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Unsupervised Exercise and Mobility Loss in Peripheral Artery Disease: A Randomized Controlled Trial

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Background—Few medical therapies improve lower extremity functioning in people with lower extremity peripheral artery disease (PAD). Among people with PAD, we studied whether a group-mediated cognitive behavioral intervention promoting home-based unsupervised exercise prevented mobility loss and improved functional performance compared to control.

Methods and Results—One hundred ninety-four PAD participants were randomized. During months 1 to 6, the intervention group met weekly with other PAD participants and a facilitator. Group support and self-regulatory skills were used to help participants adhere to walking exercise. Ninety-percent of exercise was conducted at or near home. The control group attended weekly lectures. During months 6 to 12, each group received telephone contact only. Primary outcomes have been reported. Here we compare changes in exploratory outcomes of mobility loss (the inability to climb a flight of stairs or walk one-quarter mile without assistance), walking velocity, and the Short Physical Performance Battery. Compared to controls, fewer participants randomized to the intervention experienced mobility loss at 6-month follow-up: 6.3% versus 26.5%, $P=0.002$, odds ratio=0.19 (95% CI=0.06 to 0.58) and at 12-month follow-up: 5.2% versus 18.5%, $P=0.029$, odds ratio=0.24 (95% CI=0.06 to 0.97). The intervention improved fast-paced 4-m walking velocity at 6-month follow-up ($P=0.005$) and the Short Physical Performance Battery at 12-month follow-up ($P=0.027$), compared to controls.

Conclusions—In exploratory analyses, a group-mediated cognitive behavioral intervention promoting unsupervised walking exercise prevented mobility loss and improved functioning at 6- and 12-month follow-up in PAD patients.

Clinical Trial Registration—URL: <http://clinicaltrials.gov>. Unique identifier: NCT00693940. (*J Am Heart Assoc.* 2015;4:e001659 doi: 10.1161/JAHA.114.001659)

Key Words: exercise • mobility • peripheral artery disease • randomized controlled trial

Functional decline and mobility loss are common in people with lower extremity peripheral artery disease (PAD),^{1–4} but few medical therapies have been identified that improve these outcomes in PAD. Supervised treadmill exercise

improves walking endurance in people with PAD.^{5,6} However, most PAD patients do not participate in supervised treadmill exercise.⁷ This is likely because most medical insurance companies do not pay for supervised treadmill exercise in people with PAD and because traveling to an exercise facility for regular supervised exercise is burdensome.⁷

Interventions that promote exercise outside of a supervised setting and are tailored to the individual could be effective and convenient therapy for patients with PAD. Interventions that promote unsupervised exercise at home should be more accessible and acceptable to PAD patients than supervised exercise because unsupervised exercise at home is relatively inexpensive and does not require travel to an exercise facility 3 times weekly.

Walking-related ischemic leg pain makes consistent adherence to walking exercise programs challenging for PAD patients. This may be particularly true in an unsupervised setting without encouragement from a coach. Small studies completed in the late 20th century suggested that home-based walking exercise programs had unclear or no efficacy

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for improving walking performance in PAD.^{8–10} An uncontrolled 6-month trial from the Netherlands showed significant improvement in treadmill walking time in PAD patients who were referred to a physical therapy program that provided supervised treadmill exercise 2 to 3 times per week, tapering over time to supervised exercise once every 2 weeks.¹¹ Three recent larger randomized trials demonstrated that interventions designed to help PAD patients adhere to home-based walking exercise improved treadmill walking performance and/or the 6-minute walk in people with PAD.^{12–14} However, unanswered questions remain. First, it is unclear whether unsupervised home-based exercise is sustainable. Two of the 3 recent trials were only 12 weeks in duration.^{13,14} Second, the 3 recent home-based exercise trials focused on outcomes of treadmill walking performance and the 6-minute walk. Little is known about other clinically meaningful functional outcomes that may be improved by interventions that increase unsupervised home-based exercise in PAD.

We recently reported results of the Group Oriented Arterial Leg Study (GOALS), a randomized trial that demonstrated that a group-mediated cognitive behavioral (GMCB) intervention, designed to promote home-based unsupervised walking exercise, significantly increased 6-minute walk distance, treadmill walking time, and physical activity in patients with PAD.¹² The GOALS intervention also improved the 6-minute walk at 12-month follow-up.¹⁵ The GMCB intervention used a structured intervention to encourage exercise in an unsupervised setting near home. The intervention consisted of a minimum of 260 exercise bouts over 12 months, 90% of which occurred at or near home in an unsupervised setting. Here we report the effect of the GOALS GMCB intervention on the exploratory outcomes of participant-reported mobility loss and participant-reported gain in mobility at 6- and 12-month follow-up in participants with PAD. In contrast to objective measures obtained in controlled settings, mobility loss measures participants' perceptions of their capacity in daily life. Mobility loss is a well-validated and clinically meaningful outcome that is associated with an increased risk of nursing home placement, depression, cognitive impairment, obesity, and chronic disease.^{16–20} We also report the effect of the GOALS exercise intervention on the objective measures of walking velocity and the Short Physical Performance Battery (SPPB) at 6- and 12-month follow-up. Slower walking velocity and lower SPPB scores are associated with higher rates of mobility loss and/or mortality in people with and without PAD.^{1,21–25} We hypothesized that (1) the GMCB intervention, designed to increase home-based exercise, would prevent mobility loss and improve mobility impairment compared to the control group in people with PAD and that (2) the GMCB intervention would increase or prevent decline in walking velocity and the SPPB, compared to the control group.

Methods

Methods of the GOALS randomized trial have been reported.^{12,15,26} The Institutional Review Board at Northwestern University approved the protocol, and participants provided written informed consent.

Participant Identification

The study was performed in Chicago, IL between July 22, 2008 and May 2, 2013. Recruitment methods included newspaper and radio advertisements and mailed postcards to individuals age 65 and older living in the Chicago area.^{12,15,26}

Overview of Study Design

Participants were randomized to 1 of 2 groups: a GMCB intervention, designed to help participants adhere to home-based unsupervised walking exercise versus an attention control group. During Phase I of the trial (months 1 to 6), participants randomized to the intervention attended weekly group meetings led by a facilitator at an exercise center. Participants were instructed to walk for exercise a minimum of 5 days per week, with only 1 session per week conducted at the center with their group. During the on-site weekly sessions, group support and self-regulatory skill instructions were employed to help participants adhere to unsupervised home-based walking exercise. Participants randomized to the control group attended weekly group meetings at the medical center, during which they received educational lectures on health topics unrelated to exercise. Primary outcomes were measured at 6-month follow-up and have been reported.¹² During Phase II (months 7 to 12), participants randomized to the study intervention received telephone calls from their group facilitator. Participants were encouraged to continue walking for exercise a minimum of 5 days per week. Of the minimum of 260 exercise bouts prescribed in the intervention over 12 months, only 26 of the exercise bouts took place at the study exercise center. Thus, 90% of the prescribed walking intervention sessions took place in a home-based unsupervised setting.^{12,15} Participants randomized to the control group received telephone calls from a study coordinator with information related to the educational sessions in Phase I. Follow-up testing was performed at 6- and 12-month follow-up.

Inclusion and Exclusion Criteria

All participants had an ankle brachial index (ABI) ≤ 0.90 in either leg or a resting ABI ≥ 0.91 and ≤ 1.00 with a $\geq 20\%$ drop in ABI following a heel-rise test.²⁷ Prior studies show that measuring the ABI after heel-rise exercises gives results

comparable to measuring the ABI after treadmill testing.^{27,28} For example, Amirhamzeh et al showed that in a group of 14 PAD patients with symptoms of intermittent claudication but ABIs >0.80, the ankle systolic blood pressure changes with the 2 methods were of similar magnitude, with a mean drop of 21% on the treadmill and 19% after heel-rise.²⁷ Similarly, McPhail reported that in a study of 50 consecutive patients with suspected peripheral artery disease, the correlation between the 2 methods was outstanding, with a Pearson correlation coefficient of $r=0.95$ (95% CI 0.93 to 0.97). These studies demonstrate the validity of the heel-rise testing as an alternative to treadmill testing for identifying PAD. Participants with a resting ABI >0.90 were included if they had medical-record-documented lower extremity revascularization or evidence of PAD from an accredited vascular laboratory. Evidence of PAD from an accredited vascular laboratory consisted of an ABI <0.90 or a toe brachial index <0.70. No other vascular laboratory criteria were used to diagnose PAD.

Exclusion criteria have been reported.²⁶ Briefly, potential participants with below- or above-knee amputation, wheelchair confinement, inability to walk at least 50 feet without stopping, significant cognitive impairment, and inability to return weekly to the medical center for the first 6 months of the intervention were excluded. However, potential participants were still included if they were able to attend most (but not all) of the weekly sessions during the first 6 months of the intervention. Individuals dependent on a walking aid other than a cane, those whose walking impairment was due to a condition other than PAD, those with severe visual or hearing impairment, those with foot ulcer or critical limb ischemia, and those who did not complete the study's run-in phase were excluded. Individuals who recently had undergone major surgery or lower extremity revascularization and those anticipating major surgery or lower extremity revascularization in the next 12 months were excluded. Participants already exercising at a comparable level to that targeted by the exercise intervention, those who required oxygen during activity or exercise, those who recently completed cardiac rehabilitation, and those with a history of Parkinson's disease were excluded. To screen for coronary artery disease prior to randomization, all participants underwent a baseline regular exercise stress test. Potential participants with an abnormal baseline exercise stress test were excluded, unless additional cardiac work-up by their individual physician showed no evidence of significant coronary ischemia.

ABI Measurement

A hand-held Doppler probe (Pocket Dop II; Nicolet Biomedical Inc, Golden, CO) was used to obtain systolic pressures twice in the brachial, dorsalis pedis, and posterior tibial arteries using established methods.^{29,30}

Medical History and Body Mass Index

Medical history, race, and demographics were obtained through patient report using questionnaires administered in a standardized fashion. Height and weight were measured at baseline. Body mass index was calculated as weight (kg)/[height (m)]².²⁶

Leg Symptoms

Even people with PAD who are asymptomatic have significant functional impairment, compared to those without PAD.^{3,4} Therefore, people with PAD were eligible, regardless of whether or not they had classic intermittent claudication (IC) symptoms. Leg symptoms were classified using the San Diego claudication questionnaire.³¹ Intermittent claudication was defined as exertional calf pain that did not begin at rest, caused the patient to stop walking, and resolved within 10 minutes of rest.^{2-4,31} Participants without intermittent claudication either reported no exertional leg symptoms (asymptomatic PAD) or had leg symptoms that did not meet the criteria of intermittent claudication.^{2-4,31}

Outcomes

Mobility measures

At baseline and at each follow-up visit, participants were asked whether they were able to walk up and down stairs to the second floor and walk one-quarter mile (3 blocks), "on their own," "with help," or "not at all." Mobility impairment was defined as reporting either needing help or the inability to (1) walk up and down a flight of stairs or (2) walk one quarter mile.^{1,22,23} Mobility loss was defined as reporting the inability to walk up and down 1 flight of stairs or walk one quarter mile either "at all" or "without assistance" during follow-up among participants without mobility impairment at baseline.^{1,22,23} We also studied rates of regaining mobility in the exercise and control groups, by determining the proportion of participants with mobility impairment at baseline who reported being able to both (1) walk up and down 1 flight of stairs and (2) walk one quarter mile without assistance at the 6- or 12-month follow-up visits. Participants' report of their mobility is valid and reliable.^{32,33} When patient-reported measures of mobility were tested 3 weeks apart, agreement was 89%.³³ Patient-reported mobility loss predicted rates of nursing home admission, disability, and mortality in the Established Populations for the Epidemiologic Study of the Elderly.²² Furthermore, mobility loss measures patient perception of their functional performance in daily life, in contrast to objective assessments that are measured in controlled settings.

Short Physical Performance Battery (SPPB)

The SPPB consists of the usual paced 4-m walking velocity, repeated chair rises, and standing balance. A score of 0 to 4 is assigned for each task according to established methods, with a score of 0 assigned for tasks that are not able to be completed.^{22,25} Scores from the 3 components are summed to obtain a total SPPB score ranging from 0 to 12. Lower SPPB scores are associated with higher rates of mobility loss and mortality in people with PAD.^{1,21,22}

Four-meter walking velocity. For usual-paced walking velocity, participants were timed walking a 4-m distance after instructions to walk at their “usual pace, as if walking down the street to go to the store.” Participants were also timed walking 4 m after instructions to walk at their “fastest pace.” Each 4-m walk was performed twice, and the faster of the 2 trials for each test was used for analyses.^{1,21,22}

Repeated chair rises. Participants sat in a chair and were instructed to fold their arms across their chest and stand 5 times as quickly as possible. Time to complete 5 consecutive chair rises was measured.^{1,21,22}

Standing balance. Participants were instructed to perform 3 standing positions for 10 seconds each: side-by-side (standing with feet parallel and touching), semitandem (standing with feet parallel with the heel of 1 foot touching the base of the big toe of the other foot), and tandem (standing with 1 foot directly in front of the other, with the heel of the front foot touching the tips of the toes on the opposite foot).^{1,21,22} Participants received a score of “1” if they could hold the side-by-side stand for 10 seconds but could not hold the semitandem stand for 10 seconds. Participants received a score of “2” if they could hold the semitandem stand for 10 seconds but could not hold the tandem stand for more than 2 seconds. Participants received a score of “3” if they held the semitandem stand for 10 seconds and held the tandem stand for >2 to 9 seconds. Participants received a score of “4” if they could hold the tandem stand for a full 10 seconds.²²

Study Interventions

During Phase I (months 1 to 6) of the GMCB intervention, participants met weekly for 90 minutes with a group of PAD participants and a trained facilitator.^{12,26} Transportation was provided. At the first sessions, participants were instructed to walk for exercise a minimum of 5 times weekly, with 4 of the 5 sessions per week during the first 6 months conducted at or near home in an unsupervised setting. Participants were instructed to begin with ≈15 minutes of walking exercise per

exercise bout, working up to 50 minutes per exercise bout. Thus, during the first 6 months, the intervention was designed such that a minimum of 80% of exercise sessions were conducted at home in an unsupervised setting. At the weekly on-site meetings, the facilitator led discussions on a different topic each week, using principles from social cognitive theory, group dynamics, and self-regulation to motivate participants and help them acquire behavioral skills needed to adhere to unsupervised home-based exercise.^{34–36} Participants were instructed to walk for exercise at least 5 days per week at home, working up to 50 minutes of exercise per day. With each participant, the group facilitator discussed potential locations for exercising at or near the participant’s home. Home exercise locations were primarily based on each participant’s preference.

Phase I: control group

Participants in the control group attended weekly health education sessions with other PAD participants during Phase I. Healthcare professionals gave lectures on topics including cholesterol, cancer prevention, and nutrition.

Phase II: intervention and control groups

During Phase II (months 7 to 12), there were no on-site sessions. Instead, participants received regularly scheduled telephone calls. In the exercise group, the telephone calls were designed to reinforce self-regulation principals emphasized in Phase I and to encourage continued home-based exercise. As during the first 6 months, participants were instructed to walk for exercise a minimum of 5 times per week. Participants were asked to continue to record their daily walking exercise activity and mail their written walking exercise logs back to study investigators. For participants in the control group, telephone calls reviewed health education topics covered during Phase I. Telephone calls lasted ≈10 minutes and occurred every 2 weeks during 7 to 9 months and monthly once during 10 to 12 months.

Sample Size Calculations

Outcomes for this report are exploratory, were not prespecified, and therefore power calculations were not performed.

Statistical Analyses

Analyses comparing rates of mobility loss between the exercise and control groups during follow-up were limited to participants without mobility impairment at baseline. We performed 3 sets of analyses for the outcome of mobility loss. First, among participants without mobility impairment at baseline, we compared the proportion of participants in the

exercise versus control groups who reported mobility loss (inability to either walk one-quarter mile or walk up and down a flight of stairs without assistance) at the 6- and 12-month follow-up visits, respectively. Second, among participants without mobility impairment at baseline, we compared rates of cumulative mobility loss during follow-up, by reporting the proportion of participants at 12-month follow-up who reported mobility loss at either the 6- or 12-month follow-up. Third, among participants without mobility impairment at baseline, we compared the proportion of participants who reported mobility loss at both the 6- and 12-month follow-up visits (ie, persistent mobility loss).

Analyses comparing rates of regaining mobility were performed among participants who reported mobility loss at baseline (ie, those who reported inability or needing help in walking up and down a flight of stairs or walking one-quarter mile without assistance at baseline). We performed 3 sets of analyses. First, among participants with mobility loss at baseline, we compared the proportion of participants in the exercise and control groups who reported no mobility loss at the time of their 6-month follow-up visit and no mobility loss at the time of their 12-month follow-up visits, respectively. Second, among participants with mobility loss at baseline, we compared the proportion of participants in the exercise and control groups at 12-month follow-up who reported no mobility loss in at least 1 of their follow-up visits (ie, either the 6- or the 12-month follow-up visit). Third, among participants with mobility loss at baseline, we compared the proportion of participants in the exercise and control groups at 12-month follow-up with persistently improved mobility, defined as those without mobility loss at both 6-month and 12-month follow-up.

Chi-square tests and 2-sample 2-sided *t* tests were used to compare categorical and continuous characteristics of participants in the exercise and control groups, respectively, who completed 6- or 12-month follow-up. For mobility loss, we performed logistic regression to obtain odds ratios of mobility loss between the exercise and control groups at 6- and 12-month follow-up, among those without mobility loss at baseline. For regaining mobility, we performed logistic regression to obtain odds ratios for regaining mobility between the exercise and control groups, among those with mobility loss at baseline. The exact method is used when appropriate. Two sample, 2-sided *t* tests were used to compare changes in 4-m walking velocity, the SPPB, and each individual component of the SPPB between baseline and 6-month follow-up and between baseline and 12-month follow-up between the exercise and the control group. A priori, the *P* value considered statistically significant was *P*<0.05. Intention-to-treat analyses were performed. These comparisons were not prespecified and no adjustment for Type I error was made despite multiple comparisons.

All participants were asked to return for follow-up measurements, regardless of their adherence to interventions. Decedents were excluded from analyses. In addition, we performed sensitivity analyses for missing data due to loss to follow-up. First, we used multiple imputation to impute the missing outcome data at 6- and 12-month follow-up, under the assumption of missing at random. Second, to examine whether the results for mobility loss are sensitive to potential informative missing due to loss to follow-up, we conservatively imputed the missing outcome data using the worst values. Specifically, the missing mobility status was imputed as mobility loss, and the missing 4-m walking velocity, the SPPB, and each individual component of the SPPB were imputed as their corresponding lowest observed values at each follow-up visit. Analyses were performed using SAS version 9.4.

Results

One hundred ninety-four participants were randomized to the intervention (N=97) or the control group (N=97). Attendance rates for the weekly on-site sessions during the first 6 months of the intervention were 76.5% in the intervention group and 72.4% in the control group. Of the 194 participants randomized, 178 (91.8%) completed 6-month follow-up and 168 (86.6%) completed 12-month follow-up testing (Figure 1).

Table 1 compares characteristics of the exercise and control groups among participants who completed 6- and/or 12-month follow-up testing for 1 or more of the outcomes reported here. Characteristics of participants are shown for the cohort overall (N=178) and for participants with (N=46) and without (N=132) mobility loss at baseline. There were no differences between the 2 groups at baseline (Table 1).

Among the 194 participants, 70 participants randomized to the exercise group and 70 randomized to the control group reported no mobility loss at baseline. Of these, 132 completed 6-month follow-up testing and 123 completed 12-month follow-up. At 6-month follow-up, 4/64 (6.3%) of participants in the exercise group versus 18/68 (26.5%) in the control group reported new mobility loss (odds ratio=0.19, 95% CI=0.06 to 0.58, *P*=0.002) (Figure 2). At 12-month follow-up, 3/58 (5.2%) participants in the exercise group versus 12/65 (18.5%) in the control group reported mobility loss (odds ratio=0.24, 95% CI=0.06 to 0.97, *P*=0.029) (Figure 2). Cumulative rates of mobility loss, defined as the presence of mobility loss at either the 6-month or 12-month follow-up visit, were 5/58 (8.6%) in the exercise group versus 22/65 (33.9%) in the control group (odds ratio=0.18, 95% CI=0.06 to 0.53, *P*<0.001). Rates of persistent mobility loss, defined as mobility loss at both the 6- and 12-month follow-up

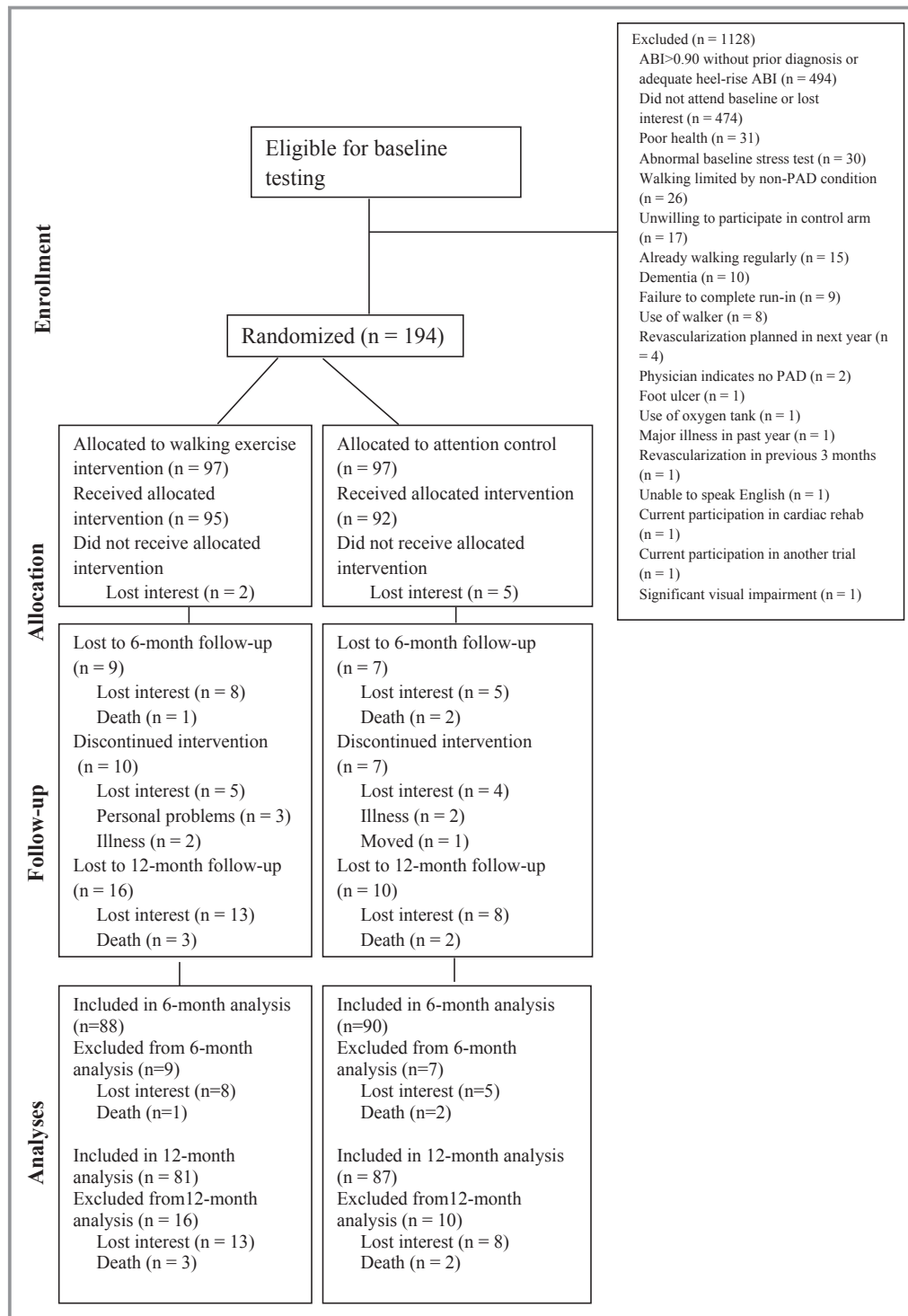


Figure 1. Overview of study design for the GOALS randomized trial. Adapted with permission from McDermott et al.¹² ABI indicates ankle brachial index; GOALS, Group Oriented Arterial Leg Study; PAD, peripheral artery disease.

visits among individuals without mobility loss at baseline, were 2/58 (3.5%) in the exercise versus 6/65 (9.2%) in the control group (odds ratio=0.35, 95% CI=0.07 to 1.81, *P*=0.194).

Among participants without mobility loss at baseline, incidence rates of reporting difficulty or inability to walk one-quarter mile without assistance were 1/69 (1.5%) in the exercise group versus 16/70 (22.9%) in the control group

Table 1. Characteristics of Peripheral Artery Disease Participants Randomized to the Home-Based Exercise Versus the Control Groups Overall and According to Presence Versus Absence of Baseline Mobility Impairment

	Entire Cohort		Participants Without Mobility Impairment at Baseline		Participants With Mobility Impairment at Baseline	
	Intervention Group (N=88)	Control Group (N=90)	Intervention Group (N=64)	Control Group (N=68)	Intervention Group (N=24)	Control Group (N=22)
Age (y), mean (SD)	69.7 (9.3)	71.6 (9.5)	69.5 (8.9)	71.1 (9.6)	70.2 (10.6)	73.2 (9.4)
Male sex, n (%)	44 (50)	44 (48.89)	38 (59.38)	39 (57.35)	6 (25)	5 (22.73)
African American race, n (%)	49 (55.68)	38 (42.22)	29 (45.31)	26 (38.24)	20 (83.33)	12 (54.55)
White race, n (%)	37 (42.1)	49 (55.4)	33 (51.6)	40 (58.8)	4 (16.7)	9 (40.9)
Asian race, n (%)	1 (1.1)	3 (3.33)	1 (1.6)	2 (2.9)	0 (0)	1 (4.6)
More than one race, n (%)	1 (1.1)	0 (0)	1 (1.6)	0 (0)	0 (0)	0 (0)
Hispanic or Latino ethnicity, n (%)	4 (4.6)	3 (3.3)	4 (6.3)	3 (4.4)	0 (0)	0 (0)
Not Hispanic or Latino, n (%)	84 (95.5)	87 (96.7)	60 (93.8)	65 (95.6)	24 (100)	22 (100)
Ankle brachial index, mean (SD)	0.67 (0.16)	0.68 (0.18)	0.69 (0.16)	0.71 (0.17)	0.61 (0.16)	0.59 (0.16)
Current smoker, n (%)	22 (25)	17 (18.89)	16 (25)	13 (19.12)	6 (25)	4 (18.18)
Body mass index, mean (SD)	28.6 (6.5)	29.1 (6.7)	28.2 (6.4)	29.3 (6.2)	29.4 (7.0)	28.5 (8.1)
Angina, n (%)	15 (17.05)	14 (15.73)	9 (14.06)	11 (16.18)	6 (25)	3 (14.29)
Myocardial infarction, n (%)	11 (12.5)	13 (14.44)	6 (9.38)	10 (14.71)	5 (20.83)	3 (13.64)
Heart failure, n (%)	9 (10.23)	11 (12.22)	4 (6.25)	8 (11.76)	5 (20.83)	3 (13.64)
Diabetes, n (%)	26 (29.55)	34 (37.78)	18 (28.13)	25 (36.76)	8 (33.33)	9 (40.91)
Classic symptoms of intermittent claudication, n (%)	27 (30.68)	21 (23.33)	20 (31.25)	17 (25)	7 (29.17)	4 (18.18)
Leg symptoms other than intermittent claudication, n (%)	54 (61.36)	61 (67.78)	38 (59.38)	43 (63.24)	16 (66.67)	18 (81.82)
No exertional leg symptoms, n (%)	7 (7.95)	8 (8.89)	6 (9.38)	8 (11.76)	1 (4.17)	0 (0)
Lack of mobility impairment at baseline, n (%)	64 (72.73)	68 (75.56)	64 (100)	68 (100)	0 (0)	0 (0)
Usual-paced 4-m walking velocity (m/s), mean (SD)	0.91 (0.18)	0.88 (0.15)	0.95 (0.16)	0.90 (0.16)	0.79 (0.18)	0.82 (0.10)
Fastest paced 4-m walking velocity (m/s), mean (SD)	1.24 (0.28)	1.22 (0.22)	1.31 (0.25)	1.26 (0.22)	1.07 (0.29)	1.10 (0.18)
Short Physical Performance Battery (0 to 12 score, 12=best), mean (SD)	9.84 (2.25)	9.81 (1.92)	10.31 (1.75)	10.07 (1.89)	8.52 (2.92)	9.00 (1.83)
Statin use, n (%)	37 (42.1)	48 (53.3)	28 (43.8)	36 (52.9)	9 (37.5)	12 (54.6)
Cilostazol use, n (%)	1 (1.1)	7 (7.8)	1 (1.6)	4 (5.9)	0 (0)	3 (13.6)

(odds ratio=0.05, 95% CI=0.00 to 0.32, $P<0.001$) at 6-month follow-up and 3/62 (4.8%) in the exercise group versus 12/67 (17.9%) in the control group (odds ratio=0.23, 95% CI=0.05 to 0.93, $P=0.027$) at 12-month follow-up. Among participants without mobility loss at baseline, rates of reporting difficulty or the inability to climb a flight of stairs without assistance were 3/77 (3.9%) in the exercise group versus 8/83 (9.6%) in the control group (odds ratio=0.38, 95% CI=0.08 to 1.69, $P=0.214$) at 6-month follow-up and 3/71 (4.2%) in the intervention versus 2/80 (2.5%) in the control group (odds ratio=1.72, 95% CI=0.26 to 14.17, $P=0.666$) at 12-month follow-up. Thus, most of the benefit of the exercise intervention on preventing mobility loss was due to preserving the ability to walk one-quarter mile without assistance.

Fifty-four participants (27 in the exercise group and 27 in the control group) reported mobility loss at baseline. Of these, 46 completed 6-month follow-up and 45 completed 12-month follow-up. At 6-month follow-up, 17/24 (70.8%) of participants in the exercise group and 7/22 (31.8%) of participants in the control group reported no mobility loss (odds ratio=5.20, 95% CI=1.48 to 18.29, $P=0.008$). At 12-month follow-up, 16/23 (69.6%) of participants in the exercise group and 4/22 (18.2%) of participants in the control group reported no mobility loss (odds ratio=10.29, 95% CI=2.53 to 41.75, $P<0.001$) (Figure 3). Cumulative rates of regaining mobility, defined as reporting no mobility loss at either the 6-month or 12-month follow-up visits among people with mobility loss at baseline, were 19/23 (82.6%) in the exercise versus 8/22

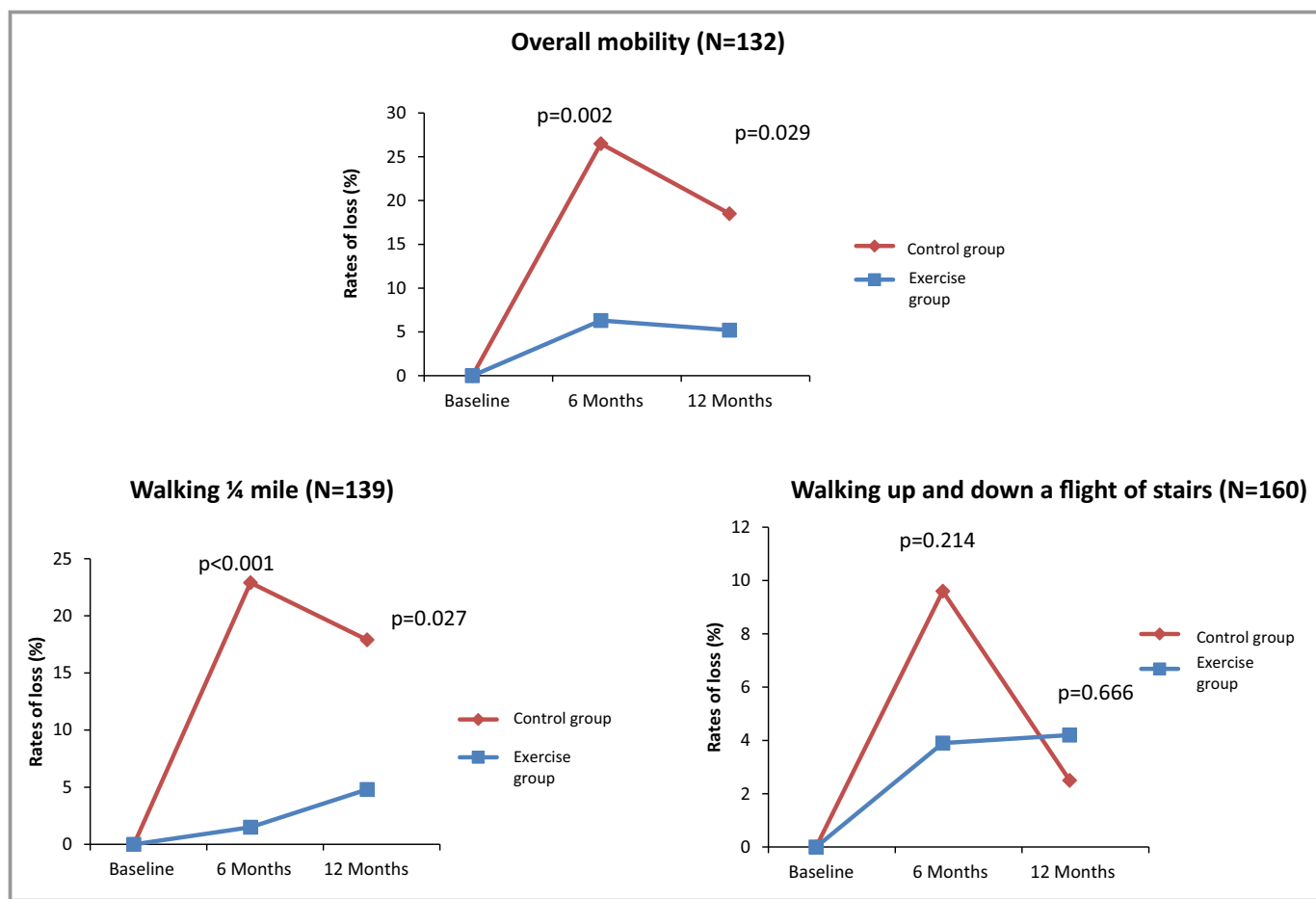


Figure 2. Rates of new mobility loss in the exercise and control groups among people with peripheral artery disease. Analyses are limited to people without mobility loss at baseline.

(36.4%) in the control group (odds ratio=8.31, 95% CI=2.08 to 33.19, $P=0.002$). Rates of persistent gains in mobility, defined as participants without mobility loss at both the 6- and 12-month follow-up among those reporting mobility loss at baseline, were 14/23 (60.9%) in the exercise group and 3/22 (13.6%) in the control group (odds ratio=9.85, 95% CI=1.99 to 46.93, $P=0.002$).

Among participants with mobility loss at baseline, rates of becoming able to walk one-quarter mile without assistance were 14/19 (73.7%) in the exercise group versus 8/20 (40.0%) in the control group (odds ratio=4.20, 95% CI=1.08 to 16.32, $P=0.034$) at 6-month follow-up and 14/19 (73.7%) in the exercise versus 3/20 (15.0%) in the control group (odds ratio=15.87, 95% CI=3.00 to 81.96, $P<0.001$) at 12-month follow-up (Figure 3). Among participants with mobility loss at baseline, rates of becoming able to climb a flight of stairs without assistance were 7/11 (63.6%) in the exercise group versus 4/7 (57.1%) in the control group (odds ratio=1.31, 95% CI=0.17 to 10.37, $P=1.00$) at 6-month follow-up and 7/10 (70.0%) in the exercise versus 4/7 (57.1%) in the control group (odds ratio=1.75, 95% CI=0.21 to 14.29, $P=0.644$) at

12-month follow-up (Figure 3). Thus, most of the benefit of exercise on regaining mobility was related to resuming the ability to walk one-quarter mile without assistance.

Figure 4 compares changes over time in fast-paced 4-m walking velocity, usual-paced 4-m walking velocity, and the SPPB in the intervention and control groups. The intervention group improved their fast-paced 4-m walking velocity at 6-month follow-up: 1.24 to 1.29 m/s in the exercise group versus 1.22 to 1.19 m/s in the control group (mean difference +0.08, 95% CI=+0.02 to +0.13, $P=0.005$). The exercise group did not improve their usual paced 4-m walking velocity at 6-month follow-up compared to the control group: 0.90 to 0.94 m/s in the exercise group versus 0.88 to 0.89 m/s in the control group (mean difference +0.03, 95% CI=-0.004 to +0.07, $P=0.080$) at 6-month follow-up. Additionally, there were no associations of exercise with improvement in usual-paced or fast-paced 4-m walking velocity at 12-month follow-up (Figure 4).

There was no difference in change in the SPPB score at 6-month follow-up between the exercise and the control group: 9.87 to 10.33 in the exercise group versus 9.93 to

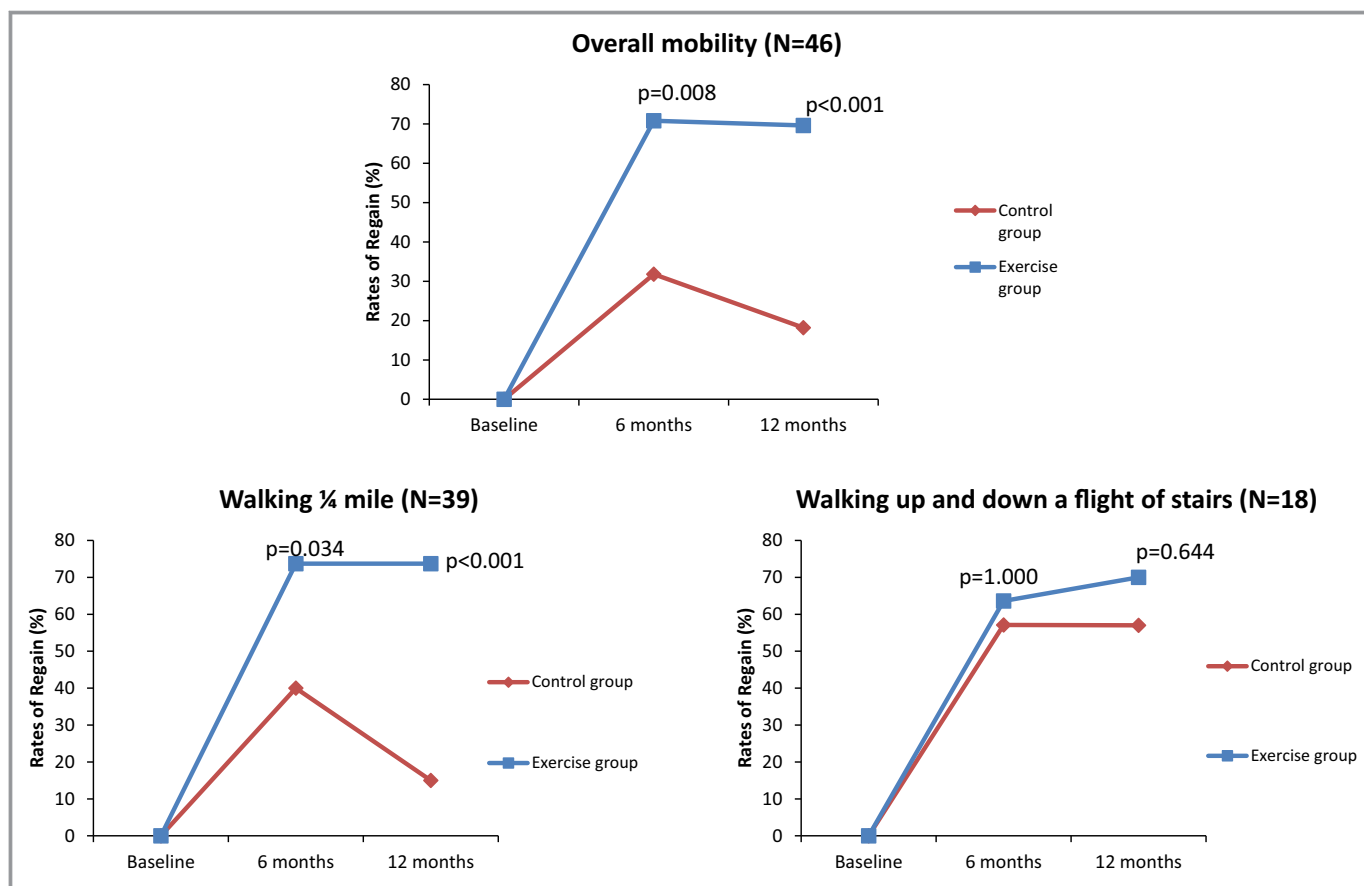


Figure 3. Rates of mobility gain in the exercise and control groups among people with peripheral artery disease. Analyses are limited to people with mobility loss at baseline.

9.95 in the control group (mean difference +0.44, 95% CI=−0.06 to +0.94, $P=0.086$). The exercise group had significant improvement in the SPPB at 12-month follow-up: 9.87 to 10.33 in the exercise group versus 9.93 to 9.81 in the control group (mean difference +0.58, 95% CI=+0.07 to +1.09, $P=0.027$). Table 2 shows changes in individual components of the SPPB in the exercise versus control groups (Table 2).

Between baseline and 6-month follow-up, 3/88 (3.4%) of the intervention group versus 4/90 (4.4%) of the control group underwent lower extremity revascularization. Between baseline and 12-month follow-up, 4/81 (4.9%) of the intervention group versus 6/87 (6.9%) of the control group underwent lower extremity revascularization. Results did not substantially change when analyses were repeated after excluding participants who underwent lower extremity revascularization while they were enrolled in the GOALS trial (data not shown).

When missing data were imputed, differences in rates of mobility loss between the intervention and control group at 12-month follow-up were no longer statistically significant (odds ratio=0.36, 95% CI=+0.11 to +1.22, $P=0.101$). There were no

other meaningful changes in results when missing data were imputed. When missing data were replaced with the worst possible outcome for each measure, rates of mobility loss at 12-month follow-up were no longer significantly different between the intervention and control groups (17.9% versus 24.3%, $P=0.361$). When missing data were replaced with the worst possible outcome, rates of decline in the fast 4-m walking velocity were no longer different between the intervention and control groups at 6-month follow-up (−0.02 versus −0.08 m/s, $P=0.100$), and rates of decline in the SPPB were no longer different between the intervention and control groups at 12-month follow-up (−0.81 versus −1.00, $P=0.695$).

Discussion

The GOALS randomized trial demonstrated that a 6-month GMCB intervention, designed to promote regular unsupervised walking exercise in people with PAD, reduced the exploratory outcome of mobility loss at 6-month follow-up, compared to a control group. These differences persisted at 12-month follow-up, 6 months after the intensive phase of the

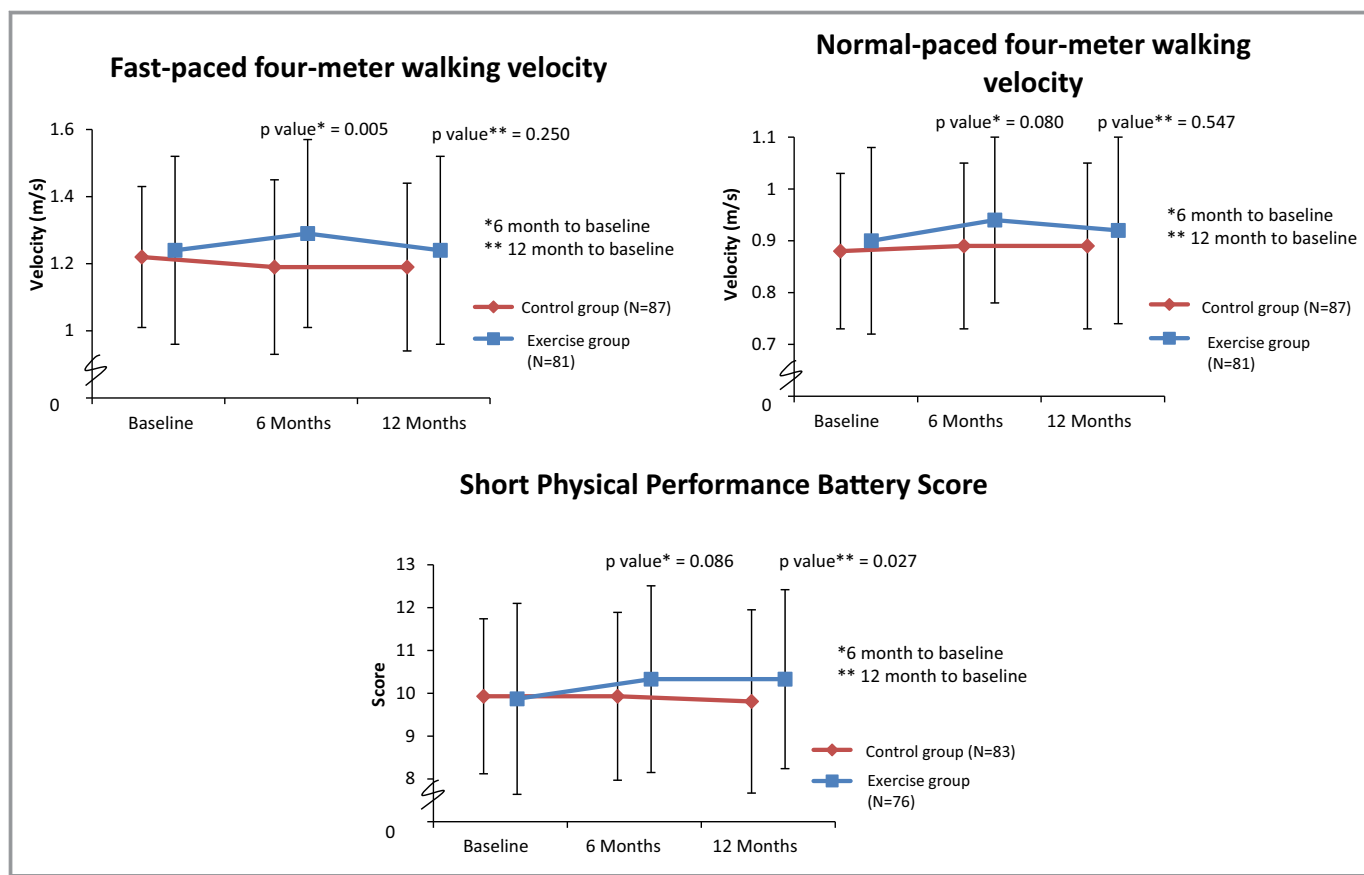


Figure 4. Changes in functional performance in the exercise vs control groups among people with peripheral artery disease.

GMCB intervention was completed. As compared to the control group, the GMCB intervention significantly reversed mobility impairment that was present at baseline. This benefit also persisted at 12-month follow-up. However, the GOALS intervention did not improve usual-paced 4-m walking velocity, improved fastest-paced 4-m walking velocity only at 6-month follow-up, and improved the SPPB only at 12-month follow-up.

Mobility loss was an exploratory outcome in the GOALS trial. However, to our knowledge, the GOALS trial is the first randomized trial to study whether any medical therapy prevents self-reported mobility loss or improves self-reported mobility loss in patients with PAD. Maintaining mobility is integral to preserving functional independence, social interactions, and activities of daily living.^{17–19} In contrast to objective measures, which are assessed in a highly controlled environment, self-reported mobility assesses participants' perceptions of their functioning in the community. Preservation of mobility has implications for using public transportation and engaging in activities that are important for work, play, and exercise.³⁷ Older people who lose mobility have higher rates of nursing home placement, morbidity, mortality, depression, hospitalizations, chronic disease, and cognitive impairment.^{16–22}

Our results show that the GMCB intervention, designed to promote home-based, unsupervised walking exercise, improved a broad range of functional limitations in people with PAD. In addition to its effect on mobility loss, the GMCB intervention improved the exploratory outcomes of fast-paced 4-m walking speed at 6-month follow-up and the SPPB at 12-month follow-up. The SPPB is a measure of balance and lower extremity strength. Poorer scores on the SPPB and in walking velocity are associated with higher rates of cardiovascular mortality and mobility loss in people with PAD.^{1,21} A previous analysis used observational and clinical trial evidence to link changes in the SPPB to changes in patient-reported quality of life and mobility loss and defined a clinically meaningful change in the SPPB as a change of 0.5 or greater.³⁸ Thus, the 12-month change in SPPB in the intervention group as compared to the control group was clinically meaningful. To our knowledge, clinically meaningful change for the fast-paced 4-m walking velocity has not been defined.

Prior studies by Bendermacher et al and Kruidenier et al assessed associations of supervised treadmill exercise therapy delivered by physiotherapists for the outcome of improved treadmill walking performance in PAD patients with intermittent claudication.^{11,39} However, these studies were not randomized controlled trials and outcome measures were

Table 2. Six- and 12-Month Changes in Each Component of the Short Physical Performance Battery Intervention Among Peripheral Artery Disease Participants Enrolled in the Group Oriented Arterial Leg Study

Outcome Measures—6-Month Comparisons	N	Baseline Mean (SD)	6-Month Mean (SD)	Within-Group Change (95% CI)	With-Control Comparison (95% CI)	P Value
Walking velocity score (0 to 4 scale, 4=best)						
Control group	87	3.61 (0.56)	3.66 (0.55)	0.05 (−0.06 to 0.15)	Reference group	0.5858
Intervention group	81	3.67 (0.61)	3.75 (0.56)	0.09 (−0.02 to 0.19)	0.04 (−0.11 to 0.19)	
Standing balance score (0 to 4 scale, 4=best)						
Control group	87	3.09 (1.00)	3.07 (1.09)	−0.02 (−0.26 to 0.21)	Reference group	0.1596
Intervention group	80	3.01 (1.26)	3.24 (1.02)	0.23 (−0.04 to 0.49)	0.25 (−0.10 to 0.59)	
Time for 5 chair rises (0 to 4 scale, 4=best)						
Control group	83	3.19 (1.16)	3.19 (1.04)	0 (−0.22 to 0.22)	Reference group	0.3546
Intervention group	77	3.14 (1.16)	3.29 (1.10)	0.14 (−0.07 to 0.36)	0.14 (−0.16 to 0.45)	
Outcome Measures—12-Month Comparisons						
	N	Baseline Mean (SD)	12-Month Mean (SD)	Within-Group Change (95% CI)	With-Control Comparison (95% CI)	P Value
Walking velocity score (0 to 4 scale, 4=best)						
Control group	87	3.61 (0.56)	3.62 (0.60)	0.01 (−0.11 to 0.13)	Reference group	0.8799
Intervention group	81	3.67 (0.61)	3.69 (0.65)	0.02 (−0.10 to 0.15)	0.01 (−0.16 to 0.19)	
Standing balance score (0 to 4 scale, 4=best)						
Control group	87	3.09 (1.00)	2.97 (1.06)	−0.13 (−0.38 to 0.13)	Reference group	0.0263
Intervention group	80	3.01 (1.26)	3.28 (1.01)	0.26 (0.03 to 0.49)	0.39 (0.05 to 0.73)	
Time for 5 chair rises (0 to 4 scale, 4=best)						
Control group	83	3.19 (1.16)	3.19 (1.18)	0 (−0.23 to 0.23)	Reference group	0.2656
Intervention group	77	3.14 (1.16)	3.31 (1.14)	0.17 (−0.02 to 0.36)	0.17 (−0.13 to 0.47)	

not blinded. In contrast to the GOALS trial, supervised exercise sessions in the trials by Bendermacher et al and Kruidenier et al occurred 2 to 3 times per week for the first 3 months, a frequency that was tapered to once every 2 weeks at 6-month follow-up and once every 8 weeks for the final 6 months of the intervention. Participants were also advised to walk at home, but information on the frequency of home exercise was not reported.^{11,39} Dropout rates were high (60% follow-up rate at 6-months and 47% follow-up rate at 12 months). Among the PAD participants who did not drop out, maximum treadmill walking distance increased by 191% at 6-month follow-up and by 197% at 12-month follow-up.^{11,39} In contrast to these prior studies, the GOALS intervention required a substantially lower rate of on-site exercise activity during the first 3 months, used a randomized trial design, included a GMCB intervention, and had substantially lower dropout rates.

Study Limitations

The GOALS Study has limitations. First, the first 6 months of the GOALS trial consisted of weekly visits to the medical center and consisted of a somewhat complex GMCB

intervention that required both assembling a group of PAD participants and a facilitator to lead each session. For these reasons, the intervention may be difficult to implement in clinical practice. Further study is needed to determine whether the GOALS intervention is effective with fewer on-site visits. Second, the GOALS trial included a large number of exclusion criteria. Results may not be generalizable to people with PAD who were excluded from participation, including participants who were unwilling to attend weekly visits to the exercise center. Third, our analyses included multiple comparisons. Our results require confirmation in other cohorts of PAD participants. Fourth, we did not collect data on the cost of the intervention. Fifth, we did not specifically collect data from participants about the degree to which they value mobility loss.

Conclusions

In conclusion, a GMCB intervention that promoted home-based walking exercise reduced rates of self-reported mobility loss in patients with PAD at 6-month follow-up. The home-based exercise intervention improved self-reported mobility in

participants who reported mobility impairment at baseline. All of these benefits persisted at 12-month follow-up, 6 months after the intensive phase of the exercise intervention was completed. Further study is needed to determine whether interventions designed to increase home-based exercise and that have fewer on-site visits improve walking performance and prevent mobility loss in people with PAD.

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Disclosures

None.

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