

Efficacy of Quantified Home-Based Exercise and Supervised Exercise in Patients With Intermittent Claudication A Randomized Controlled Trial

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Background—This prospective, randomized, controlled clinical trial compared changes in exercise performance and daily ambulatory activity in peripheral artery disease patients with intermittent claudication after a home-based exercise program, a supervised exercise program, and usual-care control.

Methods and Results—Of the 119 patients randomized, 29 completed home-based exercise, 33 completed supervised exercise, and 30 completed usual-care control. Both exercise programs consisted of intermittent walking to nearly maximal claudication pain for 12 weeks. Patients wore a step activity monitor during each exercise session. Primary outcome measures included claudication onset time and peak walking time obtained from a treadmill exercise test; secondary outcome measures included daily ambulatory cadences measured during a 7-day monitoring period. Adherence to home-based and supervised exercise was similar ($P=0.712$) and exceeded 80%. Both exercise programs increased claudication onset time ($P<0.001$) and peak walking time ($P<0.01$), whereas only home-based exercise increased daily average cadence ($P<0.01$). No changes were seen in the control group ($P>0.05$). The changes in claudication onset time and peak walking time were similar between the 2 exercise groups ($P>0.05$), whereas the change in daily average cadence was greater with home-based exercise ($P<0.05$).

Conclusions—A home-based exercise program, quantified with a step activity monitor, has high adherence and is efficacious in improving claudication measures similar to a standard supervised exercise program. Furthermore, home-based exercise appears more efficacious in increasing daily ambulatory activity in the community setting than supervised exercise.

Clinical Trial Registration—URL: <http://www.ClinicalTrials.Gov>. Unique identifier: NCT00618670. (*Circulation*. 2011;123:491-498.)

Key Words: claudication ■ exercise physiology ■ peripheral artery disease

A primary therapeutic goal for patients with peripheral artery disease (PAD) and intermittent claudication is to regain lost physical function through exercise rehabilitation.¹ Medically supervised exercise programs are efficacious for the clinical management of intermittent claudication²; improvements are noted for claudication onset time (COT) and peak walking time (PWT).³ Thus, supervised exercise has been given a Class I recommendation by the American College of Cardiology and the American Heart Association, indicating general agreement for effectiveness of treatment, supported by Level of Evidence A derived from multiple randomized controlled trials and meta-analyses.⁴

Clinical Perspective on p 498

Unfortunately, reimbursement is not provided for supervised exercise programs, and of the few programs that exist in

research centers, only a small percentage of eligible patients can feasibly attend regularly. The majority of PAD patients could, however, benefit from an exercise program transported to the community setting (ie, home-based walking). To date, the efficacy of home-based exercise has been poorly studied and has suffered from methodological flaws,⁵⁻¹⁵ most notably the inability to accurately quantify the volume of exercise performed. Thus, home-based unsupervised exercise has been given a Class IIb recommendation by the American College of Cardiology and the American Heart Association, indicating conflicting evidence for efficacy, supported only by Level of Evidence B derived from nonrandomized trials.⁴

We have recently used a step activity monitor to quantify daily ambulatory activity in patients with intermittent claudication,¹⁶ and we further explored its utility to address the primary flaw of home-based exercise programs by directly

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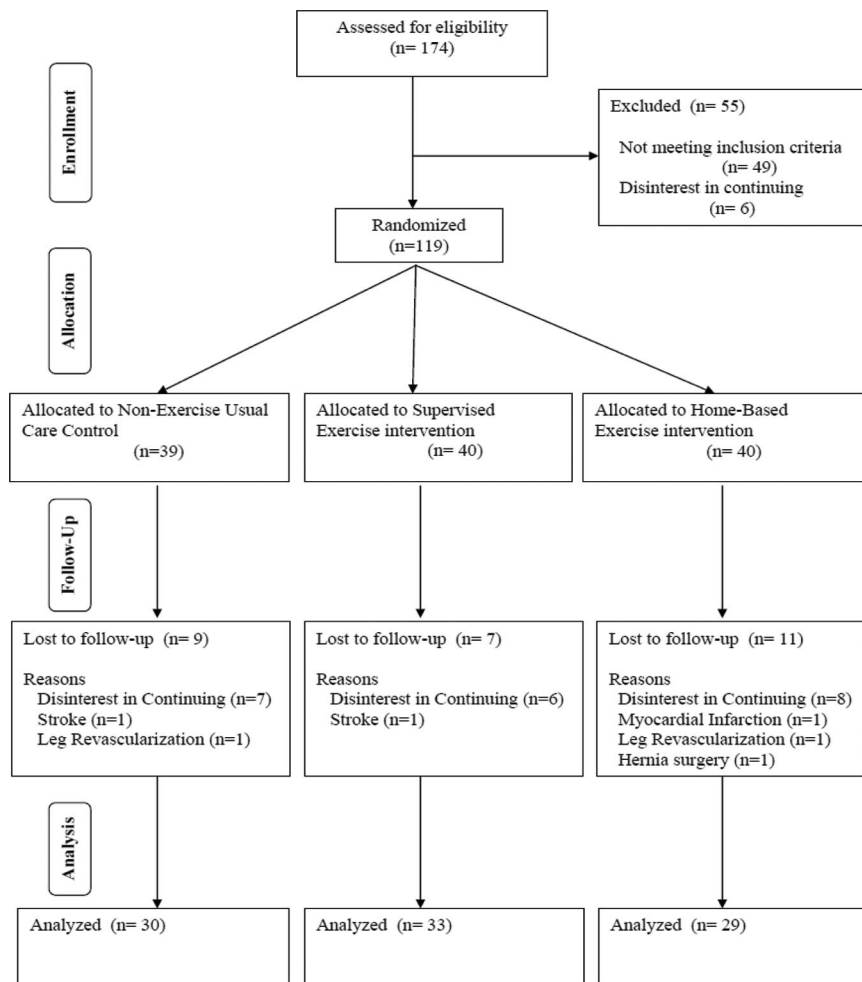


Figure. Consolidated Standards of Reporting Trials (CONSORT) flow diagram of patients through each stage of the trial.

measuring exercise adherence and exercise volume performed. This prospective, randomized, controlled clinical trial compared changes in exercise performance and daily ambulatory activity in PAD patients with intermittent claudication after a home-based exercise rehabilitation program, a supervised exercise program, and a usual-care control group. We hypothesized that home-based exercise using step activity monitor technology will result in greater changes in our primary outcome measures (COT and PWT) and secondary outcomes (daily ambulatory cadences) than usual-care control and that these changes will be similar to those obtained with standard, supervised exercise.

Methods

Patients

Recruitment

Patients participated at the General Clinical Research Center at the University of Oklahoma Health Sciences Center from September 2004 to April 2007. Patients were recruited by Health Sciences Center vascular clinic referrals and newspaper advertisements. Procedures were approved by the Institutional Review Board at the University of Oklahoma Health Sciences Center. Written informed consent was obtained from each patient before investigation.

Screening

Patients who had intermittent claudication secondary to vascular insufficiency were included if they met the following criteria: a

history of any type of exertional leg pain, ambulation during a graded treadmill test limited by leg pain consistent with intermittent claudication,¹⁷ and an ankle-brachial index (ABI) ≤ 0.90 at rest⁴ or an ABI ≤ 0.73 after exercise.¹⁸ Patients were excluded for the following conditions: (1) absence of PAD (ABI >0.90 at rest and ABI >0.73 after exercise), (2) inability to obtain an ABI measure because of noncompressible vessels, (3) asymptomatic PAD determined from the medical history and verified during the graded treadmill test, (4) use of cilostazol and pentoxifylline initiated within 3 months before investigation, (5) exercise tolerance limited by factors other than leg pain, and (6) active cancer, renal disease, or liver disease. Patient flow in the study is shown in the Figure.

Intervention and Control Groups

Home-Based Exercise Rehabilitation Program

Exercise sessions in our home-based exercise program were rigorously quantified with a step activity monitor (StepWatch3, Cyma Inc, Mountlake Terrace, WA) to accurately record the duration and cadence of ambulation. The home-based exercise program, designed to be as similar to the supervised exercise program as possible, consisted of 12 weeks of intermittent walking to near-maximal claudication pain 3 d/wk at a self-selected pace. Walking duration began at 20 minutes for the first 2 weeks and progressively increased 5 minutes biweekly until a total of 45 minutes of walking was accomplished during the final 2 weeks of the program. These exercise durations were 5 minutes longer throughout the program than in the supervised program in an attempt to better match the programs on total volume of exercise, determined by multiplying the intensity and the duration of walking. Intensity of walking, expressed as metabolic equivalents (METs), was determined by first converting

the cadence of each home-based exercise session to an average speed of walking and then estimating oxygen uptake from walking speed. Speed was calculated by comparing the cadence of home-based exercise sessions with cadence obtained at several speeds during overground walking trials before the intervention. Oxygen uptake of walking was then estimated by the following equation from the American College of Sports Medicine: $\dot{V}O_2$ ($\text{mL} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$) = $3.5 + (0.1 \times \text{speed} [\text{m/min}])$.¹⁹ METs were calculated by dividing oxygen uptake value by 3.5, and MET-minutes were calculated by multiplying the MET value by the duration of exercise sessions to yield a measure of exercise volume.

Patients were given a step activity monitor and were instructed to wear it on the right ankle during each exercise session and then to remove the monitor at the completion of each session. Additionally, they received an exercise logbook to record their walking sessions. Patients returned their step activity monitors and logbooks to the research staff at the end of weeks 1, 2, 4, 6, 8, 10, and 12 of the program, and data from the monitor were downloaded. During these brief 15-minute meetings, patients discussed their progress with an exercise physiologist, were given feedback about the data from the step activity monitor, and were given new instructions on changes in exercise duration. No exercise was performed by the patients in our facility during these meetings with the research staff.

Supervised Exercise Rehabilitation Program

The supervised program was designed to elicit increases in COT and PWT according to our previous studies.^{2,3,20} This standardized program consisted of 3 months of supervised, intermittent treadmill walking for 3 d/wk at a speed of ≈ 2 mph. Walking duration began at 15 minutes for the first 2 weeks of the program and progressively increased by 5 minutes biweekly until a total of 40 minutes of walking was accomplished during the final 2 weeks of the program. Because we have previously shown that changes in COT and PWT are similar for patients who train at a relatively high exercise intensity (80% of peak workload) and patients who train at a lower intensity (40% of peak workload) for longer duration,²¹ we selected the lower-intensity program for the patients in the present study because it is well tolerated. Thus, patients walked at a grade equal to 40% of the final workload from the baseline maximal treadmill test to the point of near-maximal claudication pain, at which point they stopped to relieve their leg pain. Patients then repeated the intermittent walking and rest periods until the prescribed total number of minutes of exercise was attained for the training session. During each exercise session, patients wore a step activity monitor on the right ankle to quantify the cadence and time of ambulation. To quantify volume of exercise performed in the supervised exercise program, expressed as MET-minutes, intensity of each exercise training session was determined from objectively measured oxygen uptake during the baseline maximal treadmill test of each patient. Oxygen uptake corresponding to the training grade was then divided by 3.5 to convert to METs, and this value was multiplied by the duration of each supervised exercise session to yield a MET-minute value. Patients in the supervised program were not given advice or instructions to perform additional exercise away from our research center.

Nonexercise, Usual-Care Control Group

Patients randomized to this group were encouraged to walk more on their own but they did not receive specific recommendations about an exercise program during the study. This approach is similar to advice typically given by clinicians during routine follow-up vascular appointments. No other risk factor management, lifestyle modification, or educational programming interventions were provided to any of the 3 groups.

Measurements

Medical History and Physical Examination

Patients arrived in the morning fasted but were permitted to take their usual morning medication regimen. Demographic information, height, weight, cardiovascular risk factors, comorbid conditions, claudication history, blood samples, a list of current medications, and

ABI were obtained from a medical history and physical examination.²²

Gardner Maximal Treadmill Test

Patients performed a progressive, graded treadmill protocol on 2 separate days. The first test was to determine study eligibility by assessing whether exercise performance was limited by claudication; the second test was done on another day to obtain the outcome measures of COT, PWT, and peak oxygen uptake. COT was defined as the walking time at which the patient first experienced pain, and PWT was defined as the time at which ambulation could not continue because of maximal pain. Peak oxygen uptake was measured as previously described.²³ The final grade attained during this test at baseline was used to calculate training intensity for the patients in the supervised exercise group.

Walking Economy Test

Oxygen uptake was measured during a constant, submaximal work rate at a treadmill speed of 2 mph and a grade of 0% until maximal claudication pain or for a maximum of 20 minutes at baseline.²⁴ The walking economy test at follow-up was performed for the same duration as at baseline. Walking economy was measured as oxygen uptake during the final minute of exercise. Fractional utilization was calculated as walking economy oxygen uptake divided by peak oxygen uptake.

Ambulatory Activity Monitoring

Ambulatory activity was measured with a step activity monitor during 7 consecutive days before and after the intervention period.¹⁶ None of the exercise interventions were included in the monitoring period. The monitor, attached to the right ankle above the lateral malleolus with elastic Velcro straps, continuously recorded the number of strides taken on a minute-to-minute basis. Variables are expressed as the average daily cadence and maximum cadence for 60, 30, 20, and 5 continuous minutes of ambulation each day. These daily measures were recorded and then averaged over the 7-day monitoring period.

Walking Impairment Questionnaire

Self-reported ambulatory ability was obtained with a validated questionnaire for PAD patients that assesses ability to walk at various speeds and distances and to climb stairs.²⁵

Baltimore Activity Scale for Intermittent Claudication

Self-reported physical activity level was assessed with the Baltimore Activity Scale for Intermittent Claudication questionnaire for patients with PAD.²⁶

Health-Related Quality of Life

Self-reported physical function was assessed with the Medical Outcomes Study Short-Form 36 General Health Survey.²⁷

Statistical Analyses

Patients were randomized to 3 groups using an offsite NCSS random number program (NCSS Inc., Kaysville, UT) with blocking to ensure that group sizes never differed by >2 at any time during allocation. Study personnel were allowed access to the allocation list only after subject eligibility was determined and baseline data were completed. A 1-way ANOVA examined group means for baseline measurement variables. A 2×3 χ^2 test examined group proportions for dichotomous variables. Independent t tests assessed differences in means between the 2 exercise groups for the exercise rehabilitation measures. For each response variable, an ANOVA appropriate for a 2-factor study design with repeated measures on 1 factor was used as the initial procedure. This was followed by 2 procedures that directly address issues likely to be of clinical interest. Within each group, the simple effect of change from baseline was tested for difference from zero with a paired t test. A more detailed analysis was made of the interaction component through the use of comparisons among the change means by 1-way ANOVA, followed by a Tukey-Kramer test for pairwise comparisons. To address the issue that some differences might be attributed to differences in dropout patterns across groups,

Table 1. Baseline Clinical Characteristics

Variables	Control Group (n=39)	Supervised Exercise Group (n=40)	Home-Based Exercise Group (n=40)	P
Age, y	65 (10)	66 (12)	65 (11)	0.902
Weight, kg	83.8 (18.4)	82.2 (21.5)	85.2 (17.6)	0.789
Body mass index, kg/m ²	29.7 (6.9)	29.2 (7.1)	29.9 (5.6)	0.885
ABI	0.76 (0.22)	0.71 (0.25)	0.72 (0.23)	0.613
White, %	62	45	65	0.155
Currently smoking, %	10	10	10	0.999
Male, %	54	45	45	0.663
Diabetes mellitus, %	31	43	43	0.467
Hypertension, %	79	88	88	0.519
Dyslipidemia, %	85	88	90	0.771
Abdominal obesity, %	49	45	55	0.665
Metabolic syndrome components, n	3.1 (1.3)	3.4 (1.4)	3.5 (1.1)	0.372
Metabolic syndrome, %	69	73	83	0.366
Obesity, %	41	43	48	0.830

Values are means (SD) when appropriate.

all ANOVAs were repeated as intent-to-treat analyses using imputed data, and the results were compared with the initial values. All analyses and the imputing multiple regression routine were performed with the NCSS statistical package (NCSS Inc., Kaysville, UT).

Results

Randomization resulted in similar ($P>0.05$) baseline clinical characteristics among groups (Table 1). Ninety-two patients completed the study; 27 did not (the Figure). Baseline characteristics remained similar among the groups ($P>0.05$) after inclusion of only the 92 patients who completed the trial (data not shown). Of the 27 patients who did not complete the trial, no significant difference among the groups was noted for total number of dropouts ($P=0.56$), dropouts owing to disinterest ($P=0.845$), and dropouts resulting from adverse events ($P=0.592$). Furthermore, no group difference ($P=0.896$) was found for the total number of adverse events (4 in the control group, 3 in the supervised group, and 4 in the home-based exercise group).

Adherence to home-based exercise and supervised exercise was similar ($P=0.712$; Table 2). Patients in the home-based exercise program walked for a longer duration per exercise session than patients in supervised exercise ($P<0.001$) but at a slower cadence ($P=0.019$), resulting in a similar total exercise volume, expressed as MET-minutes ($P=0.150$).

The groups were similar ($P>0.05$) at baseline on each treadmill measure (Table 3). Home-based exercise increased the primary outcome measures of COT ($P<0.001$) and PWT ($P<0.01$), which were significantly different ($P<0.05$) from changes in the control group. Supervised exercise increased COT ($P<0.001$) and PWT ($P<0.001$). These changes were significantly different ($P<0.05$) from changes in controls but were not different ($P>0.05$) from changes in home-based exercise.

Table 2. Exercise Intervention Measures

Variables	Supervised Exercise Group (n=33)	Home-Based Exercise Group (n=29)	P
Exercise sessions completed, %	84.8 (20.9)	82.5 (27.7)	0.712
Total exercise time, min	795 (249)	1218 (577)	<0.001
Total exercise strides, n	40 376 (7403)	46 357 (25757)	0.386
Total volume of exercise, MET-min*	2394 (818)	2832 (1491)	0.150
Average exercise time, min/exercise session	25.4 (3.0)	41.6 (21.4)	<0.001
Average exercise strides, n/exercise session	1170 (142)	1529 (703)	0.058
Average exercise cadence, strides/min	43.3 (4.7)	37.4 (8.6)	0.019

Values are means (SD).

*MET-minutes of exercise were determined by multiplying estimated intensity of walking (expressed in METs) and total exercise time for each session.

Groups were similar ($P>0.05$) at baseline on each daily ambulatory activity measure (Table 4). Home-based exercise increased maximal cadences for 20, 30, and 60 minutes of ambulation ($P<0.01$), average daily cadence ($P<0.01$), and the Baltimore Activity Scale for Intermittent Claudication questionnaire score ($P<0.001$). These changes were significantly different ($P<0.05$) from changes in controls, and the increases in maximal cadence for 30 minutes and average daily cadence were significantly greater ($P<0.05$) than changes with supervised exercise. When each variable in Tables 3 and 4 was reanalyzed with an intent-to-treat approach, all of the significant group-by-time interactions found in the original ANOVA analyses remained significant except for physical function score (Table 3). These findings indicate that attrition patterns across groups had minimal influence on study results.

Discussion

Home-Based Exercise Program: Adherence and Exercise Volume

A unique feature of this investigation was direct measurement of adherence to home-based exercise and quantification of exercise time, cadence, and total ambulatory volume during the program. The relatively high adherence rate in home-based exercise was similar to that found with supervised exercise. No other randomized controlled trial has reported adherence to home-based exercise, whereas 5 uncontrolled trials determined adherence through exercise diaries and telephone contact.^{6,8,10,12,13}

Home-based exercise is inherently different from supervised exercise, and it was not the intent of this project to duplicate a supervised program in the community setting because this would simply compare treadmill training at various exercise facilities in the community with treadmill training at our university-based program. Instead, the home-based group walked at their freely chosen pace on level ground around their homes and neighborhoods. We attempted

Table 3. Exercise Performance Measures in Patients Completing Usual-Care Control (n=30), Supervised Exercise (n=33), and Home-Based Exercise (n=29)

				ANOVA <i>P</i> , Observed			ANOVA <i>P</i> , ITT		
Variables	Pretest	Posttest	Change Score	G	T	G×T	G	T	G×T
COT, s									
Control group	225 (157)	209 (168)	−16 (125)	NS	<0.01	0.01	NS	<0.01	<0.01
Supervised exercise group	196 (144)	361 (264)	165 (173)‡§						
Home-based exercise group	204 (137)	337 (250)	134 (197)‡§						
PWT, s									
Control group	505 (216)	494 (240)	−10 (176)	NS	<0.01	<0.01	NS	<0.01	<0.01
Supervised exercise group	325 (169)	540 (281)	215 (207)‡§						
Home-based exercise group	402 (285)	526 (374)	124 (193)†§						
Peak oxygen uptake, mL · kg ^{−1} · min ^{−1}									
Control group	13.7 (3.7)	12.8 (3.5)	−1.00 (1.9)†	NS	NS	<0.01	NS	NS	<0.05
Supervised exercise group	11.4 (2.5)	11.7 (2.9)	0.3 (1.9)§						
Home-based exercise group	11.8 (3.8)	12.4 (3.8)	0.6 (2.0)§						
Walking economy, mL · kg ^{−1} · min ^{−1}									
Control group	10.3 (1.9)	10.5 (2.2)	0.2 (1.4)	NS	NS	<0.01	NS	NS	<0.05
Supervised exercise group	10.6 (2.0)	9.5 (1.9)	−1.1 (1.6)‡§						
Home-based exercise group	9.4 (2.0)	9.3 (1.9)	−0.1 (1.2)						
Fractional utilization, %									
Control group	80 (19)	87 (21)	8 (20)*	NS	<0.05	<0.01	NS	<0.01	<0.01
Supervised exercise group	94 (11)	82 (14)	−12 (10)‡§						
Home-based exercise group	83 (18)	78 (16)	−5 (12)*§						
WIQ distance score, %									
Control group	43 (34)	44 (31)	1 (34)	NS	<0.05	NS	NS	<0.01	NS
Supervised exercise group	25 (26)	38 (31)	13 (28)*						
Home-based exercise group	32 (29)	42 (33)	10 (25)*						
WIQ speed score, %									
Control group	39 (25)	44 (20)	4 (25)	NS	<0.01	NS	NS	<0.01	NS
Supervised exercise group	27 (19)	36 (24)	9 (15)†						
Home-based exercise group	30 (22)	41 (22)	11 (22)*						
WIQ stair climbing score, %									
Control group	47 (32)	50 (29)	3 (25)	NS	<0.01	NS	NS	<0.01	NS
Supervised exercise group	32 (32)	44 (34)	12 (15)‡						
Home-based exercise group	38 (26)	48 (27)	10 (22)*						
Physical function score, %									
Control group	55 (19)	54 (18)	−1 (17)	<0.01	<0.01	<0.05	<0.05	<0.01	NS
Supervised exercise group	37 (17)	46 (21)	9 (16)†§						
Home-based exercise group	40 (22)	48 (23)	8 (15)†						

G indicates group effect; T, test effect; G×T, group-by-test interaction; ITT, intention to treat; and WIQ, Walking Impairment Questionnaire. Values are means (SD). Walking economy is the oxygen uptake obtained during final minute of a constant, submaximal treadmill test. Fractional utilization is walking economy oxygen uptake divided by peak oxygen uptake.

Change from pretest: **P*<0.05, †*P*<0.01, and ‡*P*<0.001.

§Different from the control group: *P*<0.05.

||Different from home-based exercise group: *P*<0.05.

to match the 2 programs on total volume of exercise, expressed as MET-minutes. Because the training intensity of home-based exercise is limited by the speed of ambulation that patients are willing to sustain or are capable of sustaining, which is not the case for supervised training typically performed at various treadmill inclines, we increased the duration of home-based exercise by ≈5 minutes per session

to achieve a similar exercise volume. Thus, by design, we anticipated that average time per training session would be 5 minutes longer in the home-based program. In fact, the home-based group members chose to walk for 11 additional minutes beyond that prescribed per training session, but they accomplished this by ambulating at a slower, freely chosen cadence than the supervised group, yielding similar exercise

Table 4. Daily Ambulatory Activity Measures in Patients Completing Usual-Care Control (n=30), Supervised Exercise (n=33), and Home-Based Exercise (n=29)

Variables	Pretest	Posttest	Change Score	ANOVA <i>P</i> , Observed			ANOVA <i>P</i> , ITT		
				G	T	G×T	G	T	G×T
Total strides, n/d									
Control group	3778 (1723)	3819 (1590)	51 (1265)	NS	NS	NS	NS	NS	NS
Supervised exercise group	2912 (1358)	3153 (1553)	169 (1120)						
Home-based exercise group	3139 (1860)	3464 (1805)	324 (1256)						
Total activity time, min/d									
Control group	301 (98)	312 (94)	4 (81)	NS	NS	NS	NS	NS	NS
Supervised exercise group	255 (98)	270 (101)	11 (69)						
Home-based exercise group	266 (104)	269 (100)	3 (76)						
Maximum 5-min cadence, strides/min									
Control group	32.7 (8.4)	31.5 (7.6)	−1.2 (8.1)	<0.05	NS	NS	<0.01	NS	NS
Supervised exercise group	26.2 (4.7)	28.2 (7.2)	2.0 (6.0)						
Home-based exercise group	28.0 (8.2)	30.1 (10.2)	2.1 (6.0)						
Maximum 20-min cadence, strides/min									
Control group	20.4 (7.6)	18.5 (7.1)	−1.9 (6.9)	<0.05	NS	<0.01	<0.05	NS	<0.01
Supervised exercise group	14.9 (4.2)	15.3 (5.4)	0.4 (5.5)						
Home-based exercise group	16.5 (7.3)	19.8 (10.9)	3.3 (6.1)†§						
Maximum 30-min cadence, strides/min									
Control group	17.1 (6.3)	15.3 (5.6)	−1.8 (5.3)	<0.05	NS	<0.01	NS	NS	<0.01
Supervised exercise group	12.7 (3.9)	12.8 (4.3)	0.1 (4.3)						
Home-based exercise group	14.1 (6.8)	17.5 (10.3)	3.4 (5.7)†§						
Maximum 60-min cadence, strides/min									
Control group	12.4 (4.9)	11.1 (4.0)	−1.3 (4.2)	<0.05	NS	<0.01	NS	NS	<0.01
Supervised exercise group	9.2 (3.0)	9.3 (3.3)	0.1 (2.8)						
Home-based exercise group	10.4 (5.2)	12.9 (7.8)	2.5 (4.7)†§						
Average cadence, strides/min									
Control group	12.3 (3.2)	12.0 (2.6)	−0.3 (1.8)	NS	NS	<0.01	NS	NS	<0.01
Supervised exercise group	11.6 (2.5)	11.5 (2.3)	−0.1 (1.2)						
Home-based exercise group	11.3 (2.7)	12.4 (3.2)	1.1 (2.0)†§						
BASIC score									
Control group	3.5 (2.2)	2.9 (1.7)	−0.6 (1.9)	NS	<0.05	<0.01	NS	<0.01	<0.01
Supervised exercise group	2.2 (1.6)	2.9 (1.9)	0.6 (1.9)§						
Home-based exercise group	2.1 (1.7)	3.5 (1.9)	1.4 (1.5)†§						

G indicates group effect; T, test effect; G×T, group-by-test interaction; ITT, intention to treat; and BASIC, Baltimore Activity Scale for Intermittent Claudication. Values are means (SD).

Change from pretest: * $P<0.05$, † $P<0.01$, and ‡ $P<0.001$.

§Different from the control group: $P<0.05$.

||Different from the supervised exercise group: $P<0.05$.

volumes between groups. Overall, the home-based exercise program was characterized by longer ambulation at a slower pace than the supervised exercise program. This is the first study to provide direct and accurate measurements of the exercise stimulus in a home-based exercise program.

It is likely that monitoring ambulation, meeting periodically with staff, and providing feedback to patients in home-based exercise enhanced their motivation to adhere to the program. Another possibility is that patients noticed improvements in their ambulation during the program, encouraging them to continue. Our home-based exercise program consisted of 7 brief office-based meetings with an exercise

physiologist interspersed throughout the program in which data from the step activity monitor were downloaded and reviewed, along with the exercise logbooks. At the end of the 15-minute meeting, new instructions were given about increasing exercise duration and overcoming any challenges that might exist until the next visit. It is difficult to speculate whether adherence would be similar without these visits, but it is reasonable to guess that adherence would be equal or worse without them. Furthermore, the quality of the program would probably suffer without periodic meetings because appropriate increases in exercise duration and problem solving might not occur.

The overall attrition rate of study participation was 23%, but this rate was not different among groups. Nearly 80% of dropouts were due to disinterest in continuing, and this typically occurred early in both home-based and supervised exercise programs. Careful medical screening and appropriate inclusion and exclusion criteria for study participation were factors contributing to the relatively low occurrence of 11 patients (9%) having an adverse event, forcing only 6 patients (5%) to discontinue. We believe that there is no systematic effect of attrition on study results among the groups. Furthermore, it is possible that home-based training can be done as safely as, if not more safely than, supervised exercise as a result of slower ambulatory cadences that patients self-select during exercise.

Efficacy of Home-Based Exercise Program Versus Usual-Care Control

Another unique aspect was the randomized, controlled design comparing the efficacy of home-based exercise with usual-care control. Home-based exercise resulted in a 65% increase in COT and a 31% increase in PWT, and these improvements were greater than changes seen in the controls. Two other studies directly compared home-based exercise and control, but neither used a randomized design.^{14,15} One study reported increases in COT and PWT after unsupervised exercise,¹⁵ whereas the other did not evaluate these measures.¹⁴ Additionally, we are the first to report that home-based exercise was efficacious in improving fractional utilization during treadmill exercise, daily ambulatory cadence for durations between 20 and 60 minutes, and average daily ambulatory cadence. Improvement in fractional utilization was due to the combination of small changes in walking economy and peak oxygen uptake, indicating that relative exercise intensity of ambulation was lower after rehabilitation. Thus, daily ambulation performed at a given pace can be done with less exertion after a program of home-based exercise.

Home-based exercise is efficacious in improving claudication measures, exercise performance, and daily ambulatory activity in patients with intermittent claudication. Consequently, participating in a home-based exercise program with minimal, periodic feedback may be a viable alternative for most patients compared with participating in a structured, onsite, supervised exercise program. This has significant clinical implications of managing many more patients with home-based exercise compared with the relatively small, select group who are candidates for supervised exercise.

Efficacy of Home-Based Exercise Program Versus Supervised Exercise

Previous studies have compared home-based exercise with supervised exercise,^{5-7,9-11} which were recently summarized.²⁸ In contrast to the present randomized controlled trial, supervised exercise resulted in significantly greater increases in COT and PWT.²⁸ However, none of the home-based programs objectively quantified the amount of exercise accomplished, thus making a comparison with supervised exercise difficult to interpret. Our study also demonstrated that home-based exercise increases daily ambulatory cadences at sustained exercise durations between 20 and 60

minutes and average daily cadence, indicating that home exercise is efficacious in increasing community-based ambulation apart from the home exercise program. These increases in daily ambulatory cadences were greater than changes in the control and supervised exercise groups. Thus, home-based exercise may be superior to supervised exercise to increase community-based ambulation.

Limitations

Although this trial supports the efficacy of home-based and supervised exercise rehabilitation for PAD patients, several limitations exist. First, patients who participated in this trial were volunteers and therefore may represent those more interested in exercise, those who had better access to transportation to the program, and those in relatively better health than patients who did not volunteer. Second, although patients were randomized into one of the groups before intervention, the possibility that those who participated in home-based exercise were more motivated than other patients cannot be ruled out.

Conclusions and Clinical Implications

A home-based exercise program, quantified with a step activity monitor, has high adherence and is efficacious in improving claudication measures similar to a standard supervised exercise program. Furthermore, home-based exercise appears more efficacious in increasing daily ambulatory activity in the community setting than supervised exercise. The clinical implication is that home-based exercise programming, with patient monitoring and periodic feedback, may serve as a new model for improving claudication measures in more patients with less effort and fewer resources.

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Disclosures

None.

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CLINICAL PERSPECTIVE

A primary therapeutic goal for patients with peripheral artery disease and intermittent claudication is to regain lost ambulatory function through exercise rehabilitation. Medically supervised exercise programs are efficacious for improving claudication onset time and peak walking time, but more patients could benefit from an exercise program transported to the community setting (ie, home-based walking). However, home exercise has been poorly studied. This prospective, randomized, controlled clinical trial compared changes in claudication onset time, peak walking time, and daily ambulatory activity in peripheral artery disease patients with intermittent claudication after home-based exercise, supervised exercise, and usual-care control. Both exercise programs consisted of intermittent walking to near-maximal claudication pain for 12 weeks. We used a step activity monitor to address the primary flaw of previous home exercise programs by objectively measuring ambulatory cadence during home exercise sessions. Patients in home-based exercise completed 83% of their exercise sessions, averaging 42 minutes per session at a cadence of 37 strides per minute, and they increased claudication onset time, peak walking time, and daily ambulatory cadences apart from the exercise sessions. The changes in claudication onset time and peak walking time after home-based exercise were similar to those after supervised exercise, whereas the change in daily ambulatory cadences was greater. The clinical implication is that a home-based exercise program consisting of ambulatory monitoring, biweekly 15-minute meetings with staff, and feedback motivated patients to adhere to the program and may serve as a new model for improving claudication measures in more patients with less effort and fewer resources than a traditional supervised exercise program.

Efficacy of Quantified Home-Based Exercise and Supervised Exercise in Patients With Intermittent Claudication: A Randomized Controlled Trial

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