reliable tool in this population [25]. Involvement in community activities was measured using the Frenchay Activities Index (FAI) at baseline, the commencement of the intervention and at the completion of the intervention. The FAI has been validated in people with chronic disease [26]. DEA was measured every 12 weeks from study commencement using the formula: weekly exercise frequency (number of times) × time (hours) × age/100 [27]. Self-reported falls based on the falls reporting method used in the Mobilize Boston Study

[28] was undertaken every 12 weeks. In this study, a fall was defined as 'an event, which results in a person coming to rest inadvertently on the ground or other lower level' [29]. In addition, falls confidence was measured every 12 weeks from study commencement using the Modified Falls Efficacy Scale [30]. Biochemical and dialysis-related data routinely measured during haemodialysis (i.e. mid-week post-dialysis weight, mid-week pre- and post-sitting blood pressures) were recorded every 12 weeks from study commencement. Morbidity was measured by the number of hospital admissions, reason for hospital admission and length of stay and was recorded for all participants for the duration of the study.

### Sample size calculation

Sample size calculation is detailed in the protocol publication [21]. The 30-s STS test is the most clinically meaningful primary outcome measure and was used in the sample size calculations for this study. The inability to stand quickly from a chair is associated with poor muscle strength, power and function [31, 32]. The magnitude of change reflecting a clinically significant result was postulated at a change in STS of at least one unit. Likely effect sizes were estimated from the STS test data from two previous studies [33, 34]. Power was set at 0.80. Based on our previous pilot work, a 30% attrition rate over 12 months was expected [35]. A design effect (DE = 1.25) was postulated to account for clustering (ICC = 0.029,  $m = 9.73$ ). The study required 15 clusters, with each cluster representing one haemodialysis clinic. Based on these assumptions, 180 participants were needed to be recruited for the study consisting of 12 participants in each cluster.

## Statistical analyses

To evaluate any exercise-induced changes in the primary and secondary outcome measures, repeated measures were analysed using latent growth curve modelling (LGCM) [36]. LGCM extends traditional repeated measures analysis of variance by modelling changes in the mean and the variance of initial status (intercept) and the growth rate (slope) simultaneously. In the present study, the latent intercept factor was centred relative to scores at the first time point. The slopes (linear and quadratic) represent the functional form of the growth trajectories over the five time points.

The variable of intervention group with three categories was dummy coded into two binary variables (e.g. Group 2 versus 1 and Group 3 versus 1), which were used as covariates to account for variability in the growth factors [37]. The latent growth factors were regressed on the binary grouping variables.

All models were estimated in the Mplus 7.3 structural equation modelling programme [38], and a robust maximum likelihood (MLR) procedure was used to account for the non-normality nature of the data. Model fit was evaluated using  $\chi^2$  with a scaling correction factor for MLR, comparative fit index (CFI), Tucker–Lewis index (TLI), root mean-square error of approximation (RMSEA) and standardized root mean-square residual (SRMR). Models are considered good fit if CFI > 0.95, TLI > 0.95, RMSEA < 0.05 and SRMR < 0.05, with a  $\chi^2$  P-value or its scaling correction factor for MLR > 0.05.

Missing data studies [e.g. 39] showed that maximum likelihood estimation using the expectation and maximization algorithm with a non-normality correction (MLR) outperformed other methods. The models were estimated under missing data theory [40] using all available information [38].

## RESULTS

A total of 228 participants were recruited to the study. Participants were randomized to one of the three groups using the dialysis clinic as the randomizing cluster unit. A total of 57 participants withdrew from the study prior to the second time point, leaving 171 participants remaining with at least two points of data for analysis. Exercise compliance was recorded with participants all exercising at least once per week during the intervention period. One serious adverse event was reported; however, on investigation it was not found to be caused by the intervention. Details of participant numbers and attrition from each group at the five time points are illustrated in Figure 2.

### Baseline measures

Table 2 shows the baseline mean, standard deviation, minimum, maximum, and missing values, median and interquartile range where applicable and percentages for the nine outcome measures.

To examine the effectiveness of the intervention, outcome measures were taken at Weeks 0 (Time 1), 12 (Time 2), 24 (Time 3), 36 (Time 4) and 48 (Time 5) for the 30-s STS, 8-foot TUG and FSST. The observed means of these outcome

measures showed a decrease in the number of 30-s STSs before the intervention and then an increase after the intervention started; an increase in time for the TUG before the intervention and a decrease after the commencement of the intervention; minimal change over time was observed for the FSST (Figure 3).

### LGCM results

The proposed LGCM models (linear or quadratic) with and without dummy covariates (i.e. groups) fitted the data well or reasonably well as indicated by the fit statistics across nine outcome measures in the Supplementary data, Table S1. Table 3 shows the estimated means and variances for the intercepts, linear and quadratic slopes in the LGCM without covariates. The regression coefficients between the growth factors and the covariates are also presented from the LGCM with covariates (see Supplementary data, Table S2).

**Significant changes over time.** Significant changes were observed in the 30-s STS, 8-foot TUG, and mean arterial pressure. As shown in Table 3, there was a significant average downward change before the intervention and a significant upward change after the exercise training for the 30-s STS. A significant linear increase for the TUG and a significant decrease for mean arterial pressure were found before the interventions. Individual changes over time for the 30-s STS, TUG and mean arterial pressure are presented in Supplementary data, Table S3.

**Quality of life, activity and falls.** The KDQOL index was used to measure QoL among dialysis patients. Initially, participants were requested to complete this at the five time points; however, answering 80 items became burdensome for many participants, so the KDQOL index was only measured at baseline, immediately before the intervention and at the completion of the intervention. Because of this response burden, the information obtained for these secondary outcomes was limited and statistical analyses were not performed. The FAI was used to measure uptake and involvement in community activity and the Mobilize Boston Study scale was used to measure self-reported falls. Similar to the KDQOL index, the response burden may have led to limited data, thus statistical analyses were not performed. The percentages of missing data are presented in Supplementary data, Table S3.

## DISCUSSION

This is the first reported stepped-wedge prospective RCT demonstrating physical function decline during non-exercise and improvement associated with resistance exercise. In all three groups, decline was seen over the periods of 3, 6 and 9 months where no exercise was being performed. In all three groups, this deterioration in physical function was arrested and improved as a result of the resistance training intervention.

Resistance exercises were chosen over the more commonly used aerobic exercise training using stationary cycles because dialysis patients have a significant loss of strength and physical function over their dialysis life. Resistance exercise is well placed



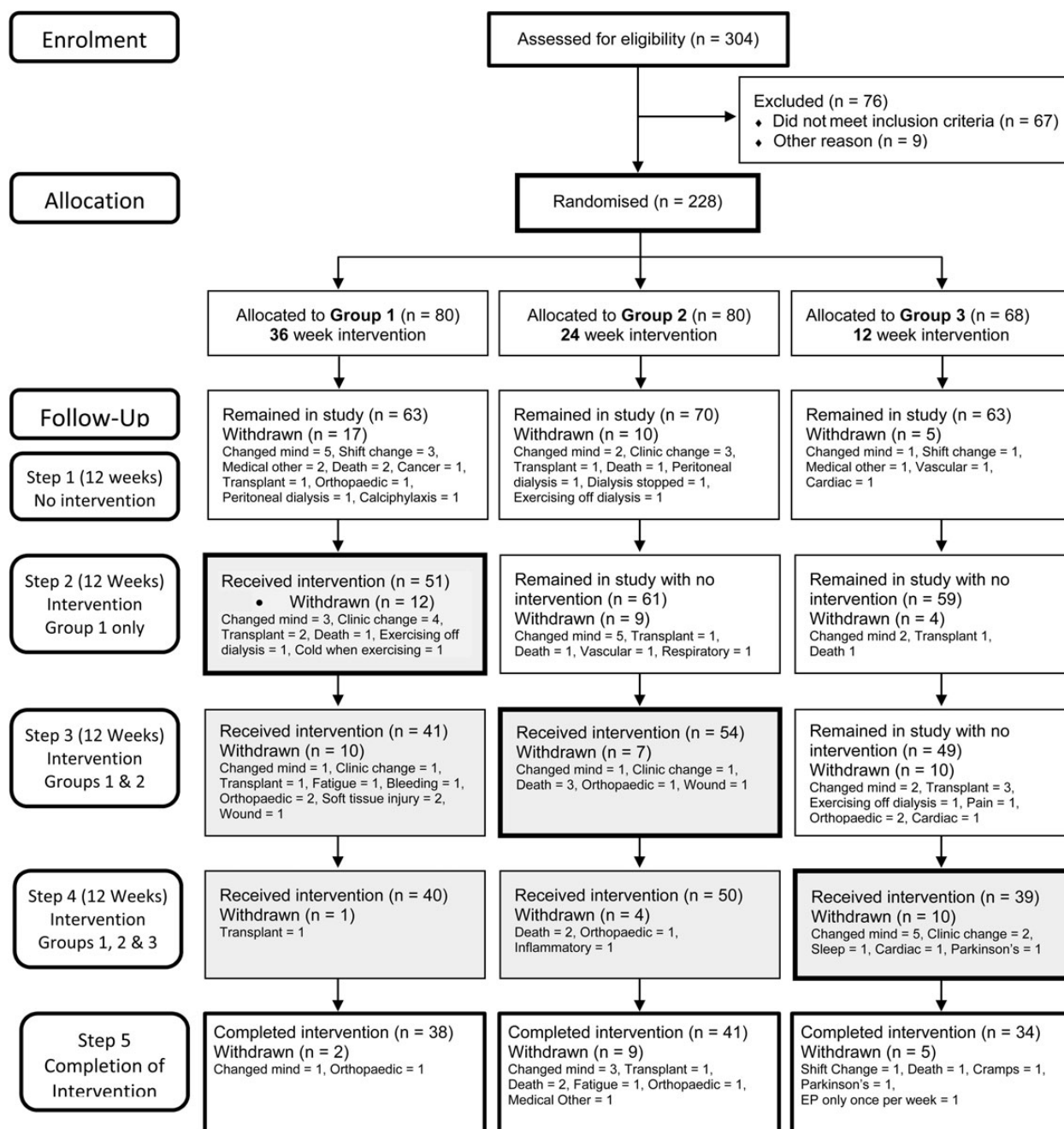


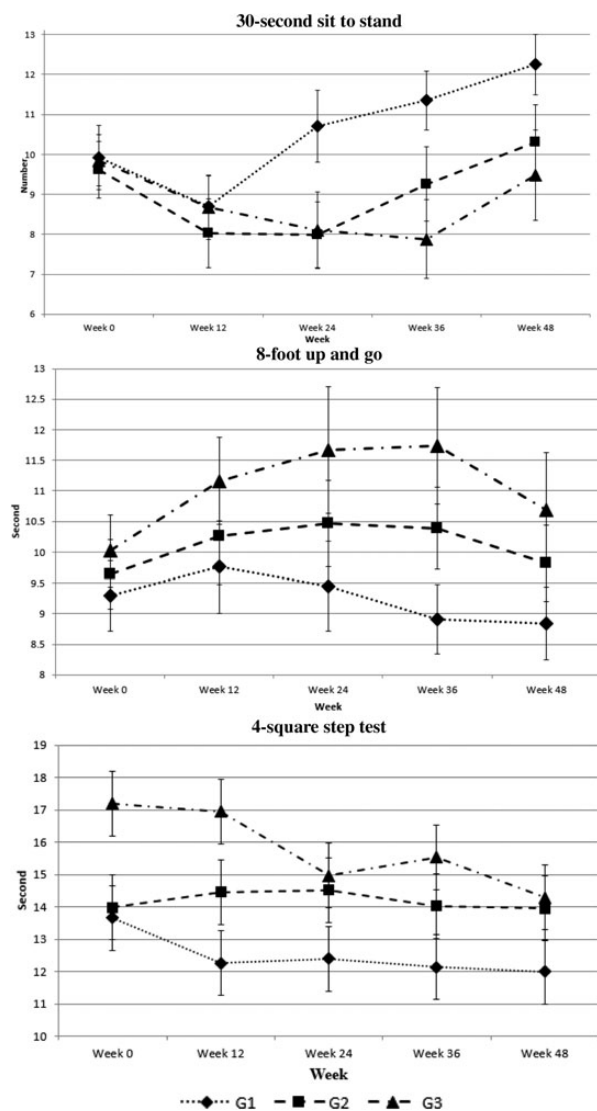
FIGURE 2: Stepped wedge modified CONSORT diagram.

Table 2. Baseline data

Outcome measures	Mean	SD	Minimum	Maximum	Missing (%)
1. 30-s STS	9.79	5.11	0	23	16 (9.4)
2. 8-foot TUG	9.67	3.92	0	24.7	11 (7.3)
3. FSST	15.04	6.99	7	62	17 (12)
4. Weight	76.11	18.42	45.6	141	1 (0.6)
5. Phosphate	1.57	0.42	0.67	2.89	1 (0.6)
6. Urea reduction ratio	76.28	5.54	58.5	89	2 (1.2)
7. Albumin	35.15	4.01	20	46	1 (0.6)
8. Mean arterial pressure	94.45	13.94	64.3	129.3	1 (0.6)
9. DEA	0.83	2.35	0	22	2 (1.2)

to be the exercise of choice in this group given the QoL benefits that ensue from increased strength and physical function [10].

Both physical function and muscle strength are important in this group. Muscle strength typically provides a measure of peak muscle force, so simply improving strength does not mean that function will improve. In saying this, there is a moderately high correlation between chair-stand performance and maximum weight-adjusted leg-press performance for both men and women ( $r = 0.78$  and  $0.71$ , respectively), supporting the criterion-related validity of the chair stand as a measure of lower body strength [24]. This moderate correlation with functional measures also highlights that other factors are important to function, particularly neuromuscular adaptations.



**FIGURE 3:** Means and standard errors of means of 30-second sit to stand, eight foot up and go, and four square step tests across three groups over five time periods.

Exercise professionals have been identified as an important component of the dialysis exercise team [41]. Exercise professionals are commonly known as exercise physiologists, physical therapists, physiotherapists or kinesiologists. Although each group may have varying contexts and foci, each has the knowledge of exercise physiology that is required to design and implement resistance exercise programmes for dialysis patients. Without exercise professionals, resistance dialysis programmes would be difficult to sustain [42]. The involvement of exercise professionals for a sustained period was a key contributor to the improved physical function of participants.

This study involved an intradialytic exercise programme rather than exercise before, after or on a non-dialysis day. Although limitations include being seated and having needles *in situ*, exercise during the first 2 h of dialysis using elastic bands to undertake resistance exercise is feasible. Similar to a recent meta-analysis of 24 studies and 997 patients [16], patients

**Table 3.** Estimated means and variances of baseline and growth factors

	Intercept	Linear slope	Quadratic slope
<b>1. 30-s STS</b>			
Mean	9.71** (0.42)	−1.59** (0.25)	0.38** (0.05)
Variance	21.63** (3.38)	3.96* (1.90)	0.12 (0.09)
<b>2. 8-foot TUG</b>			
Mean	9.77** (0.33)	1.06** (0.23)	−0.24 (0.05)
Variance	11.77** (3.19)	2.43 (1.97)	0.10 (0.08)
<b>3. FSST</b>			
Mean	15.18** (0.63)	−0.21 (0.13)	−
Variance	44.40* (18.93)	0.50 (0.40)	−
<b>4. Weight (kg)</b>			
Mean	75.40** (1.38)	−0.00 (0.13)	−
Variance	315.99** (42.63)	0.91* (0.43)	−
<b>5. Phosphate (mmol/L)</b>			
Mean	1.55** (0.03)	−0.00 (0.01)	−
Variance	0.12** (0.02)	0.01 (0.01)	−
<b>6. Urea reduction ratio (%)</b>			
Mean	76.46** (0.40)	0.26 (0.29)	−0.01 (0.07)
Variance	20.50** (4.26)	4.57 (3.10)	0.27 (0.18)
<b>7. Albumin (mmol/L)</b>			
Mean	35.19** (0.30)	−0.12 (0.23)	−0.01 (0.06)
Variance	12.13** (3.15)	1.63 (1.94)	0.13 (0.09)
<b>8. Mean arterial pressure (mmHg)</b>			
Mean	94.28** (0.99)	−1.28** (0.47)	−
Variance	105.02** (17.12)	2.89 (1.96)	−
<b>9. DEA (ratio)</b>			
Mean	0.67** (0.15)	−0.04 (0.02)	−
Variance	3.45 (2.34)	0.04 (0.02)	−

Values in parentheses are standard errors of the estimates. \*P < 0.05, \*\*P < 0.01.

undertaking intradialytic resistance exercise in this study did not exhibit increased unwanted symptoms such as cramps or hypotensive episodes. There was no evidence of increased exercise-related symptoms in our study, supporting the potential for decreased symptoms associated with intradialytic exercise [43].

Intradialytic exercise is particularly suited for community dialysis units, commonly known as satellite dialysis units. Satellite dialysis units are nurse run, have limited nephrologist attendance and generally have ambulant or semi-ambulant patients attending [44]. With limited support from exercise professionals, nurses can potentially assist patients to perform resistant exercises with minimal supervision. Thus, a resistance exercise programme where each patient has their own reusable, washable and inexpensive resistance band may progress the mission of a sustainable intradialytic exercise model.

### Strengths and limitations

The major strength of this study was the use of a stepped-wedge design over a more traditional RCT. The stepped-wedge design was able to match participants as their own control and facilitated all participants to participate in at least 3 months of the intervention. Furthermore, the design enabled the use of 6 rather than 15 exercise physiologists, contributing to a more consistent training programme. The stepped-wedge design required the first 12 weeks to be a washout period where no intradialytic exercise was performed, which led to more participant withdrawals. A second strength of this study was the duration of the intervention. A clear picture of the deterioration and improvement in physical function over time was a feature of this study. Generalizability of

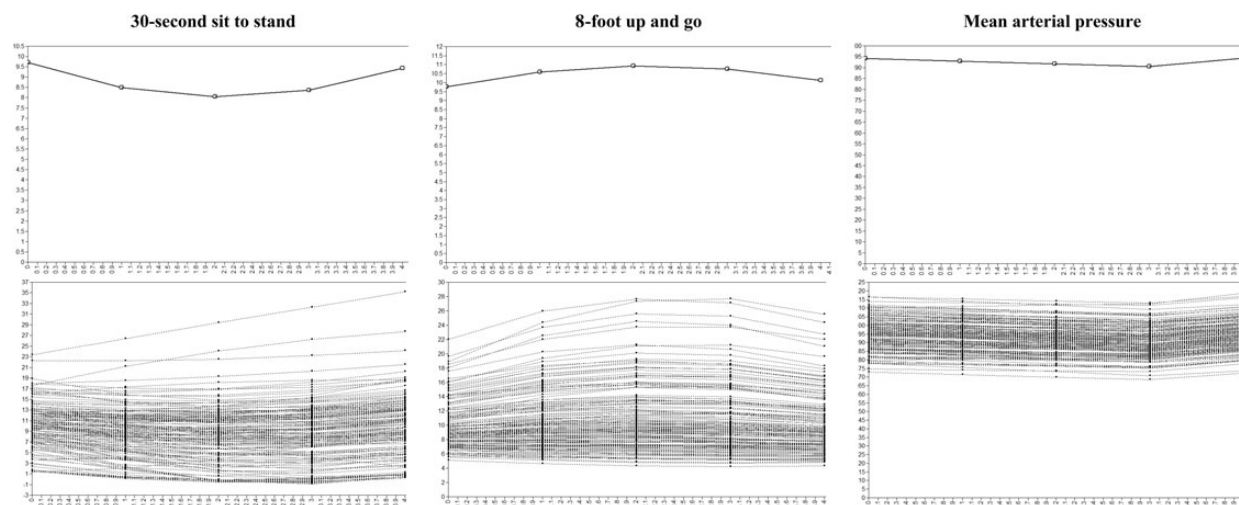


FIGURE 4: Estimated individual and mean growth curves.

these results to dialysis patients with multiple co-morbid conditions should be cautioned, as participant recruitment may have been biased towards those who were able to undertake the exercise programme and not those who were less physically able.

## CONCLUSION

This study demonstrated a decline in physical function for patients on dialysis before commencing the exercise programme and a subsequent improvement associated with intradialytic resistance exercise. The exercise programme was sustained with the majority of participants completing at least 3 months of exercise for a minimum of 3 days per week during the first hour of haemodialysis treatment. Resistance exercise is a feasible way to improve the physical function of patients undergoing treatment in a community dialysis unit.

## SUPPLEMENTARY DATA

Supplementary data are available online at <http://ndt.oxfordjournals.org>.

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## CONFLICT OF INTEREST STATEMENT

None declared.

(See related article by Mallamaci *et al.* Physical exercise in haemodialysis patients: time to start. *Nephrol Dial Transplant* 2016; 31: 1196–1198)

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