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ORIGINAL ARTICLE

Effects of intradialytic cycling compared with pedometry on physical function in chronic outpatient hemodialysis: a prospective randomized trial

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ABSTRACT

Background. Individuals on hemodialysis have low physical function and activity levels. Clinical trials have shown improvements in these parameters with exercise programming. Pedometers have not been extensively evaluated in individuals on hemodialysis. This randomized clinical trial compared the effects of intradialytic cycling versus a pedometer program on physical function, physical activity and quality of life.

Methods. Sixty patients were randomly assigned to two study groups. The ergometer group cycled during each hemodialysis session for 24 weeks. Pedometer participants followed a home-based walking program for 24 weeks. The primary outcome was aerobic capacity [VO_{2peak} and 6-minute walk (6MW) test]. Secondary outcomes included lower extremity strength [sit-to-stand (SS) test], flexibility [sit-and-reach (SR) test], physical activity (accelerometer) and health-related quality of life. Measurements were collected at baseline and at 12 and 24 weeks.

Results. At 12 and 24 weeks, there was no significant change in the VO_{2peak} or 6MW test between or within study groups. SS testing in the ergometer group improved from 10.2 (SD 3.4) to 11.4 (SD 2.5) cycles from baseline to 24 weeks ($P < 0.005$). Similarly, in the pedometer group, SS cycles improved from 10.1 (SD 3.3) to 12.2 (SD 3.5) ($P < 0.005$). The SR test also significantly improved over time in both the study groups. No significant changes were noted for other secondary outcomes.

Conclusions. Both intradialytic cycling and pedometer programming improved aspects of physical function. Neither intervention had a significant effect on aerobic capacity. No significant differences in any outcomes were identified between interventions groups.

Keywords: exercise, hemodialysis, pedometers, physical activity, physical function

INTRODUCTION

Individuals with end-stage renal disease (ESRD) have low levels of physical function and activity [1–3]. Both physical activity and function decline over time on dialysis [4]. Self-

reported functional status and quality of life are known to be significantly lower in individuals on hemodialysis compared with age and sex-matched controls [5]. Poor functional status and low physical activity levels have repeatedly been associated with poor outcomes such as an increased risk of hospitalization and decreased survival in observational studies in the dialysis population [6–10].

Numerous small randomized controlled studies have demonstrated benefits of aerobic exercise to physical fitness, function and quality of life in ESRD. A Cochrane review of studies examining exercise programming in patients with all stages of chronic kidney disease confirmed significant improvements in the above outcomes with this intervention [11]. Although benefits have been demonstrated using both intradialytic and interdialytic exercise programs, cycling during hemodialysis was associated with higher adherence than an exercise program administered outside of dialysis [12].

Despite this evidence, several barriers to routine implementation of intradialytic exercise programs remain. First, the dose and progression of exercise required for effect remains unclear. Most investigators have not reported the intensity of exercise achieved or the total number of sessions completed. In addition, as structured in many research studies, such an exercise program would require additional staff to provide exercise supervision during each dialysis session. This is neither financially feasible nor practical for many dialysis units. As a result, less resource intensive exercise programs should be explored. Pedometers are low-cost, simple devices that provide information regarding physical activity level that is easy to understand and accessible to diverse literacy levels. This information can then be used to motivate or sustain behavioral changes related to physical activity [13]. The prescription of pedometers has been shown to improve physical activity levels in non-hemodialysis populations [14, 15]. A single, small, uncontrolled study which examined the use of pedometers in hemodialysis patients showed increased physical activity over a 4-month period with this intervention [16]. More data on the relative effectiveness of this lower cost intervention versus higher cost intradialytic exercise programs are needed to inform clinical decision-making.

We therefore conducted a randomized trial comparing the effects of a pragmatically designed, intradialytic cycling exercise program versus a home-based pedometer program on aerobic capacity, physical function and quality of life in prevalent hemodialysis patients.

MATERIALS AND METHODS

The study was reviewed and approved by the University of Manitoba Biomedical Research Ethics Board. All patients gave written informed consent before enrollment into the study. This study was registered with clinicaltrials.gov (Identifier NCT00492362).

Study design and participants

This 24-week, pragmatic, non-blinded trial randomized 60 patients to either intradialytic cycling or to a home-based pedometer program. Patients were recruited from four hospital-based outpatient hemodialysis units in Winnipeg, Manitoba, Canada from 1 July 2007 to 1 October 2007. All of the participating dialysis units belong to the Manitoba Renal Program, a provincially administered program.

Patients were eligible for enrollment if they were adults (≥18 years old) on chronic hemodialysis for ≥3 months, with stable hemoglobin ≥100 g/L and stable dialysis treatments (single-treatment Kt/V ≥1.2, no shortened runs or access problems) over the month prior to study entry. Eligible individuals were required to comprehend instructions in English.

Patients were excluded if they were clinically unstable (acute medical illness in the past month; frequent hypotension during dialysis; symptomatic cardiovascular disease in the past 3 months and labile glycemic control); were unable to exercise (lower extremity amputation with no prosthesis); had severe musculoskeletal pain at rest or with minimal activity precluding walking or stationary cycling; unable to sit, stand or walk unassisted (walking device such as cane or walker allowed); had shortness of breath at rest or with activities of daily living (NYHA Class IV) or would be otherwise unable to complete the protocol due to impending travel, relocation or living-related renal transplantation.

Randomization and interventions

Following informed consent, subjects were randomized to the two study arms in fixed blocks of four. Allocation sequence was computer generated by a third party prior to commencement of enrollment.

Subjects in the cycling group were assigned to ergometer cycling during hemodialysis. At each hemodialysis session, a Monark Rehab Trainer 881E (Monark Exercise AB, Vansbro, Sweden) cycling ergometer was placed in front of the participant's dialysis chair. Subjects were allowed to cycle anytime during the first half of each dialysis session. During the first three exercise sessions, a dedicated study kinesiologist was present to provide assistance. During this time, cycling sessions were individualized by the kinesiologist based on baseline physical performance measures. Thereafter, in an attempt to mimic real-life dialysis unit conditions, the ergometer was set up by the patient, with assistance from unit staff, as necessary. The study kinesiologist checked in with participants every 2 weeks to provide individualized guidance regarding progression of exercise intensity and duration and on an *ad hoc* basis as needed. Participants kept an exercise log, which included duration of cycling per session, total counts (fly wheel rotations) per session, heart rate and blood pressure. Average intensity achieved during each session was measured subjectively by average Borg Rate of Perceived Exertion (RPE) [17] and objectively using the average Watts reported during each session as per the ergometer display screen. These values were also recorded in the participants' logs for each session. During the first three cycling sessions, RPE, blood pressure, heart rate and oxygen saturation were measured every 5 min during and 15 min post exercise. Subsequently, monitoring of RPE was decreased to every 10 min during exercise and vital signs were measured before, at completion of and 15 min post cycling (in addition to routine dialysis unit monitoring).

Initial exercise prescription was individualized based on ability and fitness level. Participants generally started with no resistance and cycled between 10 and 30 min per session during the first week of the study. All participants were educated regarding gradual exercise progression using the FITT principle (Frequency, Intensity, Time and Type) and the ultimate goal exercise session duration of 60 min, 3× per week. The goal intensity for each session was 12–14 (moderate to somewhat hard) on the 20-point Borg RPE [17].

Study participants randomized to the pedometer group received a pedometer (Steps Count Steps Only®, Steps Count, Deep River, ON, Canada) and were educated regarding its use, the goal of 10 000 steps per day, the goal exercise intensity of 12–14 (moderate to somewhat hard) on the Borg RPE and the format of a typical exercise session using the FITT principle [18]. Subjects were instructed to wear the pedometer on their dominant hip during waking hours and were asked to complete a weekly steps log for the duration of the study. The frequency and purpose of kinesiologist visits was the same as in the ergometer group.

All baseline demographics and clinical information were collected from the participants' dialysis charts or by clinical history at the time of study enrollment.

Outcomes

'Primary outcome' was aerobic exercise capacity measured by estimated VO_{2peak} calculated through exercise testing. Six-minute walk (6MW) test was used as a second measure of aerobic capacity.

'Secondary outcomes' included lower extremity function as measured by sit-to-stand (SS) testing, flexibility measured by the sit-and-reach (SR) test, health-related quality of life measured by Short Form 36 (SF36) and physical activity level measured by accelerometry.

All outcomes were measured at baseline, 12 weeks (mid-study) and 24 weeks (study end).

Testing protocols

Exercise testing was performed at a single site (Wellness Institute, Seven Oaks General Hospital, Winnipeg, Canada). Estimated VO_{2peak} following exercise testing was calculated using the Foster's equation which has been validated in an elderly population [19]. Two individuals underwent baseline exercise testing using an ergometer protocol due to inadvertent deviation from the study protocol. The remainder underwent treadmill testing using the modified Bruce or Bruce protocol, as appropriate [20].

All assessments of physical function were performed at the same site by the same kinesiologist at all time points for each individual. Testing in each participant was performed at the same time of day, pre-dialysis and on a mid-week dialysis day when possible throughout the study.

The '6MW testing' followed the protocol outlined by the American Thoracic Society [21]. Distance covered in 6 min was recorded in meters. 'SS testing' was modified from that described by Csuka and McCarty [22]. Due to concerns that patients might not be able to complete 10 SS cycles, the number of full SS cycles performed in 30 s was recorded. The 'SR test' was performed using a flexometer with a ruler arm attached at the 26-cm point. The test was repeated twice and the highest score (distance stretched) was recorded in centimeters.

Health-related quality of life was measured using the Physical Component Summary (PCS) and Mental Component Summary (MCS) scores calculated using the SF36 Version 2 (QualityMetric, Lincoln, RI) [23].

To document physical activity level, all participants wore a biaxial accelerometer (Biotrainer Pro™, IM Systems, Arnold, MD) for five consecutive days at each of the three measurement time points. Participants were instructed to wear the accelerometer on their dominant hip during waking hours. Accelerometer data files were assessed for minimum compliance in terms of monitor wear time. A valid file for analysis required at least 3 days with a minimum of 8 h of wear time per day. Total active minutes were calculated by summing the minutes per day spent in light intensity and moderate-to-vigorous physical activity (MVPA) based on pre-specified activity count cut points (1 and 4 g, respectively) [24].

Different approaches to document the exercise intensity achieved were used in each of the study groups. In the ergometer group, an objective estimate of power output during each exercise session was obtained using the average Watt reading on the ergometer display screen. The mean of this reading was then obtained for the three sessions closest to each study measurement time point (i.e. baseline, 12 and 24 weeks). In a similar manner, a weekly mean estimate of subjective exercise intensity as measured by the Borg RPE recorded in participant logs was calculated at each measurement time point. In the pedometer group, cadence as measured by total weekly steps achieved divided by total weekly time spent walking was used as a measure of intensity. A cadence of 100 steps per minute has previously been noted to correspond to moderate exercise intensity [25].

Data analysis

Baseline continuous variables are expressed as mean (standard deviation) and were compared between intervention groups using independent two-tailed Student's *t*-test or Mann–Whitney *U*-test, depending on distribution. Categorical variables are expressed as percentage and were compared between groups using Fisher's exact test. All outcome analysis was performed in an intention-to-treat manner. Due to the presence of repeated measures, linear mixed-effects models with time and intervention group as fixed variables and time as a random variable were performed for each outcome. Owing to small sample size, no additional variables were added to these models. Changes in primary and secondary outcomes were also compared at each study time point between groups by independent two-tailed *t*-tests and within groups by paired two-tailed Student's *t*-tests. P-values are considered significant at the 0.05 level.

All statistical analysis was performed using SPSS Version 19 (SPSS, Inc., Chicago, IL) and STATA Version 12 (StataCorp LP, College Station, TX).

RESULTS

One hundred and ninety-one patients were assessed for eligibility (Figure 1). Of these, 60 patients consented to participate and were randomized to the intervention arms. Over the course of the study, 10 participants from the ergometer arm and 7 subjects from the pedometer arm withdrew from the study. The most common causes for withdrawal in the ergometer group were medical illness and renal transplantation. In the pedometer arm, the most common reasons were personal preference and medical illness. Data from 43 individuals were available for analysis at the 24-week time point. Baseline demographics, characteristics and measures of physical function in those who withdrew and those who remained in the study were broadly similar. However, individuals who withdrew had significantly lower weekly erythropoietin dose, more hypertension and higher weekly fluid gains (data not shown).

Baseline characteristics

Baseline demographic characteristics were similar between the two study groups (Table 1) with the exception of duration on hemodialysis (median 37 versus 21 months cycling and pedometer groups, respectively) and prevalence of ischemic heart disease (3 and 26% cycling and pedometer groups, respectively). Baseline measures of physical function and aerobic fitness were not significantly different between the two study groups (Table 2).

Aerobic capacity

Estimated VO_{2peak} did not differ between groups at any time point. In addition, estimated VO_{2peak} did not change within each group over time (Table 3). Similarly, no statistically significant change in the 6MW test was noted between or within groups at the 12-week or 24-week measurement points (Table 3).

Physical function

Lower extremity function as measured by SS improved significantly in both groups over time, but no significant change

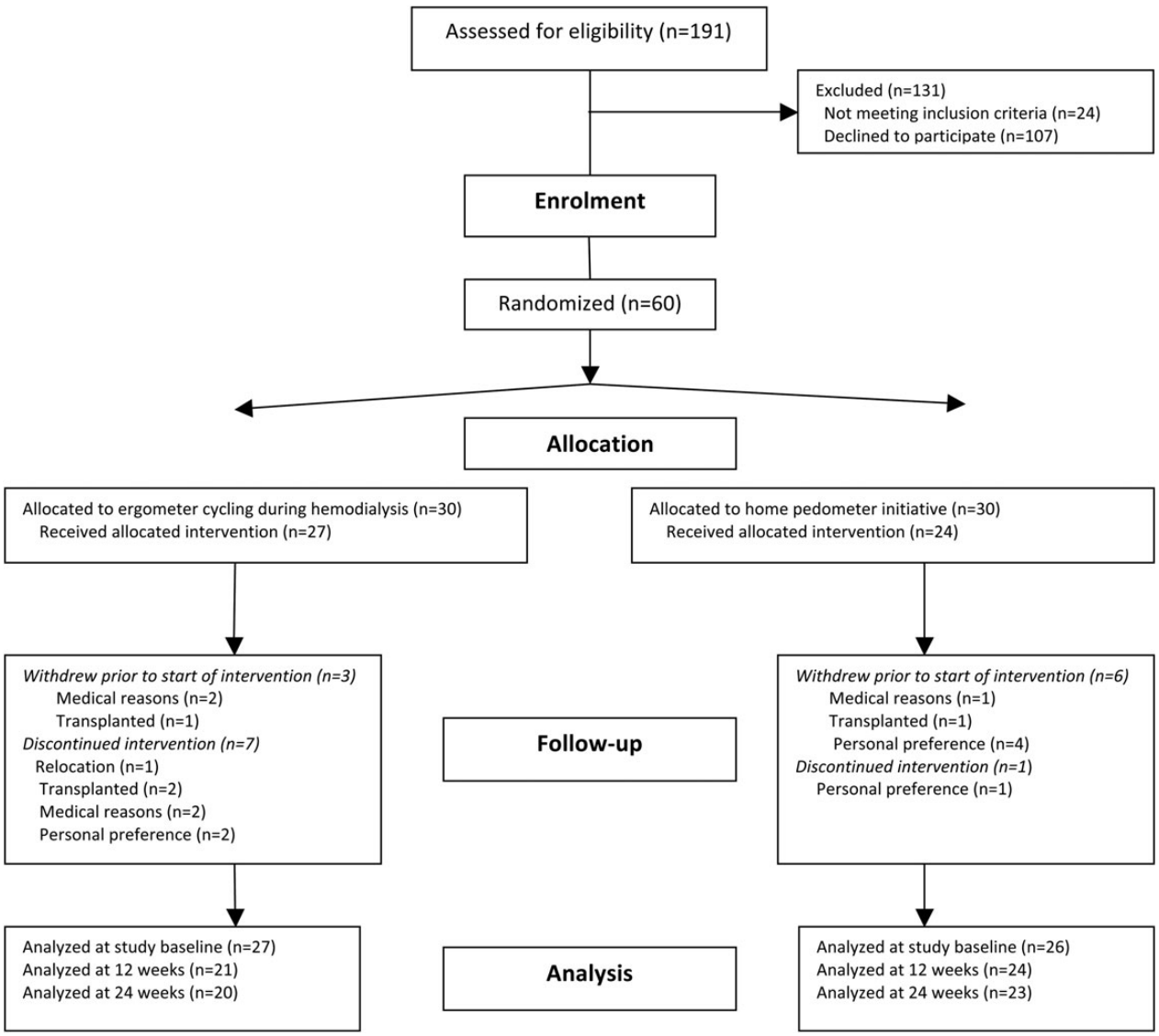

FIGURE 1: Participant flow chart.

Table 1. Baseline demographics and clinical characteristics by study group

	Ergometer ($n = 30$)	Pedometer ($n = 30$)
Age (years)	52 (14.5)	53 (16.9)
Male (%)	73	60
Diabetes (%)	47	53
BMI (kg/m^2)	28 (5.8)	28 (7)
Arteriovenous fistula (%)	75	57
Time on hemodialysis (months) Median (IQR)[a]	37 (69)	21 (30)
Albumin (mg/dL)	35.8 (4.2)	35.9 (2.5)
Hemoglobin (g/L)	117 (8.9)	121 (11.4)
Erythropoietin dose (units)	8815 (8440)[b]	10 724 (5738)[c]
Kt/V	1.5 (0.2)[b]	1.7 (0.3)[c]
Weekly fluid gains (L)	7.8 (3.1)[b]	7.2 (4)[d]
SBP (mmHg)	144 (23)[d]	142 (23)[c]
DBP (mmHg)	77 (12)[d]	78 (11)[c]
# of BP meds median (range)	1 (0–4)[b]	1 (0–4)[c]
Prescribed duration of HD (h)	3.8 (0.4)[d]	3.8 (0.3)
Ischemic heart disease[e] (%)	3	26
Hypertension (%)	53	70
Peripheral vascular disease (%)	3	23

Mean (SD) unless otherwise specified.
[a]P = 0.047 between group comparison (Mann–Whitney *U*-test).
[b]$n = 27$.
[c]$n = 29$.
[d]$n = 28$.
[e]P = 0.026 between group comparison (Fisher's exact test).

Table 2. Baseline physical function by intervention arm

	Ergometer	Pedometer	P-value
VO_{2peak} (mL/kg/min)[a]	18.2 (8.2)	18.1 (6.2)	0.97
6MW (m)[a]	404.2 (110)	390.2 (77)	0.31
SS score[b]	10.2 (3.6)	10.1 (3.3)	0.51
SR (cm)[c]	12.6 (8.1)	14.5 (7.5)	0.90

Values denote mean (SD).
[a]Ergometer $n = 27$ and pedometer $n = 25$.
[b]Ergometer $n = 26$ and pedometer $n = 25$.
[c]Ergometer $n = 25$ and pedometer $n = 25$.

between study groups was observed using the mixed-effects model (P < 0.001 and P = 0.72 for time and group, respectively). Mean improvement in SS using this model was 0.85 cycles (95% CI 0.54, 1.16) per 12-week time period (Table 3).

Similarly, SR improved significantly over time, but was not significantly different between study groups (P < 0.001 and P = 0.41 for time and group, respectively) (Table 3). Mean improvement in SR was 2.4 cm (95% CI 1.8, 3.1) per 12-week period using study baseline as reference (Table 3).

Physical activity

Baseline, mid- and end-point physical activity (Table 3) were similar between groups. There was no statistically significant change in the amount of physical activity at any intensity level over time in either study group.

Exercise dose and intensity

In those individuals who remained enrolled in the study for greater than 1 month, 24/24 (100%) individuals completed log sheets for at least some portion of the study in the ergometer group, whereas only 16/24 (67%) completed log sheets for at least some portion of the study in the pedometer group.

Ergometers. When accounting for the number of cycling sessions completed out of total possible number of sessions in these 24 individuals, the mean completion rate was 53% (95% CI 41, 65). Median weekly time spent biking during hemodialysis at baseline was 52.5 min (IQR: 27) and increased to a median of 129.5 min (IQR: 95) at the 12-week time point (P = 0.0006). At 24 weeks, median weekly time spent biking was 142 min (IQR: 108). This was a statistically significant increase from baseline, but not from the 12-week values (P = 0.012 and 0.970, respectively). Both subjective and objectively measured exercise intensity increased over time in this group. Mean power output during exercise over the week at baseline was 7.8 W (95% CI 4.9, 10.7) and increased to 18.1 W (95% CI 11.5, 24.8) and 20.0 W (95% CI 12.4, 27.5) at 12 and 24 weeks, respectively (Figure 2). This change at 12 and 24 weeks from baseline was statistically significant (P = 0.003 and 0.007, respectively). Similarly, subjective exercise intensity during each session as measured by mean weekly Borg RPE at each study time point increased significantly over time from 10.7 (95% CI 10.2, 11.2) at baseline to 12.0 (95% CI 11.5, 12.4) and 11.8 (95% CI 12.4, 27.5) at 12 and 24 weeks, respectively (Figure 2). Only the change from baseline to 12 weeks was statistically significant (P = 0.004). Over the course of the study, a total of six individuals (25%) achieved the goal of 180 min of cycling or more per week (60 min per session).

Pedometers. Weekly step logs were completed by participants for a mean of 14 weeks (95% CI 9, 18). This is indicative of 58% (95% CI: 38, 75) overall compliance with the 24-week initiative. At baseline, median total number of steps walked per week was 9935 (IQR: 17 879). This increased to 17 169 (IQR: 21 521) and 29 873 (IQR: 19 532) at 12 and 24 weeks, respectively, but was not statistically significant (P = 0.065 and 0.101, respectively). There was also no significant difference in weekly step count between study weeks 12 and 24 (P = 0.571). A limited number of participants (4/24) recorded time spent walking in logs in the pedometer group. In these individuals, mean step cadence was 194 steps/min (95% CI 10, 577) at baseline, 215 steps/min (95% CI 161, 270) at 12 weeks and 172 steps/min (95% CI 167, 177) at 24 weeks. In view of the small number of individuals for which these data were available, no inferential analysis was performed. No individuals in the pedometer group achieved the theoretical goal of 10 000 steps per day.

Health-related quality of life

Using linear mixed-effects model analysis, mean PCS score was significantly higher in the pedometer group than in the ergometer group (P = 0.028). This was particularly evident at baseline where mean PCS score was 35.3 (SD 9.9) and 43.3 (SD 6.7) in the ergometer and pedometer groups, respectively. Although PCS appeared to increase in the ergometer group, change over time was not significant in the mixed-effects model or with paired *t*-test in either study group. The mean

Table 3. Physical function and physical activity between groups over time

Performance measure	Ergometer[a]	*n*	95% CI	Pedometer[a]	*n*	95% CI
VO_{2peak} (mL/kg/min)						
Baseline	18.2 (8.2)	27	15.0, 21.4	18.1 (6.2)	25	15.6, 20.6
12 weeks	20.0 (8.2)	16	15.9, 24.1	17.5 (6.0)	18	14.7, 20.3
24 weeks	18.2 (7.9)	17	14.4, 22.0	18.4 (6.2)	20	15.6, 21.2
6MW (m)						
Baseline	404.2 (110)	27	396.6, 411.8	390.2 (77)	25	358.3, 422.1
12 weeks	430.8 (104)	21	383.6, 477.9	396.7 (74)	22	364.0, 429.4
24 weeks	420.2 (102)	19	370.9, 469.4	390.0 (92.6)	21	347.8, 432.1
SS (cycles)[b,c]						
Baseline	10.2 (3.6)	26	8.7, 11.6	10.1 (3.3)	25	8.8, 11.5
12 weeks	11.4 (3.7)	20	9.6, 13.1	11.0 (4.0)	22	9.2, 12.8
24 weeks	11.4 (2.6)	20	10.2, 12.6	12.2 (3.5)	23	10.7, 13.7
SR (cm)[b,d]						
Baseline	12.6 (8.1)	25	9.2, 16.0	14.5 (7.5)	25	11.4, 17.6
12 weeks	15.3 (10.2)	20	10.5, 20.1	15.4 (7.8)	23	12.0, 18.7
24 weeks	18.1 (9.3)	19	13.6, 22.6	19.2 (7.7)	22	15.8, 22.6
Total active minutes/day						
Baseline	101 (60)	23	74.8, 126.8	112 (72)	20	78.0, 145.6
12 weeks	84 (32)	12	64.0, 104.9	92 (79)	13	43.9, 139.9
24 weeks	120 (69)	17	84.3, 155.7	127 (71)	13	83.8, 170.5
MVPA[e] per/day (min)						
Baseline	8 (15)	23	1.4, 14.1	11 (21)	20	0.9, 20.9
12 weeks	6 (11)	12	0, 13.1	7 (10)	13	0.4, 12.7
24 weeks	10 (14)	17	3.1, 17.8	7 (11)	13	0.7, 14.3

Values denote mean (SD).
[a]No significant difference between groups at any time point.
[b]$P < 0.001$ for change over time within both groups by mixed-effects model.
[c]Using paired *t*-test: $P < 0.005$ for change from baseline to 24 weeks within each study group. $P < 0.05$ for change from baseline to 12 weeks within each study group. $P < 0.05$ for change from 12 to 24 weeks in the pedometer group but not in the ergometer group.
[d]Using paired *t*-test: $P < 0.0001$ for change from baseline to 24 weeks within each study group. $P < 0.01$ for change from 12 to 24 weeks within each study group.
[e]Moderate/vigorous physical activity.

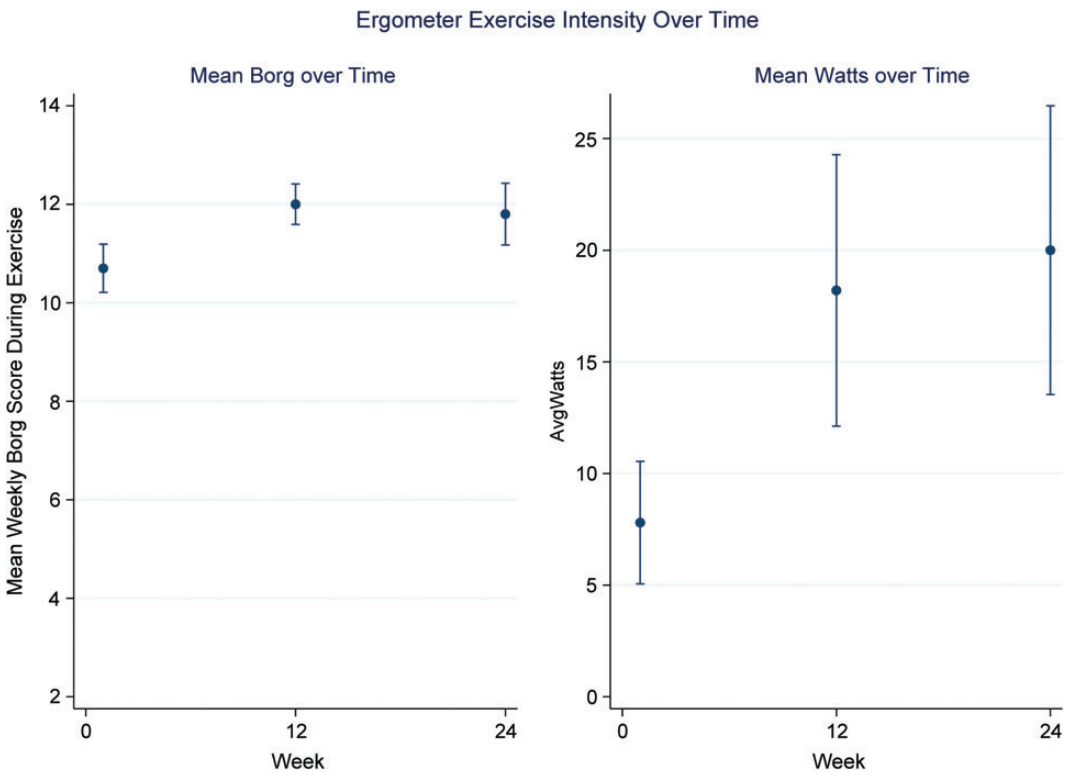

FIGURE 2: Mean weekly exercise intensity in the ergometer group over time. Watts: baseline $n = 25$, 12 weeks $n = 14$; 24 weeks $n = 9$. Borg Rate of Perceived Exertion: baseline $n = 26$, 12 weeks $n = 14$; 24 weeks $n = 9$.

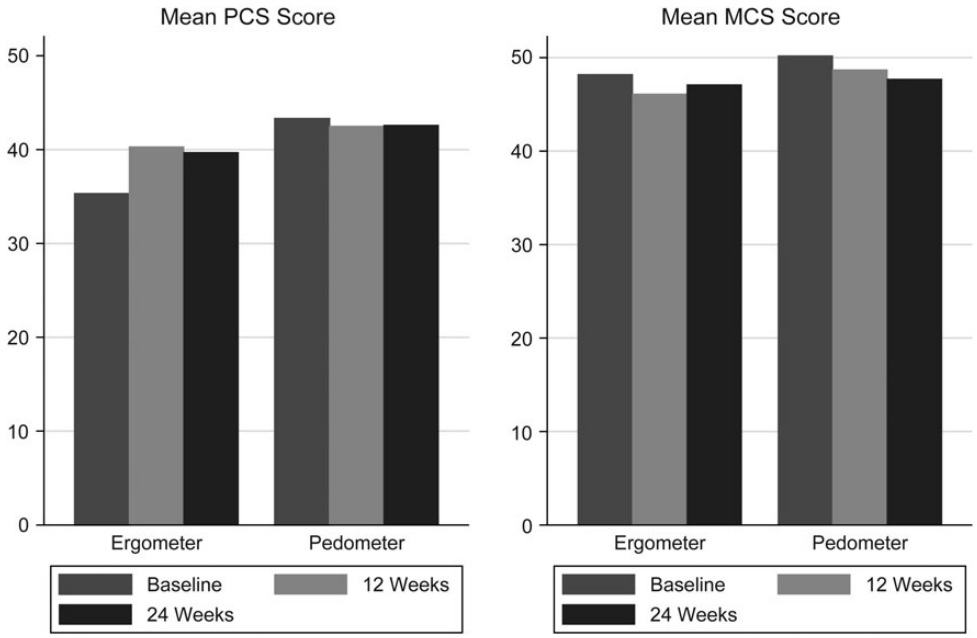

FIGURE 3: Mean PCS and MCS score by study group over time. *P = 0.001 for difference in the mean PCS score between ergometer and pedometer groups at baseline (*t*-test). No significant change over time in either group for PCS or MCS. No significant difference between groups for MCS. Baseline: ergometer $n = 26$, pedometer $n = 25$. Twelve weeks: ergometer $n = 19$, pedometer $n = 23$. Twenty-four weeks: ergometer $n = 19$, pedometer $n = 21$.

MCS score did not show any statistically significant difference over time (Figure 3).

Adverse events

Adverse events were collected by report from participants, nurses and research assistants. One fistula 'blow' (tissue infiltration) while cycling during hemodialysis occurred. Other than topical ice to the area of infiltration at the time of the event, no treatment was required. Another individual in the cycling arm scraped his ankle on the ergometer pedals. A subsequent wound infection was successfully treated with antibiotic therapy. No additional adverse events were reported in either group during the study period.

DISCUSSION

In this pragmatic randomized trial evaluating cycling during hemodialysis compared with a home-based pedometer intervention, no improvement in aerobic capacity after 24 weeks was observed. In contrast, both study groups demonstrated significantly improved lower extremity function and flexibility, suggesting a benefit of both exercise interventions to these outcomes.

The lack of significant improvement in aerobic capacity in our study as measured by VO_{2peak} and 6MW test contrasts with previous findings in this population [11]. Overall physical activity level and exercise intensity at baseline and throughout the study were very low. Most individuals had minimal levels of MVPA. It is thus possible that the intensity of activity achieved in this study was not adequate to trigger a change in aerobic capacity [11]. Owing to the lack of reporting of exercise dose and intensity achieved in many previous trials, it is difficult to determine whether intensity and dose in this trial were similar to that achieved in previous investigations. As well, our small sample size does not permit stratification of the analysis by intensity of exercise performed to determine if this was a factor. In addition, a 'ceiling effect', for aerobic capacity as estimated by 6MW test, has been observed in healthy elderly populations and this phenomenon may apply to our results for this measure [26, 27]. The 6MW results were higher than values used in our sample size calculation and similar to those of Koh *et al.* [28] who also showed no significant change in this outcome with exercise programming. Finally, attendance rate for exercise testing was low and the dropout rate for this study was higher than anticipated. This limited power to detect differences in the primary outcome over time and between study groups.

Physical activity levels also did not change significantly over time in this study. This is surprising, given the nature of the intervention. This lack of change may partially be explained by a seasonal effect in the pedometer group and by the activity-specific limitations of accelerometers. This initiative occurred during fall and winter. Walking outside can be treacherous for deconditioned individuals due to snow and ice during these seasons in Winnipeg. Finding alternate places to walk indoors requires planning and motivation, creating a potential barrier to exercise participation in the pedometer group. It is possible that a non-exercise intervention arm may have demonstrated substantial declines in physical activity due to the challenging climatic conditions. This would then have demonstrated a benefit in the intervention groups that maintained activity levels over the study period. In addition, any increase in physical activity caused by stationary cycling in the

ergometer group would not have been accurately reflected by the waist worn accelerometers. In future studies, wearing of the accelerometer on the dominant ankle during stationary cycling may help measure physical activity in a more precise manner.

Our results did show a statistically significant improvement in lower extremity function and flexibility (increase of approximately two cycles and 5 cm, respectively) over the course of the study in both study groups. This improvement was observed despite the performance of relatively low intensity exercise. Although clinically important differences have not been established for these measures in the dialysis population, this observation is important, as these parameters may be more relevant to daily functioning and overall quality of life than aerobic fitness in this population [29]. For example, measures of lower extremity strength including SS have been shown to predict mortality and dependence with activities of daily living (ADLs) in community-dwelling older adults. More importantly, improvements in physical performance measures have also been associated with a decreased risk of disability with ADLs in the elderly [30]. In view of the decline in physical performance and functional status that has been observed over time in hemodialysis patients [4], the use of exercise programming, even at a low-intensity level, to maintain or improve these measures may be an important strategy for long-term independence and well-being.

Clinical and research implications

Despite the challenges of adherence and dropout, our study observed a significant improvement in objectively measured physical function following 6 months of cycling during hemodialysis or a pedometer initiative in hemodialysis patients. Although previous studies have demonstrated similar benefits with exercise programming, the pragmatic design of this study and its minimal exclusion criteria add new information to the literature by demonstrating that even low intensity exercise can provide benefits and that such programs are feasible within the confines of a regularly functioning hemodialysis unit without the need for significant additional resources. Based on the current observations, an outpatient pedometer initiative may have similar benefits to physical function as an intradialytic ergometer program. However, it is important to note that this study was not designed or powered to demonstrate non-inferiority.

Future studies should focus on the effects of exercise programming on clinically relevant performance measures and correlation of these changes with downstream clinical outcomes such as independent living, hospitalization and falls risk. As well, further investigations regarding the dose and intensity of exercise required to obtain clinically significant effects are required. Finally, documentation of effective measures to improve participation in and compliance with exercise programming initiatives is needed.

Strengths and limitations

The major strengths of our study are its randomized format and the pragmatic approach to the design and implementation of each intervention, which can easily be translated to clinical practice. The novelty of this study lies in the focus on effectiveness and real-life conditions with minimal monitoring and additional staff required as part of the study protocol. As well, the documentation of some measure of exercise dose and intensity achieved, often missing from previous reports, will help with the design of future studies in this area. Although adherence rates of 53 and 52% appear to be rather low, these rates are similar to or higher than rates achieved for adherence to exercise programs in the literature in both the general population and chronic disease populations [31, 32]. This lends credence to the pragmatic nature of this study and provides evidence that these interventions may be beneficial and feasible in clinical practice. As well, we chose a well-validated surrogate measure as the primary outcome and included several clinically relevant measures of physical function, physical activity and quality of life as secondary measures.

The major limitation of our study is limited power due to study withdrawal and lack of attendance for follow-up testing of our primary outcome VO_{2peak}. In addition, the lack of blinding of assessors could have resulted in ascertainment bias for some measures. The ceiling effects inherent to the tests of functional status may have limited our ability to detect differences in some outcomes. The lack of a true non-exercise control limits the strength of the associations observed. At the time of study implementation, it was felt that a non-exercise control was not feasible due to preexisting evidence of the benefits of exercise and culture within the unit. It was unlikely that individuals would enroll in the study if no exercise was one of the study arms. Finally, 'testing' bias may have been a significant threat to internal validity in that individuals may have improved in test results due to more familiarity with the testing procedures rather than due to a true exercise effect. However, for both the SS and the SR test, individuals had a practice test prior to the recorded test at each time point, making the lack of familiarization with measurement procedures and a practice effect over time unlikely.

Conclusion

In this pragmatic RCT, both an intradialytic cycling program and a home-based pedometer program resulted in similar improvements to lower extremity function and flexibility over 24 weeks but no changes in aerobic capacity. These results and the pragmatic design of this study provide preliminary evidence for the feasibility of implementing such programs in routine clinical practice.

AUTHORS' CONTRIBUTIONS

Research idea and study design: C.B., C.R., K.S., D.K.; data acquisition: K.S., J.O.-M.; data analysis/interpretation: C.B., C.R., D.E.; statistical analysis: C.B., C.R.; mentorship: C.R. Each author contributed important intellectual content during manuscript drafting or revision and accepts accountability for the overall work by ensuring that questions pertaining to the accuracy or integrity of any portion of the work are appropriately investigated and resolved. C.B. takes responsibility that this study has been reported honestly, accurately and

transparently, that no important aspects of the study have been omitted, and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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CONFLICT OF INTEREST STATEMENT

The results presented in this paper have not been published previously in whole or part, except in abstract format. None declared.

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