Kidney Medicine

An Exercise Program for Peritoneal Dialysis Patients in the United States: A Feasibility Study

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Background: People with end-stage kidney disease receiving peritoneal dialysis (PD) are generally physically inactive and frail. Exercise studies in PD are scarce and currently there are no PD exercise programs in the United States. The primary objective of this study was to test the feasibility of a combined resistance and cardiovascular exercise program for PD patients under the care of a dedicated home dialysis center in the United States.

Study Design: Parallel randomized controlled feasibility study.

Setting & Participants: PD patients were recruited from a single center and randomly assigned to the intervention (exercise; n = 18) or control (non-exercise; n = 18) group.

Intervention: The intervention group received monthly exercise physiologist consultation, exercise prescription (resistance and aerobic exercise program using exercise bands), and 4 exercise support telephone calls over 12 weeks. The control group received standard care.

Outcomes: The primary outcome was study feasibility as measured by eligibility rates, recruitment rates, retention rates, adherence rates, adverse events, and sustained exercise rates. Secondary outcome measures were changes in physical function (sit-to-stand test, timed-up-and-go test, and pinch-strength tests) and patient-reported outcome measures.

Results: From a single center with 75 PD patients, 57 (76%) were deemed eligible, resulting in a recruitment rate of 36 (63%) patients. Participants were randomly assigned into 2 groups of 18 (1:1). 10 patients discontinued the study (5 in each arm), resulting in 26 (72%) patients, 13 in each arm, completing the study. 10 of 13 (77%) intervention patients were adherent to the exercise program. A *t* test analysis of covariance found a difference between the treatment groups for the timed-up-and-go test (P = 0.04) and appetite (P = 0.04). No serious adverse events caused by the exercise program were reported.

Limitations: Single center, no blinded assessors.

Conclusions: A resistance and cardiovascular exercise program appears feasible and safe for PD patients. We recommend that providers of PD therapy consider including exercise programs coordinated by exercise professionals to reduce the physical deterioration of PD patients.

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Patients with end-stage kidney disease receiving peritoneal dialysis (PD) are generally physically inactive[1,2] and frail.[3,4] Low activity and frailty in these patients are associated with decreased physical function[5,6] and poor quality of life.[7] Falls risk in this group is high, with 1 fall being associated with a 60% increase in mortality.[8] PD patients aim to maintain independence at home; however, their low physical capacity can diminish this independence.

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Guidelines recommend nephrologists to encourage physical activity levels in PD patients.[9] However, nephrologists and nephrology nurses frequently lack the knowledge, resources, and skills to prescribe detailed or appropriate exercise regimens.[10] Because of this, PD patients are often discouraged from participating in exercise programs because of uncertainty about the best exercise regimen and potential barriers.[11] The result of this is a lack of sustained US exercise programs for PD patients.[1]

Patients undergoing PD are less likely to be constantly exposed to activities promoting physical activity than patients treated with hemodialysis because they do not attend clinic as frequently.[12] Because their treatment is more home based, PD patients can become socially isolated, decreasing their social and physical activity[13] and limiting their access to clinical staff, rehabilitation professionals, and other patients. This has led to low levels of physical activity,[1] even though patients want to increase their exercise, activity, and independence.[14-16] Promoting and supporting exercise and physical activity for people receiving PD has the potential to improve social activity and mental health in addition to the physical benefits.[17]

Examples of exercise programs for PD patients have been reported in China,[18,19] France,[12] and Japan,[20] with no sustained exercise programs in the United States being reported in the past 20 years.[21] Exercise in PD research studies are also scarce, consisting mainly of smaller studies and heterogeneous outcomes[21,22] with no large interventional PD exercise (PDEx) studies reported in the United States.[23] Importantly, data to guide providers in the feasibility, design, and implementation of such programs

are lacking. Therefore, the aim of this study was to test the feasibility of a PDEx program that could be pragmatically applied within the current PD delivery system in the United States.

METHODS

Objectives

The objective of a PDEx was to test the feasibility of a 3-month exercise physiologist–led exercise program. Specifically, our primary objectives were to measure eligibility rates, recruitment rates, retention rates, adherence rates, adverse events, and sustained exercise rates in an exercise physiologist–led program. Our secondary aims were to measure change in physical function measures and patient-reported outcome measures.

Patient Selection

The patient population was drawn from prevalent PD patients in 1 home dialysis center in Northern California. Sample size was restricted to the convenience sample at this 1 PD center. The inclusion criteria consisted of the ability to understand English, ability to ambulate independently or with a walking device, and PD vintage longer than 6 weeks. Patients with major amputation or unable to ambulate independently and pregnant women were excluded. Initially patients were screened by the center medical director before being approached by the research assistant and center staff.

Ethical Considerations

Human research ethics was approved through the Aspire Independent Review Board #SR065PDE. At participant recruitment, 1 member of the research study (G.A., K.M., or B.S.) described the study to each patient using a 1-page information sheet. Patients could agree to participate immediately or take the information home and discuss with their relatives and significant others. Informed consent was obtained and signed at least 1 week before the first exercise appointment.

Randomization

After informed consent was obtained, random assignment to the intervention or control groups in a 1:1 ratio was performed through Excel randomization function by an external research assistant who was not involved in the PDEx. Allocation concealment was ensured by not providing the randomized sequence until all participants had been consented. Following consent, the randomization allocation was provided to the PDEx research assistant who assigned patients to the randomly assigned study arm. This process ensured the complete separation of those involved with generation and allocation concealment from those involved in the implementation of allocating assignments. Following the first patient assessment, clinician blinding was not possible due to the nature of the intervention.

Procedure Details

Baseline Demographic Data

These data (age, sex, ethnicity, weight, body mass index, hand dominance, diastolic and systolic blood pressure, end-stage kidney disease cause, comorbid conditions, and dialysis vintage), dialysis treatment details (PD exchange volume and daytime empty or full peritoneum), and biochemical indexes (hemoglobin level and weekly Kt/V) were collected from the provider's electronic medical record system.

Intervention Group

Exercise training for participants in the intervention arm was performed by 1 exercise physiologist (M.W.). Participants met with the exercise physiologist at their monthly center appointments during a 3-month period. In addition, the exercise physiologist telephoned each intervention participant 4 times: once after the first appointment and before each succeeding appointment to record adherence and respond to any participant exercise queries.

Control Group

Besides standard care, control patients performed the pre- and post- study measures only.

Exercise routines were based on the American College of Sports Medicine guidelines and are listed in Table 1.[24] Participants started with a 5-minute warm-up exercise and ended each session with 5 minutes of cool-down exercises. The exercise prescription initially commenced with cardiovascular exercises of 30 minutes at moderate intensity 3 days per week. Cardiovascular exercise consisted of either walking or stationary cycling as negotiated to fit into each patient's lifestyle. Progression was dependent on patient adherence for the previous month and exercise tolerance. Exercise frequency was increased by 1 day per week per month of participation in the study and time was increased by no more than 10% per week per month of study participation. This progression was continued until participants were meeting 300 minutes of cardiovascular exercise per week before intensities were increased.

Resistance training was separated into upper- and lower-body categories with focus on larger muscle groups. Initial recommendations included 3 exercises per category with 2 sets of 8 to 12 repetitions and implementation of a resistance band 2 days per week. Increase in frequency, repetitions, number of exercises, and number of sets are described in Table 1. After exercise and cool down, participants were instructed to perform several stretches based on muscles exercised for 2 sets of 30 seconds.

Study Measures

Primary Outcomes

Feasibility measures were eligibility rates, recruitment rates, retention rates, adherence rates, adverse events, and sustained exercise rates (specific calculation methods

Table 1. Peritoneal Dialysis Exercise Program

Muscle Group	Initial Consultation	1 mo	2 mo	Final Consultation
Core	1-2 d/wk; 1 exercise; 8-10 repetitions; 1-2 sets	Add 1 exercise; add 2 repetitions; add 1 set	Add 1 exercise; add 2 repetitions; add 1 set	Provided resources and facility suggestions for patients so that they could continue their exercise routines
Lower body	1-2 d/wk; 2-4 exercises; 8-10 repetitions; 1-3 sets	Add 1 exercise; add 2 repetitions; add 1 set	Add 1 d; add 1 exercise; add 1 set	
Upper body	1-2 d/wk; 2-4 exercises; 8-10 repetitions; 1-3 sets	Add 1 exercise; add 2 repetitions; add 1 set	Add 1 d; add 1 exercise; add 1 set; increase weight ~5 lbs	
Cardiovascular walking or stationary cycling	3-5 d/wk; 10-30 min	Add 1 d; add 10-15min	Add 1 d; add 1 exercise; increase pace; add 10-15 min	

described in Table 2). Adherence was calculated as the total number of self-reported exercise sessions completed divided by the total number of exercise sessions prescribed. A participant was deemed adherent if they completed ≥50% of the prescribed exercise programs. Serious adverse events were defined as any injury, impairment, or medical condition that was directly or suspected to be due to performing the prescribed exercise. Adverse events were reviewed and adjudicated by the Principal Investigator, a nephrologist and Chief Medical Officer of the dialysis provider, and the Medical Director of the center, who is a nephrologist and also an investigator in the study. Sustained exercise rates were the percentage of patients still exercising 1 month after the exercise program stopped.

Secondary Outcomes: Effects on Physical Function and Patient-Related Outcome Measures

Physical function effects were assessed by comparing the difference between the 2 groups in the change in functional measures from start to end of the 3-month study period. All physical function tests were noninvasive and were conducted in the PD center. Details of the sit-to-stand test, timed-up-and-go (TUG) test, and pinch-strength test can be found in Box 1. The sit-to-stand and TUG tests measure large muscle group function, while the pinch-strength test was used to measure hand strength given the relevance to the pinch grip pressure required to perform PD catheter connections and disconnections.

Patient-reported outcome measures were measured using the London Evaluation of Illness (LEVIL) instrument.[25] LEVIL is a 6-item scale developed and used in hemodialysis patients that measures general well-being, pain, sleep, breathing, energy, and appetite.[26] The anchors for general well-being, sleep, and appetite were "very poor" to "excellent"; for pain and breathing, "extreme" to "no problem"; and for energy, "extremely fatigued" to "full of energy." Each domain uses the visual analogue scale, which allowed free selection of status along a line from worst (0) to best (100).[25]

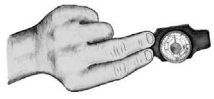
Statistical Analysis

Data for demographic and baseline characteristics were summarized using mean, standard deviation, and percentage. Nonparametric data were described by median and interquartile range. For each measure in the secondary objectives (physical function and patient-reported outcome measures), analysis of covariance for each of the physical function and patient-reported outcome measures was performed, adjusting for treatment effect using the baseline level of each outcome variable.

Table 2. Feasibility of a Peritoneal Dialysis Exercise Program

Feasibility Measure	Definition	Result	Relevance to Clinical Programs
Eligibility	% meeting eligibility criteria of no. of patients in center	76% (57/75)	Only 2 patients deemed medically ineligible; 7 non–English speaking, 3 major amputations, 2 unable to walk, and 4 on peritoneal dialysis < 6 wk were all potentially eligible to participate in a clinical exercise program
Recruitment	% recruited from total eligible	63% (36/57)	The majority of peritoneal dialysis patients are willing to be involved in an exercise study and willing to perform exercise
Retention	% completed from total commenced	72% (26/36)	The majority of patients are able to continue an exercise program over 3 mo; however, be prepared for one-third of patients to withdraw due to medical illness or other reasons
Adherence	% completed >50% of exercise program	77% (10/13)	The majority of patients who sign up for an exercise program will be adherent over a 3-mo period
Serious adverse events	No. of serious adverse events	Nil	There were no serious adverse events attributed to the exercise program, indicating the safety of an exercise program
Sustained exercise	% of intervention arm exercising 1 mo after program stopped	77% (10/13)	Patients can maintain some form of exercise or physical activity following the program stopping; exercise varied from attending gym, continuing the prescribed exercises, and walking as exercise

Box 1. Physical Function Tests

Test	Details	Equipment	Figure
Sit-to-stand	• Stand from a chair as many times as possible in 30 s[48] • Validated for people with chronic disease and used frequently in the dialysis population[32]	Chair	
Timed-up-and-go	• Time in seconds for an adult to rise from sitting in a standard chair, walk 8 ft, turn, walk back to the chair. and sit down using regular footwear[49] • Validated in older adults and used frequently in the dialysis population[50]	Chair and object at 8 ft	
Pinch-strength test-tip	• Seated on a chair without armrests, shoulder adducted, elbow flexed at 90°, forearm and wrist in neutral position • Squeezed the pinch-grip dynamometer with thumb tip to index fingertip as hard as they could • 3 measurements were repeated • The highest score was recorded in kg[51,52]	Pinch-grip dynamometer (PG-30, B&L Engineering)	
Pinch-strength test-lateral	• Seated on a chair without armrests, shoulder adducted, elbow flexed at 90°, forearm and wrist in neutral position • Squeezed the pinch-grip dynamometer with thumb pad to lateral aspect of middle phalanx of index finger as hard as they could • 3 measurements were repeated • The highest score was recorded in kilograms[51,52]		
Pinch-strength test-palmar	• Seated on a chair without armrests, shoulder adducted, elbow flexed at 90°, forearm and wrist in neutral position • Squeezed the pinch-grip dynamometer with thumb pad to pads of index and middle fingers as hard as they could • 3 measurements were repeated • The highest score was recorded in kg[51,52]		

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RESULTS

PDEx was conducted between November 2018 and March 2019 in a single home dialysis training center caring for a total of 75 PD patients. Baseline demographic, dialysis, and biochemical baseline measures are reported in Table 3, with the notable differences being shorter vintage, high fill volumes, and higher systolic blood pressures for the intervention group compared with the control group.

Primary Outcomes: Feasibility

Feasibility results can be found in Table 2. Recruitment was performed during a 2-week period in September 2018. Eligibility, recruitment, and retention rates were 76%, 63%, and 72%, respectively, resulting in 26 participants (13 in each arm). Three patients withdrew from the intervention arm in the first week and were not included in the adherence rate. From the remaining 13 participants in the intervention group, the adherence rate (completion of >50% of exercises) of the intervention group was 10 of 13 (77%). Ten of 13 intervention patients reported exercising independently 1 month after PDEx completion compared with 5 (38%) of the control group who were exercising 1 month after the study. The study flow diagram can be found in Figure 1.

No serious adverse events caused by the exercise program were reported. A total of 8 events were reported and investigated, 4 from the intervention arm and 4 from the control arm. Only 2 of these were related to the exercise intervention. One participant reported minor abdominal discomfort during 1 core exercise, which was stopped, and the participant continued the exercise program with no further symptoms. A second participant reported slight dizziness, requiring the patient to sit down for 5 minutes before continuing the exercise program. The patient had a history of dizziness that occurred both when exercising and at rest. All 6 severe events that occurred during PDEx, including 2 deaths in the control arm, were deemed unrelated to the intervention by the clinic's Medical Director and the Primary Investigator (Table S1).

Secondary Outcomes: Efficacy

Secondary measures of physical function measures and patient-reported outcome measures were compared between the 13 intervention patients and 13 control patients

Table 3. Patient Characteristics

	Intervention (n = 13)	Control (n = 13)	Whole Group (n = 26)
Age, y	57.7 ± 16.3	58.3 ± 16.7	58.0 ± 16.5
Female sex	5 (39%)	7 (54%)	12 (46%)
Race			
White	4 (31%)	5 (39%)	9 (35%)
Hispanic	7 (53%)	5 (39%)	12 (46%)
Black	1 (8%)	2 (16%)	3 (11%)
Asian	1 (8%)	1 (8%)	2 (8%)
Primary kidney disease			
Diabetes	6 (46%)	8 (62%)	14 (54%)
Hypertension	1 (8%)	2 (15%)	3 (11%)
Other	6 (46%)	3 (23%)	9 (35%)
Hb, g/dL	10.7 ± 1.5	11 ± 0.9	10.9 ± 1.2
SBP, mm Hg	146.5 ± 22.9	139.7 ± 20.1	143.0 ± 21.5
DBP, mm Hg	75.3 ± 16.2	75.9 ± 12.8	75.6 ± 14.3
PD vintage, mo[a]	18 [8-28]	23 [6-48]	22.6 [7-34]
BMI, kg/m^2	27.5 ± 5.1	28.5 ± 5.5	28.0 ± 5.3
Weekly Kt/V	2.2 ± 0.3	2.0 ± 0.4	2.1 ± 0.4
Diabetes	7 (53%)	8 (62%)	15 (58%)
Dominant hand			
Right	12 (92%)	11 (85%)	23 (88%)
Left	0	2 (15%)	2 (8%)
Neither	1 (8%)	0 (0%)	1 (4%)
Exchange volume, mL			
<2,000	2 (15%)	5 (39%)	7 (27%)
2,000-2,499	6 (46%)	6 (46%)	12 (46%)
≥2,500	5 (39%)	2 (15%)	7 (27%)
Full during day	8 (62%)	8 (62%)	16 (62%)

Note: Data presented as mean ± standard deviation or number (percent) unless noted otherwise. Modality for all patients was automated PD.
Abbreviations: BMI, body mass index; DBP, diastolic blood pressure; Hb, hemoglobin; Kt/V, urea clearance × time divided by volume; PD, peritoneal dialysis; SBP, systolic blood pressure.
[a]Median [interquartile range].

(Table 4). The t test analysis of covariance found that the difference between treatment groups for the TUG test (intervention, −1.7 ± 2.9; control, −0.8 ± 1.6; P = 0.04) and appetite (intervention, 5.8 ± 23.4; control, − 5.1 ± 5.3; P = 0.04) outcomes were statistically significant. Change in other physical function measures and change in patient-reported outcome measures were not statistically different between study groups over time (Table 4).

DISCUSSION

This study has demonstrated that in 1 US PD center, a resistance and cardiovascular exercise program is feasible. This study provides previously unknown knowledge regarding the feasibility targets that a PDEx program can expect. Notwithstanding the strict constraints of a randomized controlled trial designed study, a high number of patients were eligible for exercise. Certain ineligible patients may still have wanted to participate in an exercise program; however, they were ineligible to participate because of being non–English speaking, less than 6 weeks receiving PD, having had a previous amputation, or being unable to ambulate without assistance.

Patient inclusion rates have varied in previous PDEx studies. The 76% (57 of 75) of patients who met PDEx inclusion criteria was similar to the 82% (56 of 68) exclusion rate in a recent Japanese study,[20] but considerably higher than the 31% (14 of 45) of patients in the 1 previous US PDEx study from 2008.[27] This study excluded patients with hemoglobin levels < 11.0 g/dL, which was not an exclusion in our study and may have contributed to the high exclusion rate of the previous study.

Five patients from each arm did not complete the PDEx, resulting in an attrition rate of 38% over 3 months. Attrition rates in previous studies were 7% (Japan)[20] and 29% (United States).[27] The Japanese intervention was a combined aerobic and resistance intervention over 12 weeks,[28] with the US study consisting of aerobics only over a shorter 8-week period.[27] Lower attrition in the Japanese study may be a reflection of a culture of increased adherence to study procedures. Other PDEx intervention studies were challenging to compare given their small sample sizes.[18,29-31] The PDEx attrition rates are consistent with hemodialysis exercise studies, in which a 20% to 40% dropout rate is common during 3-month trials.[32] Importantly, the levels of recruitment, attrition, and adherence found in this study, in which more than two-thirds of recruited patients completed the study, reflected acceptable feasibility compared with the most recent and largest PDEx study,[20] demonstrating the ability to carry out a successful program in the US clinical context.

The adherence and subsequent "dose" of exercise play an important role in attaining exercise-related health-related benefits.[33] Adherence in the PDEx was 77% of people performing >50% of sessions, compared with previously reported exercise session adherence rates of 52% for aerobic and 76% for resistance exercise.[20] In hemodialysis resistance exercise studies, patients' adherence to exercise ranged between 76% and 89%,[34-38] with other exercise studies not reporting adherence.[39]

The inclusion of an exercise physiologist is a strong feature of this study and has quality and cost implications. Exercise physiologists are college-educated clinicians who are trained to improve and maintain physical and mental health and rehabilitate those with chronic disease and disabilities.[40] In PDEx, the exercise physiologist's initial physical assessments and goal-setting discussions averaged 45 minutes for each patient, with subsequent appointments lasting between 15 and 30 minutes. This exercise expertise is necessary to ensure that patients are performing the exercises correctly and as an external motivation.[41] However, this expertise comes at a cost, which we calculated at ~$10 per patient per PD patient-month if our program lasted 1 year.

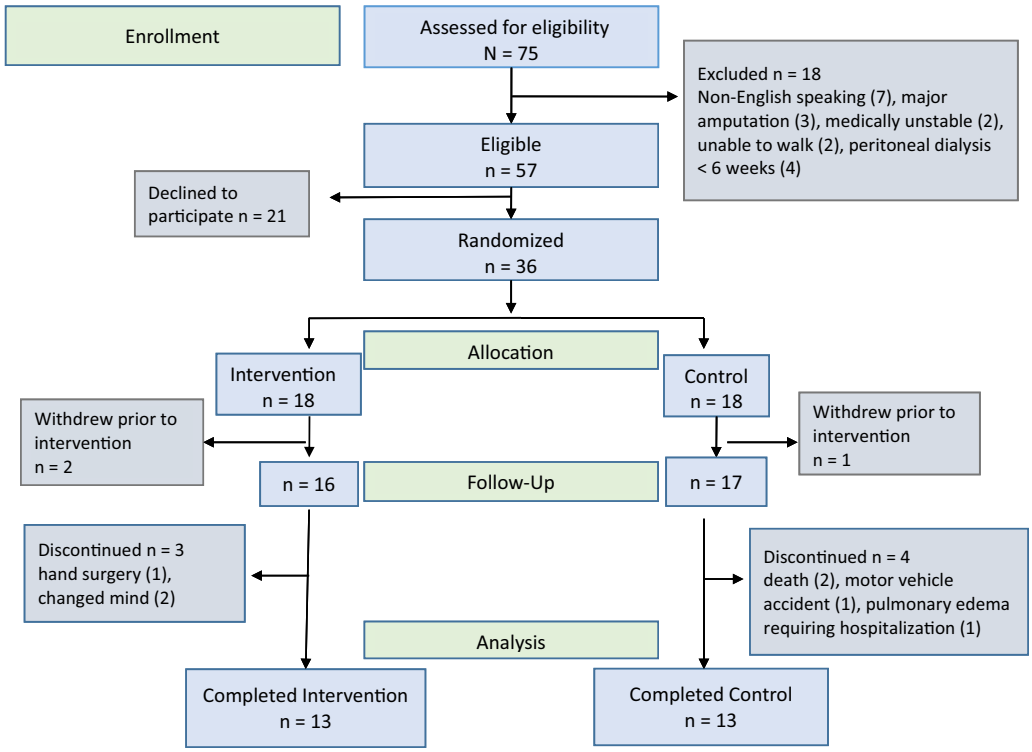

Figure 1. Participant flow diagram.

Concerns regarding the safety and comfort for PD patients performing exercise were recorded, particularly related to the peritoneal catheter and presence of PD fluid in the abdomen. Given the low numbers in our study, definitive adverse event data need to be interpreted with caution. One patient in the intervention group reported slight abdominal discomfort during 1 twisting core exercise, and this exercise was modified with resolution of the discomfort (Table S1). This was an example of the benefit of the exercise physiologist who could slightly modify an exercise using their exercise expertise. No dwell issues were reported, although a slight majority in both groups routinely were left with fluid in their peritoneum after the final cycle. We did not discourage exercising full because cycling, jogging, and resistance exercises are associated with only slightly increased abdominal pressure compared to coughing.[42]

The 3 physical function tests used in PDEx: sit-to-stand, TUG, and pinch-strength tests, showed that the

Table 4. Effects of the 12-Week Exercise Program on Physical Function and Patient-Reported Outcome Measures

	Control (n = 13)			Exercise (n = 13)			*P* for Treatment Effect, *t* Test	*P* for Treatment Effect, ANCOVA
Test	**Baseline**	**12 wk**	**Delta**	**Baseline**	**12 wk**	**Delta**		
Physical Function (higher numbers indicate better result except for TUG)								
STS30, count	11.6 ± 3.8	13.1 ± 4.1	1.4 ± 1.9	10.0 ± 3.9	12.2 ± 8.0	2.2 ± 3.4	0.07	0.09
TUG, s	8.8 ± 2.4	8.0 ± 3.1	−0.8 ± 1.6	9.7 ± 3.3	8.0 ± 2.4	−1.7 ± 2.9	0.02[a]	0.04 [a]
PST-tip, lb	12.7 ± 2.9	13.2 ± 3.0	0.5 ± 1.9	13.2 ± 5.5	14.4 ± 6.5	1.2 ± 1.8	0.35	0.42
PST-lat, lb	13.6 ± 2.7	13.9 ± 2.3	0.3 ± 1.5	14.3 ± 5.9	15.4 ± 6.2	1.1 ± 1.0	0.09	0.10
PST-palm, lb	13.2 ± 3.3	14.6 ± 3.2	1.4 ± 1.9	14.0 ± 6.3	16.1 ± 6.9	2.1 ± 1.5	0.55	0.60
Patient-Reported Outcome Measures								
General well-being (0-100)	65.8 ± 19.5	63.8 ± 27.8	−2.0 ± 18.6	59.8 ± 26.3	67.8 ± 18.8	8.0 ± 20.2	0.05[a]	0.10
Pain (0-100)	67.2 ± 27.0	63.5 ± 82.1	-3.6 ± 24.0	83.8 ± 15.0	82.1 ± 18.8	−1.7 ± 4.8	0.49	0.07
Energy (0-100)	57.8 ± 26.0	56.9 ± 28.7	−0.9 ± 3.6	55.2 ± 27.7	63.0 ± 24.8	7.8 ± 22.7	0.15	0.13
Sleep (0-100)	42.8 ± 30.3	46.3 ± 32.6	3.5 ± 3.8	61.5 ± 33.6	68.8 ± 27.8	7.3 ± 5.2	0.63	0.40
Breathing (0-100)	81.8 ± 19.2	73.2 ± 25.7	−8.6 ± 26.0	85.4 ± 19.2	90.2 ± 9.2	4.8 ± 7.1	0.08	0.06
Appetite (0-100)	64.4 ± 26.7	59.3 ± 28.3	−5.1 ± 5.3	73.6 ± 23.7	79.4 ± 20.4	5.8 ± 23.4	0.08	0.04[a]

Abbreviations: ANCOVA, analysis of covariance; PST, pinch-strength test; lat, lateral; STS30, sit to stand test; TUG, 8 ft timed-up and-go.
[a]$P < 0.05$

intervention group trended to improved performance greater than the control group, with only the TUG test reaching statistical significance. This is consistent with physical function improvement in hemodialysis studies.[43] The clinical significance of these tests is relevant to PD patients given the importance of independence and quality of life related to being able to stand from a chair, walk 8 feet, and maintain pinch grip strength to connect and disconnect PD catheter exchanges. However, the lack of a significant effect in most of the physical function measures possibly reflected the larger numbers required to detect statistically significant differences.

Appetite improved in the intervention group, with all other patient-reported outcome measures trending to improvement without statistical significance. Although studies have shown exercise to be associated with improvements in patient-reported outcome measures in hemodialysis patients,[44] there has been minimal reporting of these measures as the primary outcome for a PDEx intervention.[21] Given the recent increased interest in patient-reported outcome measures,[45] future studies may provide more insight into the effect of exercise on patient-reported outcome measures such as fatigue, sleep, breathlessness, pain, and appetite in people receiving PD.

No a priori numbers were specified given the study aim of evaluating the program in 1 center. In addition, the lack of research in this area made it difficult to predict a priori numbers and we were reluctant to make incorrect assumptions. Previous PD interventional studies had small participant numbers, with the most recent systematic review reporting 6 studies ranging from 3 to 22 participants.[21] A recent Japanese study reported a larger sample with 47 patients (24 intervention and 23 control) of a potential 68 PD patients who satisfied inclusion criteria.[20] In this study, participants had similar age and sex, but lower body mass index and diabetes prevalence, and all were receiving continuous ambulatory PD and not automated PD. Larger studies have been performed in hemodialysis patients[46] and transplant recipients[47] than in PD cohorts.

The study has certain limitations. Our study focused on feasibility and was not powered to detect a difference between the 2 groups in physical functions or patient-reported outcome measures. Therefore, the small sample size limited the ability to address any change in secondary outcomes. There is also potential bias as a result of nonblinding for pre- and post- physical function measures. A further limitation is the use of the LEVIL tool to measure patient-reported outcome measures given that this was the first use in PD patients and thus has had limited psychometric evaluation. Analysis was performed on a per-protocol rather than an intent-to-treat basis.

These limitations are counterbalanced by several strengths. This is the largest study reported in the US context and the sample was a pragmatic clinical cohort to ensure transferability and generalizability of results.

A resistance and cardiovascular exercise program appears to be safe and feasible in a US PD program. The dialysis community's past inaction in this area is likely contributing to the accelerated physical deterioration of PD patients. Current PD care models provide training to perform complex procedures. The expectation is that the patients independently cope with the physical demands of providing PD for themselves, with limited attention by providers and physicians to assist in maintaining their own physical function. A more comprehensive care approach to limit physical and psychological decline to reduce adverse events is required. Thus, services by exercise professionals encouraging a more active lifestyle, limiting the physical deterioration of PD patients, may present an opportunity to maintain more independence and an improved quality of life. This study provides meaningful data for eligibility, recruitment, retention, and adherence rates that can guide future clinical exercise programs in PD care.

SUPPLEMENTARY MATERIAL

Supplementary File (PDF)

Table S1: Adverse event report

ARTICLE INFORMATION

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