Effectiveness of a Home-Based Exercise Program on Walking Ability in Patients with Peripheral Artery Disease—The HONOR Trial

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ABSTRACT

Background: People with lower extremity peripheral artery disease (PAD) have greater functional impairment than do people without PAD, measured in part by a poorer 6-minute walk distance at baseline and faster decline in distance walked in 6 minutes. Clinical practice guidelines support home-based walking exercise, consisting of walking exercise performed in or around home, outside of a supervised setting, to improve walking performance for patients with PAD. Although home-based walking exercise has been shown to significantly improve 6-minute walk distance in people with PAD, to date, the randomized trials demonstrating the benefits of home-based walking exercise for people with PAD have required regular visits to a medical center throughout the intervention, which can be burdensome for these patients. No randomized trials have tested whether an exercise intervention without persistent periodic visits to a medical center improves walking performance in people with PAD.

Objectives: This study determined whether a home-based walking exercise intervention, consisting of 9 months of wearable activity monitors and telephone coaching but no medical center visits after the first month of the intervention, improves walking ability in patients with PAD.

Methods: The study design was a multicentered randomized clinical trial with 2 parallel groups. Participants with PAD were randomly assigned to home-based walking exercise vs usual care for 9 months. The home-based walking exercise intervention consisted of 4 weekly medical center visits for the first month, to familiarize participants with the intervention components, followed by 8 months of a wearable activity monitor (FitBit) and telephone coaching starting at weekly intervals and tapering to once monthly for the final 4.5 months of the intervention. Participants in the walking exercise intervention were coached to increase walking exercise activity to up to 50 minutes per day for 5 days a week. The usual care group received no such coaching, no medical center visits other than for baseline and follow-up testing, and no active encouragement to exercise beyond that provided by their own physicians. The primary outcome was change in 6-minute walk distance at 9-month follow-up (minimum clinically important difference = 20 m). Secondary outcomes included 9-month change in subcomponents of the Walking Impairment Questionnaire (WIQ; 0-100 score, with 100 = best), the 36-Item Short Form (SF-36) physical functioning score, the Patient-Reported Outcomes Measurement Information System (PROMIS) mobility questionnaire, the PROMIS satisfaction with social roles and activities questionnaire, the PROMIS pain interference questionnaire (lower = better, meaningful change = 3.5-4.5 points), and ActiGraph-measured physical activity. We compared changes in each outcome between baseline and 9-month follow-up between the groups using a 2-sample t test stratified by site. We imputed missing data using SAS PROC MI ([computer program] Cary, NC: SAS Institute Inc, 2015) with 80 imputed data sets.

Results: A total of 200 participants with PAD were randomly assigned (mean age = 70.2 years; SD = 10.4); 100 (50%) were black, and 105 (52.5%) were female. A total of 181 (90.5%) participants completed follow-up. At 9-month follow-up, the intervention did not improve the 6-minute walk compared with usual care (from 330.5 to 333.4 m in the intervention [site-
adjusted within-group difference: 5.5 m]) vs 336.2 to 348.2 m in usual care [site-adjusted within-group difference: 14.4 m]), between group difference in mean change from baseline to follow-up, adjusted for site = –8.9 m (95% CI = –26.0 to 8.2; p = 0.307). The usual care group improved its PROMIS pain interference score from 56.7 to 53.4 (site-adjusted within-group difference: –2.8) vs from 56.4 to 56.6 in the intervention group (site-adjusted within-group difference: 0.70), indicating that the usual care group had significant improvement in pain that interfered with activities relative to the intervention group. The site-adjusted between-group difference in mean change from baseline to follow-up was 3.5 (95% CI, 1.3-5.8; p = 0.002) in the intervention vs the control group, indicating that the home-based walking exercise group had worse pain relative to that of the usual care group. The intervention did not improve any secondary outcomes compared with usual care.

**Conclusions:** Among individuals with PAD, a home-based exercise intervention consisting of a wearable activity monitor and telephone coaching, compared with usual care, did not improve walking performance at 9-month follow-up. These results do not support home-based exercise interventions of wearable devices and telephone counseling without periodic on-site visits to improve walking performance in people with PAD.

**Limitations:** First, location of the PAD (ie, femoral and/or aorto-iliac) was not recorded. Second, there was no run-in period. Third, quantitative data were not collected for the pilot study or focus groups for aim 1, which was conducted in preparation for the intervention. Fourth, study results may not be generalizable to people with PAD who did not meet eligibility criteria.
INTRODUCTION

Some components of this report have been published previously in JAMA. Permission from JAMA to republish figures, tables, and text that are either identical or slightly modified has been requested. Figures and tables derived from the JAMA publication are noted in the figure or table legend. The full citation of the published paper is as follows:

BACKGROUND

Lower extremity peripheral artery disease (PAD) currently affects 8 million people in the United States and nearly 200 million people worldwide.\textsuperscript{2,3} People with PAD have significant functional impairment, increased rates of functional decline, and faster rates of mobility loss compared with people without PAD.\textsuperscript{4-9} Most people with PAD do not have classical symptoms of intermittent claudication.\textsuperscript{3-8} Even patients without classical claudication symptoms have greater functional impairment and faster decline than do people without PAD.\textsuperscript{4-9} However, few medical therapies are available to improve walking performance in people with PAD. Only 2 medications, cilostazol and pentoxifylline, are approved by the FDA for improving walking performance in people with PAD.\textsuperscript{10,11} Recently, research showed that pentoxifylline does not improve walking performance more than does placebo and thus is not recommended by clinical practice guidelines for improving walking performance in people with PAD.\textsuperscript{10,11} Cilostazol provides modest benefit in walking performance, but many patients discontinue cilostazol because of its adverse effects. Lower extremity revascularization improves walking performance in people with PAD\textsuperscript{10}; however, many patients with PAD are not well suited for revascularization either because of the location of their atherosclerosis or because they have significant comorbidities. In addition, lower extremity revascularization is invasive and costly, and its benefits have limited durability.\textsuperscript{10}

Supervised treadmill exercise significantly improves walking performance in people with lower extremity PAD and is recommended by clinical practice guidelines as a first-line therapy (Class IA recommendation, indicating that supervised treadmill exercise is recommended or should be performed, based on high-quality evidence from more than one randomized clinical trial).\textsuperscript{11-14} However, traveling to a medical center 3 times a week for supervised treadmill exercise can be burdensome, and many people with PAD decline participation.\textsuperscript{15} Practice guidelines also recommend home-based walking exercise for people with PAD (Class IIA recommendation, indicating that the treatment is reasonable and can be useful, based on high-quality evidence from more than one randomized clinical trial).\textsuperscript{11} This recommendation is based
on 3 randomized trials in which the home-based exercise interventions required periodic visits to the medical center, every 1 to 4 weeks, throughout the intervention.\textsuperscript{11,16-18}

Effective interventions that do not require regular medical center visits are likely to be more accessible and acceptable to patients with PAD than exercise interventions requiring periodic medical center visits. In the Home-Based Monitored Exercise for PAD (HONOR) randomized clinical trial, we used feedback from patients with PAD to design a home-based exercise intervention that appealed to them. The trial tested whether an intervention that combined telephone coaching and a wearable activity monitor (ie, FitBit) to promote home-based walking exercise—but that did not require periodic medical center visits throughout the intervention—significantly improved walking endurance and patient-reported outcomes at 9-month follow-up, compared with usual care.

The specific aims and hypotheses for this study were as follows:

- **Aim 1**: Using input from patients with PAD and their health care providers, perform feasibility studies necessary to finalize a home-based walking exercise intervention.

- **Aim 2**: In 200 patients with PAD, conduct a randomized clinical trial to determine whether the PAD patient-centered home-based walking exercise program improves walking ability, physical function, pain, and social functioning, compared with usual care. The primary outcome was 6-minute walk distance (as measured by the Six Minute Walk Test [SMWT]), an objective, well-validated measure of walking endurance. Secondary outcomes were well-validated questionnaire measures consisting of the Walking Impairment Questionnaire (WIQ) and the Patient-Reported Outcomes Measurement Information System (PROMIS) measures of physical function, leg pain, and social functioning. We hypothesized that participants randomly assigned to home-based exercise (ie, the intervention group) would see significantly greater improvement in each primary and secondary outcome than participants receiving usual care.
PARTICIPATION OF PATIENTS AND OTHER STAKEHOLDERS

Types and Number of Stakeholders Involved

Stakeholders for the HONOR study included 4 patients with PAD, 4 representatives of national organizations that advocate for better health care for patients with PAD, and 1 vascular surgeon enlisted because of his specific interest in the proposed research. The 4 representatives of national organizations were also clinicians who regularly cared for patients with PAD (including 3 vascular medicine specialists and 1 nurse who specialized in care of patients with PAD). The national organizations represented by 4 of the stakeholders were the American Heart Association and American College of Cardiology, the Society for Vascular Surgery, the Society for Vascular Medicine, and the Society for Vascular Nursing.

How the Researchers Decided On and Achieved the Desired Balance of Stakeholder Perspectives

At the time the investigators submitted the proposal to PCORI, they had determined that it was important to enlist support from organizations that were major stakeholders in the care of patients with PAD. After the project received funding, investigators contacted the organizations and included a representative from each of them (note that the American College of Cardiology was represented by 2 individuals who were also representing the American Heart Association and the Society for Vascular Medicine, respectively). Prior to submitting the grant application, investigators decided to select an approximately equal number of patients as the number of organization and clinician stakeholders. Therefore, investigators identified 4 patients to serve as patient stakeholders. Investigators also selected a patient to serve on the data and safety monitoring board (DSMB) for the study. After the project was funded, an additional vascular surgeon joined the investigative team as a stakeholder, primarily because of his interest in identifying effective exercise interventions for patients with PAD and because he has worked successfully with health care insurance companies to promote their coverage of therapies for patients with vascular disease.
Methods Used to Identify and Recruit Stakeholder Partners

To identify patient stakeholders, the principal investigator (Dr. Mary M. McDermott) and study staff identified people with PAD who had participated in research conducted by Dr. McDermott and who would be interested in helping design the HONOR study. In addition, investigators selected a diverse group of patients, including some who regularly engaged in walking exercise and others who declined exercise. Investigators sought to include approximately 50% women among the patient stakeholders. To identify the representatives of national organizations, investigators contacted the organizations’ leaders to invite participation and/or to recommend representatives.

Methods, Modes, and Intensity of Engagement

Stakeholders were involved in designing the study intervention. Two investigative team meetings were held prior to starting the randomized trial. First, on December 11, 2014, an investigative team meeting was held in Chicago to discuss the proposed study and identify additional pilot data that were necessary to collect prior to beginning the randomized trial in aim 2. Second, on March 11, 2015, a second investigative team meeting was held in Chicago to discuss results of pilot data collection and to finalize the protocol for aim 2. Stakeholders were invited to participate in both meetings, and most attended them in person. In addition, as the study team finalized the study design, telephone conference calls were held regularly during approximately the first 8 months of the funding period, and stakeholders were invited to participate in these calls. Once recruitment and randomization began, telephone calls became less frequent (approximately every 6-9 months) to update investigators and stakeholders on study progress. Co-investigators received updates to ensure that they were aware of recruitment progress and any challenges that arose during the trial, because individual co-investigators had specific roles and did not interact with all aspects of the study on a daily basis. Telephone calls with investigators and stakeholders included discussions of the decision to add additional recruitment sites in order to ensure that the enrollment target of 200 participants was met. Once results became available at the end of the trial, investigators held a conference call to discuss them. In addition to these methods, one patient stakeholder served on the DSMB.
and participated in telephone calls every 6 months. This patient stakeholder passed away in the summer of 2016.

**Perceived or Measured Impact of the Engagement on the Research**

First, stakeholders influenced the design of the intervention. Specifically, we sought patient input for designing a home-based walking exercise intervention that would be acceptable to patients with PAD. We used this information to refine some details of the intervention, such as the inclusion of group activities, how the website would be used to support the intervention, and the specific features of the website. Patient stakeholders also informed investigators that some patients with PAD randomly assigned to the intervention would be eager to participate in group meetings with other participants to discuss experiences with home exercise, while other patients with PAD would prefer not to participate in group meetings. Therefore, group telephone calls, in which participants in the intervention group could call in to discuss their experiences with exercise activity, were optional. Second, during the recruitment period, investigators held a telephone call with stakeholders to obtain their thoughts about how to maximize recruitment. Stakeholders made several suggestions, such as running a newspaper article or placing signs in assisted living homes. Investigators had experience with both methods and tried them again due to the stakeholders’ suggestions; however, these methods did not particularly increase recruitment. Third, for the investigator meeting held on March 11, 2015, Dr. McDermott invited a representative from Blue Cross Blue Shield of Illinois to discuss how and whether insurance companies might be amenable to providing funding for the study intervention, if it were effective. This representative attended the March 2015 meeting and advised the investigative team that if the intervention were successful, the representative would discuss how Blue Cross Blue Shield of Illinois could support its implementation. Fourth, those stakeholders who were clinicians and/or representatives of stakeholder organizations provided input on the manuscript resulting from this research project.
METHODS

Aim 1

Study Overview for Aim 1

The first aim was to perform a pilot study, consisting of a single group clinical trial, to test the feasibility and acceptability of the components of the home-based walking exercise intervention to patients with PAD. This pilot study was designed during an investigator and stakeholder meeting that took place in Chicago on December 11, 2014, and was conducted during January and February of 2015. Dr. McDermott then led focus groups to obtain feedback from the PAD participants in the pilot study. Feedback from the participants was summarized in a written document and presented to the team of investigators and stakeholders during a second meeting in Chicago on March 11, 2015. Thus, 2 meetings were held in Chicago and attended by investigators and stakeholders. These meetings aimed to (1) finalize planning of the pilot study that informed the main trial (completed during the meeting on December 11, 2014); (2) review results of the pilot study (completed during the meeting on March 11, 2015); and (3) make final protocol changes prior to the main trial (completed during the meeting on March 11, 2015).

Study Design for Aim 1

The purpose of the pilot study was to test the feasibility of the intervention and to obtain feedback about it from patients with PAD. There was no control group for this pilot study, and quantitative data were not collected. After this uncontrolled clinical trial was completed, we held focus groups to obtain feedback about the intervention from the pilot study’s participants. Participant feedback from the focus group was summarized in writing and presented to stakeholders and investigators during an on-site meeting in Chicago on March 11, 2015.
Study Setting for Aim 1

We used an outpatient setting because it is most relevant to a home-based exercise intervention.

Participants for Aim 1

Patients with PAD were selected from those who had participated previously in studies with Dr. McDermott and had agreed to be contacted for future studies. These PAD participants were chosen because they were readily available for contact and potential participation (ie, they could be contacted directly by telephone because they had previously provided informed consent for contact for future studies led by Dr. McDermott). We used 2 additional criteria. First, to ensure that participants in the pilot study represented a range of disability, some participants were selected because they had slower walking speed and others were selected because they had faster walking speed. Second, participants were selected if investigators believed they would be willing and able to provide meaningful feedback about the intervention.

Comparators or controls for aim 1. There were no control participants, as the aim was to test feasibility of the proposed intervention and to obtain feedback from participants with PAD about the intervention.

Interventions for Aim 1

We designed the 4-week pilot study intervention to test the feasibility and acceptability of the intervention proposed for the main clinical trial described in aim 2. Therefore, the pilot study tested the proposed intervention in a few participants with PAD and sought their feedback. Investigators were particularly interested in testing 3 components of the pilot study. First, to test acceptability of the coaching, feasibility of the intervention, and use of the FitBit activity monitor in people with PAD, participants in the pilot study received a FitBit activity monitor and instruction from the study coach. The coach administered instruction both in person and by telephone about adhering to home-based walking exercise. In addition, this component of the pilot intervention was conducted to determine whether the FitBit detected walking exercise activity in very slow walkers. Second, as part of the pilot study, we asked
participants to enter their walking exercise activity and monitor their walking exercise progress each week on the study intervention’s website. This component of the pilot study was intended to determine whether the website was appealing and easy for participants to use. Third, we held 2 group telephone calls to test the feasibility of this part of the intervention. The group telephone calls were designed to provide support for the walking exercise behavior from other PAD participants in the trial. A patient with PAD led these calls for the pilot study so we could determine whether this leadership role would be effective for the trial. Dr. McDermott and the study coach listened to these calls to assess their effectiveness.

Study Outcomes for Aim 1
We collected no quantitative data for aim 1. At the completion of the pilot study, Dr. McDermott led focus groups of pilot study participants. The purpose of the focus groups was to obtain feedback from the participants about the intervention overall and about the 3 intervention components described previously. Dr. McDermott and the study team summarized the feedback with written notes. Feedback was presented during the second stakeholder and investigator meeting in Chicago on March 11, 2015.

Analytical/Statistical Approaches for Aim 1
We performed no statistical analyses because we did not collect quantitative data.

Changes to the Original Study Protocol for Aim 1
We made no changes to the original study protocol.

Aim 2

Study Overview for Aim 2
Aim 2 was to conduct a randomized clinical trial with 2 parallel groups to determine whether the PAD patient-centered home-based exercise intervention significantly improved walking ability, physical function, pain, and social functioning, compared with usual care. We used information from the pilot study conducted in aim 1 to guide the intervention in aim 2.
**Study Design for Aim 2**

We used a randomized clinical trial (see Figure 1).

**Study Setting for Aim 2**

The study setting was outpatient, as this setting is most applicable to a home-based walking exercise intervention for people with PAD. Three medical centers (University of Minnesota, New York University, and Northwestern University) participated. New York University was added approximately 6 months after the start of recruitment, and University of Minnesota was added approximately 12 months after the start of recruitment. We included these 2 sites to ensure that the study met the recruitment targets according to study milestones and the study timeline. Stakeholders and investigators participated in the decision to add 2 recruitment sites. To ensure consistency in data collection, all staff collecting data at each site were required to read study manuals, undergo training, and successfully complete certification in data collection. Dr. McDermott’s research coordinators led the training; Dr. McDermott performed certification with a checklist to ensure quality and consistency in data collection.
Figure 1. Overview of the study design

The coaching intervention for home-based exercise consisted of 4 weekly on-site visits at each trial location, followed by telephone calls at scheduled intervals. Trained coaches at each study site delivered the intervention. Coaches at New York University and the University of Minnesota received specific training to deliver the on-site intervention, while coaches at Northwestern were trained for delivering both the on-site intervention and the telephone calls.
coaching calls. This was because after the on-site sessions at each medical center were completed, all telephone coaching was delivered by coaches in Chicago. All coaches were trained by Dr. Jack Rejeski, a co-investigator and internationally recognized behavioral expert who is based at Wake Forest University, and by Dr. McDermott. Northwestern’s trained coaches assisted with training coaches at New York University and the University of Minnesota. Because Dr. Rejeski was located at Wake Forest University, he trained coaches by telephone using both didactic methods and role-playing. Dr. McDermott performed training both by telephone, using mock telephone calls, and in person. Coaches from New York University and the University of Minnesota traveled to Northwestern for at least one visit before beginning their coaching activities. At Northwestern, they met with Dr. McDermott and with Northwestern’s senior behavioral coach for training in the intervention.

**Participants for Aim 2**

The target sample size was 200 participants (see Power Calculations for Aim 2). Participants were identified from physician referrals, lists of patients with PAD, advertisements, and mailings to people aged ≥ 50. Details about these recruitment sources are as follows. First, at each participating medical center, we notified vascular surgeons and other physicians who treat patients with PAD about the study and encouraged them to refer eligible patients. Investigators did not keep track of all individual physicians notified of the study; rather, investigators aimed to publicize as widely as possible that the HONOR trial was ongoing and recruiting patients with PAD. Second, at Northwestern and at the University of Minnesota, the electronic health record was used to obtain names of patients with an ICD-9 (International Classification of Diseases, Ninth Revision) diagnosis consistent with PAD. Following IRB-approved methods at each site, we mailed these patients a recruitment letter to notify them of the study and invite them to participate. Third, we placed advertisements on Chicago Transit Authority buses and trains and in newspapers of interest to older men and women in Minneapolis. Fourth, we purchased mailing lists of people living in and around Chicago and Minneapolis aged 50 and older and mailed postcards to the individuals on these lists, advising them of the research study and inviting participation. In addition to these methods, we
contacted people with PAD who had previously participated in research at each medical center and had expressed interest in future research.

Inclusion criteria for aim 2. Inclusion criteria included an ankle-brachial index (ABI) ≤ 0.90 at baseline. Potential participants with ABI > 0.90 at baseline were eligible if a hospital-affiliated vascular laboratory report demonstrated PAD, a lower extremity angiogram showed stenosis ≥ 70%, or medical records documented prior lower extremity revascularization. Any evidence of definite PAD from a hospital-affiliated vascular laboratory was sufficient for inclusion: For example, a participant with a toe-brachial index < 0.70 and a study ABI > 0.90 was considered eligible. Additionally, individuals with ABI 0.90 to 1.00 were eligible if their ABI dropped by 20% after a heel-rise test.

Exclusion criteria for aim 2. Potential participants with a below- or above-knee amputation, wheelchair use, use of a walking aid other than a cane, walking impairment for a reason other than PAD, foot ulcer, critical limb ischemia, or significant visual or hearing impairment were excluded. Examples of participants excluded because their walking was primarily impaired by a reason other than PAD consisted of those whose walking was primarily limited by a significant limp (such as foot drop or debilitating stroke), chest discomfort, or dyspnea. Other exclusion criteria included major surgery or revascularization during the previous 3 months or planned during the next 9 months; current or recent (ie, in the past 3 months) participation in a clinical trial or cardiac rehabilitation; Parkinson disease; or requiring oxygen with activity. Potential participants with Class III or IV New York Heart Association heart failure or angina, increase in angina pectoris during the previous 6 months, or abnormal baseline stress test were excluded. Individuals whose walking was primarily limited by symptoms other than PAD or who did not speak English were excluded. Individuals already exercising at a frequency and duration comparable to the exercise intervention (ie, at least 3-5 days per week for a minimum of 30 minutes per session) were excluded because it was less likely that they would improve in response to the exercise intervention. Individuals treated for cancer in the past 2 years were excluded unless the cancer was early stage, the prognosis was excellent, and the cancer was unlikely to return during the participant’s enrollment. For these
individuals, eligibility was determined either by medical record review or by direct consultation between Dr. McDermott and the individual’s physician. Those with a Mini-Mental Status Examination score < 23 were excluded.\textsuperscript{21}

**Baseline Data Collection for Aim 2**

**Ankle-brachial index.** We used a handheld Doppler instrument (Nicolet Vascular Pocket Dop II, Golden, CO) to measure systolic pressures in the right brachial, dorsalis pedis, and posterior tibial arteries and the left dorsalis pedis, posterior tibial, and brachial arteries. Each pressure was measured twice. We calculated the ABI by dividing average pressures in each leg by the average of the 4 brachial pressures.\textsuperscript{22}

**Other measures.** Trained staff obtained medical history and race/ethnicity using an open-ended question, measured height and weight, and calculated body mass index (BMI) as weight (kilograms) divided by height (square meters).\textsuperscript{2}

**Leg symptoms.** We used the San Diego Claudication Questionnaire to characterize leg symptoms.\textsuperscript{17} This questionnaire measures the presence and specific nature of leg symptoms in people with PAD. Participants were classified according to their leg symptoms, based on their responses to the questionnaire. Participants with symptoms of intermittent claudication were individuals who reported exertional calf pain that did not begin at rest, caused the participant to stop walking, and resolved within 10 minutes of rest. Participants without intermittent claudication were either asymptomatic (ie, reported no exertional leg symptoms) or had exertional leg symptoms that did not meet the criteria for intermittent claudication.\textsuperscript{23}

**Randomization for Aim 2**

A randomization list generated by computer randomly assigned participants to 1 of 2 groups in a 1:1 allocation. Randomization was stratified by study site and used block randomization, with block sizes randomly selected from 4, 6, or 8.
Intervention for Aim 2

*Home-based walking exercise.* We designed the home-based walking exercise intervention based on input from published evidence, behavioral change theories, and patient feedback. The intervention consisted of multiple components, including (1) 4 in-person on-site meetings with the exercise coach that took place at weekly intervals during the first 4 weeks of the intervention; (2) scheduled telephone calls at decreasing frequency (beginning once per week and tapering to once per month) throughout the 9-month intervention; (3) a FitBit that recorded daily step count; (4) a study website, used by the participant and coach to monitor progress during the study; and (5) group telephone calls held once per month. A screenshot of the intervention website is included in the appendix.

During the first month of the intervention, participants attended 4 weekly on-site sessions. In the first 2 weekly sessions (weeks 1-2), they met with the coach. In the second 2 weekly sessions (weeks 3-4), they met with other PAD participants and the coach.

There were 3 primary coaches at Northwestern during the study. One of the coaches was an exercise physiologist with many years of experience working with people with PAD; 2 of the coaches were specifically hired to work on the study and trained to deliver the intervention. During the 4 on-site sessions, coaches educated participants by showing them how to use the FitBit and the study website. They also instructed participants to set walking exercise goals and taught them how to self-monitor their progress. We used the intervention website to monitor participants’ progress. Participants who owned a computer or tablet could use their own device to upload the FitBit data and monitor their progress on the website. If participants did not own a computer or tablet, they were provided with an iPad for the study duration. At the 4 on-site visits during the first 4 weeks of the intervention, participants were asked to walk for exercise with the coach. Walking with the coach can be helpful to build self-efficacy and to show participants how to manage ischemic leg symptoms during exercise. After the first month, participant contact with the coach was primarily by telephone, and there were no scheduled on-site medical center visits. The coach called participants once per week during months 1 through 2, once every other week during months 3 through 4.5, and once per month during
months 4.5 through 9. Telephone calls were structured to include discussion of progress toward exercise goals, review of the FitBit data, challenges encountered, strategies to overcome challenges, setting of new walking exercise goals, and a summary of the telephone call content.

The intervention was individualized—this was important because participants varied in their ability to walk for exercise. Some participants could not walk more than 20 minutes per day for exercise; others had no difficulty walking 55 minutes per day. Coaches helped participants set walking exercise goals that were appropriate for their ability. Participants were typically advised to exercise 5 days per week either indoors or outdoors, beginning with 10 to 15 minutes of exercise per session and working up to 50 minutes per session if they were able. Participants were asked to walk until they experienced severe leg discomfort and then rest until they were able to resume walking. Specifically, participants were asked to walk to achieve a leg symptom severity of 4 to 5 on a 1-to-5 scale. If participants could walk for 10 minutes without stopping due to ischemic leg symptoms, they were asked to increase their walking exercise speed (ie, intensity). Participants without exertional leg discomfort were asked to walk to an intensity of 12 to 14 out of 20 on the Borg Rating of Perceived Exertion scale.

Participants received a wearable activity monitor (FitBit Zip) to measure physical activity. The FitBit Zip, a quantitative measure of physical activity, was used as part of the intervention and was not an outcome measure. We selected the FitBit Zip because patients in a pilot study prior to submitting the grant application for the HONOR study indicated that it motivated them to walk for exercise. The coach used the FitBit data to monitor the amount of walking participants completed throughout the day.

The FitBit Zip wearable device has been shown to be a valid and reliable measure of walking activity, with less than 1% error compared with validated activity measures. The FitBit Zip collected data on steps walked each day; however, it could not measure which steps were part of a bout of walking exercise. The FitBit Zip did not record walking intensity. Participants uploaded data from the FitBit (step count) to the study website via Bluetooth, and these data were visible in a bar graph to the participant and coach. Participants were asked to upload step count data at least once per week. Coaches used the data to provide feedback to participants.
During telephone contact, the coach entered exercise goals (exercise frequency and duration) on the website. Participants were asked to enter the minutes they walked for exercise on the website, and this information was visible to the coach.

Twice per month, the coach led group telephone calls for intervention participants. These calls included a “topic of the month,” such as managing pain during exercise and exercising in cold weather. Participants were encouraged to share their successes and challenges with other participants. These calls were optional for participants.

Usual care. Participants randomly assigned to usual care received no study interventions. Usual care consisted of the therapies prescribed by each participant’s individual physician. Although supervised treadmill exercise is recommended by clinical practice guidelines, most patients with PAD were not participating in supervised treadmill exercise, in part because at the time the study started, the Center for Medicare & Medicaid Services was not covering supervised treadmill exercise therapy and because traveling to the medical center 3 times weekly for exercise is burdensome and difficult for many people who have PAD. Other potential therapies that might have been prescribed as part of usual care included lower extremity revascularization or 1 of 2 FDA-approved medications for claudication (ie, cilostazol and pentoxifylline). Medications for PAD-related walking limitation might have been prescribed for participants in the usual care group during the study period, but these therapies are not particularly effective, and patients were asked not to start new therapies for PAD during the study, if possible.

Study Outcomes for Aim 2

Staff members blinded to group assignment obtained all prespecified outcomes at baseline and follow-up, and investigators remained blinded to outcome data until the end of the trial. The primary outcome was change in 6-minute walk distance between baseline and 9-month follow-up. Secondary outcomes were changes between baseline and 9-month follow-up in WIQ distance, speed, and stair climbing scores; the 36-Item Short Form (SF-36) physical functioning score; the PROMIS measures of mobility, pain interference, and satisfaction with
social roles and activities, and change in ActiGraph-measured physical activity. In prespecified, exploratory analyses, these outcomes were also measured at 4.5-month follow-up.

In addition, a study coordinator other than the coach called all participants monthly to obtain data on adverse events. Information on physical activity and walking exercise frequency during the previous 2 weeks was collected during these telephone calls every 3 months.

A summary of the time points at which we measured each outcome follows: We measured 6-minute walk distance, WIQ scores, SF-36, PROMIS, and ActiGraph physical activity measures at baseline, 4.5-month follow-up, and 9-month follow-up. We obtained participant self-reports of physical activity and exercise duration and frequency at baseline and at 3-month, 6-month, and 9-month follow-ups. We measured all primary and secondary outcomes at baseline and 9-month follow-up. We measured exploratory outcomes at baseline and 4.5-month follow-up or at baseline, 3-month, 6-month, and 9-month follow-up. Investigators chose to measure patient-reported physical activity and walking exercise behavior every 3 months because these data were collected at the time that adverse event telephone calls were made and because it allowed investigators to track changes throughout the study more frequently. In contrast, we measured primary and secondary outcomes at 9-month follow-up because we considered a longer follow-up period more clinically important. We implemented the 4.5-month measurement because, after this time, the frequency of telephone calls from the coach significantly declined.

We selected outcome measures after consulting with patients with PAD during focus groups conducted prior to submitting our grant proposal. We chose the outcome measures based on feedback about which measures best represented patients’ perceived disability from PAD. Coordinators collecting data from participants were blinded to their group assignment. Participants received $25.00 after completing 9-month follow-up testing.

**Six-minute walk test.** Change in 6-minute walk distance (as measured by the SMWT) is a well-validated, objective measure of walking endurance in people with PAD. The
SMWT was the primary outcome for the following reasons: First, because it is conducted in a hallway, it is similar to the type of walking required in daily life. Second, a minimum clinically important difference has been defined for the SMWT. Third, the SMWT is well validated in people with PAD and predicts mobility loss and mortality. Fourth, greater decline in the SMWT predicts higher rates of mobility loss and mortality. Fifth, previous trials have showed that in people with PAD, the SMWT improves in response to supervised treadmill exercise interventions and in response to home-based walking interventions. Sixth, in a focus group held prior to the submission of the grant application for this study, people with PAD identified 6-minute walk distance as a meaningful outcome for their walking limitations from PAD.

A trained and certified research assistant, following a standardized protocol, administered the SMWT. Dr. McDermott certified research staff performing the SMWT and blinded them to group assignment. Participants walked up and down a 100-foot hallway for 6 minutes after instructions to cover as much distance as possible. The distance completed after 6 minutes was recorded; 20 m was defined as a small meaningful change.

**Questionnaire outcome measures.** Participants self-administered the questionnaires (see Table 1). The WIQ is a PAD-specific measure of self-reported limitations with 3 domains: walking distance, walking speed, and stair climbing. Each domain is scored on a 0-to-100 scale (100 = best). We used the SF-36 to assess functional status in the physical functioning domain (0-100 scale, 100 = best). The PROMIS questionnaires measured perceived change in mobility (short-form mobility questionnaire); ability to engage in social roles and activities (PROMIS satisfaction with social roles and activities short form); and the degree to which pain interfered with activities (PROMIS short-form pain interference questionnaire). PROMIS measures use a T score metric, with a mean of 50 and a standard deviation of 10 compared with the general population. Higher scores are better for mobility and social roles questionnaires and worse for the pain interference questionnaire. Minimal clinically important differences are 2.0 points for mobility and 3.5 to 4.5 for pain interference but are not established for satisfaction with social roles. A small minimal clinically important difference
has not been established for the WIQ scores, while changes of 5 to 7 points have been used for the SF-36 physical functioning score.\textsuperscript{29}

### Table 1. Questionnaires Used as Secondary Outcomes in the HONOR Study

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Purpose of Questionnaire</th>
<th>Score Range</th>
<th>Meaningful Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>WIQ</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WIQ distance</td>
<td>To measure patients’ perception of the ease with which they can walk long distances</td>
<td>0-100 (100 = best)</td>
<td>Not defined</td>
</tr>
<tr>
<td>WIQ speed</td>
<td>To measure patients’ perception of their ability to walk a range of speeds</td>
<td>0-100 (100 = best)</td>
<td>Not defined</td>
</tr>
<tr>
<td>WIQ stair climbing</td>
<td>To measure patients’ perception of their ability to climb stairs</td>
<td>0-100 (100 = best)</td>
<td>Not defined</td>
</tr>
<tr>
<td>PROMIS questionnaires</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PROMIS mobility short form</td>
<td>To measure patient-reported ability to move and get about in daily life</td>
<td>( T ) score metric, ( \mu = 50, \sigma = 10 )</td>
<td>2.0</td>
</tr>
<tr>
<td>PROMIS satisfaction with social roles and activities short form</td>
<td>To measure patient-reported satisfaction with the degree to which patients can complete their social roles</td>
<td>( T ) score metric, ( \mu = 50, \sigma = 10 )</td>
<td>Not defined</td>
</tr>
<tr>
<td>PROMIS pain interference short form</td>
<td>To measure patients’ perception of the degree to which pain interferes with their daily life activities</td>
<td>( T ) score metric, ( \mu = 50, \sigma = 10 )</td>
<td>3.5-4.5</td>
</tr>
<tr>
<td>Quality-of-life questionnaire</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SF-36 physical functioning</td>
<td>To measure patient-reported quality of life, measured by patients’ physical health and well-being</td>
<td>0-100</td>
<td>5.0-7.0</td>
</tr>
</tbody>
</table>

Abbreviations: PROMIS, Patient-Reported Outcomes Measurement Information System; SF-36, 36-Item Short Form; WIQ, Walking Impairment Questionnaire.
ActiGraph. Over 7 days, the ActiGraph accelerometer recorded physical activity, measured as total counts per minute. We collected data at baseline, 4.5-month follow-up, and 9-month follow-up. We recorded the date of randomization for each participant after collecting all baseline data, including the ActiGraph measure of physical activity. At 4.5-month and 9-month follow-up, we repeated the ActiGraph physical activity outcome measure. We gave the ActiGraph to participants at the conclusion of a study visit at which we collected other study outcome measures (such as the 6-minute walk distance and questionnaire administration). We gave participants detailed instructions about wearing the ActiGraph and asked them to wear it for 10 days. The ActiGraph accelerometer is worn on the right hip and removed only for bathing or sleeping. Participants were provided with a stamped and addressed envelope to mail the ActiGraph back to study staff at the end of the 10 days. The first 7 full days of physical activity during which the participant wore the ActiGraph for at least 10 hours during each day were used in analyses. We asked participants to wear the ActiGraph for 10 days but included only 7 days in analyses to account for days when they forgot to wear it.

Patient-Reported Physical Activity and Exercise Activity

Every 3 months, we called participants in each group to ask about their walking exercise activity and their physical activity in the past 2 weeks. The purpose of collecting this information was to monitor whether exercise behavior and physical activity changed in the intervention and the usual care group throughout the study.

Time Frame for the Study

The intervention lasted 9 months; the longest prior trial of a successful home-based exercise intervention had been 6 months. Investigators aimed to design a longer trial, which could be even more clinically useful than a shorter intervention. Originally, investigators aimed to conduct a 12-month intervention; however, the 3-year funding period of the study and the requirement for 200 participants necessitated a shorter intervention (9 months).
**Data Collection and Sources for Aim 2**

We called all study participants at least once per month throughout the study. If participants indicated that they did not want to continue with the study, they were asked the reason for wanting to drop out. Three proxies were identified for each participant at the time of enrollment. If investigators could not reach a study participant, a proxy was contacted.

**Adverse Events**

To monitor safety of the intervention relative to usual care, we collected adverse events from participants in both groups. A study staff member called all randomly assigned participants once each month and inquired about new or worsening symptoms of chest pain, dyspnea, or weakness on exertion. Participants were also questioned about any new hospitalizations during the past month. We compared rates of adverse events and serious adverse events (hospitalizations or deaths) between the intervention and usual care groups.

**Power Calculations for Aim 2**

We calculated statistical power for the 6-minute walk distance primary outcome and for the secondary questionnaire outcomes. We anticipated a 10% dropout at 9-month follow-up, based on prior studies.\(^{12,13,18}\) The standard deviation of change in 6-minute walk distance was 51 to 69 m in a previous trials of exercise in people with PAD.\(^{13,18}\) Therefore, 200 participants provided 80% power for detecting a difference in change of 21 to 29 m in 6-minute walk distance between the 2 groups, using a 2-sided, 2-sample t test with a significance level of 0.05. Twenty meters is the minimum clinically important difference for the SMWT.\(^{40}\) For the secondary questionnaire outcomes, based on standard deviations from prior studies,\(^{13,18,30}\) the trial had 80% power to detect a difference of 10.1 in the WIQ distance score, 9.2 in the WIQ speed score, and 3.3 in the PROMIS pain interference score. The clinically meaningful change (minimum clinically important difference) was defined, where available, for each questionnaire (see Table 1).
Statistical Analysis

We assessed primary and secondary outcomes from baseline to 9-month follow-up. Analyses from baseline to 4.5-month follow-up were prespecified, exploratory outcomes. We performed analyses according to intention to treat, meaning that all participants were asked to return for follow-up testing regardless of whether they had adhered to their intervention or had undergone lower extremity revascularization. We summarized baseline characteristics as mean and SD for continuous measures and number and percentage in each group. We performed tests for normality. We compared changes in each outcome between baseline and 9-month follow-up and between baseline and 4.5-month follow-up between the groups using a 2-sample t test stratified by site. We constructed 95% CIs for the between-group differences. In analyses for changes in outcomes between baseline and 4.5-month follow-up and between baseline and 9-month follow-up, we handled missing data with multiple imputation method (SAS PROC MI: https://support.sas.com/documentation/onlinedoc/stat/141/mi.pdf). The final results are based on 80 imputed data sets with imputed missing values. Variables used for imputation include age, ABI, BMI, sex, race, smoking status, leg symptoms, comorbidities, and all outcome measures. The final statistical inference accounted for imputation variabilities. The a priori level for statistical significance was 2-sided \( p < 0.05 \). We used SAS version 9.4 (https://www.sas.com/en_us/software/sas9.html) in analyses.

Subgroup analyses. We performed prespecified analyses to evaluate outcomes according to the following subgroups: (1) participants who dropped out of the intervention vs those who did not drop out (a dropout was an individual who either could not be reached or indicated that they did not wish to be contacted any further by study staff or investigators); (2) participants grouped into tertiles according to the frequency with which they viewed their data on the study website (the frequency of data viewing was determined based on the number of times per week or month that a participant logged into the HONOR website); (3) participants grouped by tertiles according to how frequently they wore their FitBit (frequency of wearing the FitBit was determined according to data uploaded on the study website, which indicated the days in which the step count measured by the FitBit was > 0); and (4) participants
categorized according to whether they participated in group telephone calls. We repeated the comparisons within subsets of participants grouped by baseline characteristics in post hoc exploratory analyses using tests for interaction to determine statistical significance. We defined the subgroups according to participant age, sex, race, baseline ABI, presence vs absence of intermittent claudication, current smoking status, presence vs absence of diabetes, baseline 6-minute walk performance, and site; we selected subgroups before the analyses. We also tested the interaction between the factors defining the subgroup and the treatment using the analysis of covariance. The objective was to examine if the treatment effect varied across different subgroups and to identify potential subgroups of patients who may have benefited from the home-based exercise. Due to the exploratory nature of the analysis, we employed no multiple testing adjustment.

Changes to the Original Study Protocol for Aim 2

As described previously, 2 meetings of study investigators and stakeholders were held in Chicago to finalize protocol details for specific aim 1 and aim 2. Participants made some modifications to the study protocol during these meetings. First, during the first investigator and stakeholder meeting held on December 11, 2014, in Chicago, investigators and stakeholders decided to add the ActiGraph physical activity measurement as a secondary outcome. This was added because only one other objective outcome measure (the 6-minute walk distance) existed, and investigators determined that having more than one objective outcome measurement might be important. Second, during the meeting on December 11, 2014, participants decided to add an outcome measurement in order to evaluate change between baseline and 4.5-month follow-up. The 4.5-month follow-up measurement was added because the frequency of contact between the coach and study participants dropped after that time point. Investigators wanted to measure whether there was a benefit in study outcomes at 4.5-month follow-up (compared with baseline) among those randomly assigned to exercise, compared with those randomly assigned to usual care. The change from baseline to 4.5-month follow-up outcome measures was a prespecified exploratory outcome. Third, because of difficulty with recruitment, 2 new sites were added during the study (New York University and
the University of Minnesota). IRB approval was obtained at each of the 3 study sites (Northwestern, New York University, and the University of Minnesota) for all aspects of the study.
RESULTS

Aim 1

*Using input from patients with PAD and their health care providers, perform feasibility testing necessary to finalize methods for a home-based walking exercise intervention.*

**Results for Aim 1**

Seven participants with PAD participated in the feasibility pilot study, including 3 identified because they were slow walkers. The pilot study collected no quantitative data. After completion of the feasibility pilot study, Dr. McDermott led focus groups with participants to obtain feedback from them about their experience in the pilot study. Feedback was summarized in written paragraph form.

*Results of the pilot study testing feasibility of interactions with coach and use of FitBit.* Participants in the pilot study attended most of the study sessions, communicated with the coach, responded to coaching directions, and began walking for exercise. The participants who were selected because of their slow walking speed reported to the coach that the FitBit was detecting their steps. Based on data collected from very slow walkers, we determined that the FitBit was sufficiently sensitive to capture walking activity of slow walkers. This was also observed during on-site sessions in which participants and the coach walked together and the coach checked to ensure that steps recorded on the FitBit were the same as the steps actually walked during these exercise sessions.

*Results of the pilot study relevant to participants’ interactions with the intervention website.* During the focus group conducted after the pilot study, many participants said that they did not visit the website regularly, had difficulty accessing it, or found it bland. One participant expressed that the website’s purpose seemed to be to help investigators rather than participants. No pilot study participants posted a message board comment during the pilot study. Investigators and stakeholders reviewed and discussed this feedback during the Chicago meeting on March 11, 2015. Based on this feedback from the pilot
study, we made additional changes to the website after the March 11, 2015, meeting. Specifically, pictures and colors were altered or added to the website. The website was modified so that it had fewer buttons and a larger font size.

After we altered the website, subsequent focus groups were held with PAD participants to obtain feedback on the revised website. We developed the final study website according to additional feedback from participants and study investigators and stakeholders.

Results of pilot study regarding group telephone calls. The principal investigator and a study coach participated in 2 group telephone calls with participants to observe the feasibility of this component of the intervention. In the pilot study, a patient with PAD, who was a study investigator, led the group telephone calls; the calls were short, and engaging the participants in in-depth discussions was somewhat difficult. Therefore, during the Chicago meeting on March 11, 2015, with stakeholders, the investigators decided to have the study coach (instead of a patient with PAD) lead these group telephone calls during the larger randomized trial in aim 2.

Aim 2

Conduct a randomized trial in 200 patients with PAD to determine whether a patient-centered home-based exercise program improves walking ability compared with usual care.

Results for Aim 2

Of 503 participants who provided written informed consent, 200 were randomly assigned. Reasons for exclusion are shown in Figure 2. Follow-up rates at 9 months were 89% in the intervention group and 93% in the usual care group (Figure 2).

Overall among participants, the mean age was 70.2 years (SD = 10.4), the mean ABI was 0.73 (SD = 0.26), 105 (52.5%) were women, and 100 (50%) were black. The usual care group had a higher prevalence of current or former cigarette smoking, but baseline characteristics were otherwise balanced between the groups (Table 2). Table 3 shows the number and characteristics of participants at each study site.
Figure 2. Study participation and follow-up rates

- Signed informed consent form (n = 503)
  - Allocation
  - Randomized (n = 200)
  - Allocated to home-based exercise (n = 99)
    - Declined participation in the intervention (n = 4)
    - 4.5-month follow-up
      - Six-minute walk
      - WIQ scores
      - SF-36 and PROMIS
      - ActiGraph physical activity
  - Allocated to usual care (n = 101)
    - 9-month follow-up
      - Six-minute walk
      - WIQ scores
      - SF-36 and PROMIS
      - ActiGraph physical activity

Excluded (n = 303)
- No PAD—not eligible (n = 242)
- Not currently interested (n = 34)
- Treadmill test (abnormal or unwilling/unable to complete) (n = 8)
- Exercising at a level comparable to the amount targeted with the intervention (n = 7)
- Gait problems other than PAD that affect walking (n = 6)
- Other health problems that affect walking (n = 2)
- Did not complete baseline testing (n = 2)
- Mini-Mental Status Examination score < 23 (n = 1)
- Current enrollment in another clinical trial (n = 1)

85 Completed 4.5-month follow-up
- 1 Died
- 8 Lost to follow-up
- 5 Canceled visit

93 Completed 4.5-month follow-up
- 3 Lost to follow-up
- 5 Canceled visit

88 Completed 9-month follow-up
- 2 Died
- 9 Lost to follow-up

94 Completed 9-month follow-up
- 4 Lost to follow-up
- 3 Canceled visit

Abbreviation: PAD, peripheral artery disease; PROMIS, Patient-Reported Outcomes Measurement Information System; SF-36, 36-Item Short Form; WIQ, Walking Impairment Questionnaire.

a This figure was adapted from a previously published figure. The figure shows that of 503 participants randomly assigned, 303 were excluded because they did not meet one or more eligibility criteria. Reasons for exclusion among participants who signed a consent form are listed in the box titled “Excluded (n = 303).” Reasons for exclusion were not obtained for people who did not provide informed consent. The reason for not obtaining these data is that hundreds of people were excluded over the telephone prior to attending a baseline study visit. Available resources did not allow investigators to systematically record the reasons for exclusion for encounters that occurred prior to a baseline visit with a signed informed consent form. The Mini-Mental Status Examination score ranges from 0 to 30. Participants with a score < 23 were excluded from participation. Primary comparisons were change between 9-month follow-up and 4.5-month follow-up, respectively.
Table 2. Characteristics of Participants Randomly Assigned to Home-Based Exercise vs Usual Care

<table>
<thead>
<tr>
<th></th>
<th>Home-Based Exercise n = 99</th>
<th>Usual Care n = 101</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y), mean (SD)</td>
<td>70.1 (10.6)</td>
<td>70.4 (10.1)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>54 (54.5)</td>
<td>51 (50.5)</td>
</tr>
<tr>
<td>African American, n (%)</td>
<td>49 (49.5)</td>
<td>51 (50.5)</td>
</tr>
<tr>
<td>Lowest leg ABI, mean (SD)(^b)</td>
<td>0.65 (0.15)</td>
<td>0.67 (0.14)</td>
</tr>
<tr>
<td>Highest leg ABI, mean (SD)(^b)</td>
<td>0.83 (0.26)</td>
<td>0.88 (0.24)</td>
</tr>
<tr>
<td>BMI (kg/m(^2)), mean (SD)</td>
<td>29.6 (5.3)</td>
<td>29.9 (5.3)</td>
</tr>
<tr>
<td>Current or former smoker, n (%)</td>
<td>79 (79.8)</td>
<td>91 (90.1)</td>
</tr>
<tr>
<td>Myocardial infarction, n (%)(^c)</td>
<td>16 (16.2)</td>
<td>21 (21.2)</td>
</tr>
<tr>
<td>Heart failure, n (%)(^d)</td>
<td>8 (8.1)</td>
<td>11 (11.0)</td>
</tr>
<tr>
<td>Stroke, n (%)</td>
<td>10 (10.1)</td>
<td>16 (15.8)</td>
</tr>
<tr>
<td>Angina, n (%)</td>
<td>18 (18.2)</td>
<td>24 (24.0)</td>
</tr>
<tr>
<td>Cancer, n (%)</td>
<td>18 (18.2)</td>
<td>19 (18.8)</td>
</tr>
<tr>
<td>Diabetes, n (%)</td>
<td>35 (35.4)</td>
<td>32 (31.7)</td>
</tr>
<tr>
<td>Classical claudication symptoms, n (%)</td>
<td>17 (17.2)</td>
<td>22 (21.8)</td>
</tr>
<tr>
<td>Exertional leg pain other than claudication, n (%)</td>
<td>68 (68.7)</td>
<td>67 (66.3)</td>
</tr>
<tr>
<td>No exertional leg symptoms, n (%)</td>
<td>14 (14.1)</td>
<td>12 (11.9)</td>
</tr>
<tr>
<td>Taking a claudication medication at baseline, n (%)</td>
<td>13 (13.1)</td>
<td>12 (11.9)</td>
</tr>
<tr>
<td>History of prior lower extremity revascularization, n (%)</td>
<td>36 (36.4)</td>
<td>44 (43.6)</td>
</tr>
<tr>
<td>Six-minute walk distance (m), mean (SD)</td>
<td>331 (100)</td>
<td>336 (97)</td>
</tr>
<tr>
<td>SF-36 physical component score (0-100, 100 = best), mean (SD)(^e)</td>
<td>35.35 (9.4)</td>
<td>36.86 (9.0)</td>
</tr>
<tr>
<td>WIQ distance score (0-100, 100 = best), mean (SD)(^f)</td>
<td>37.70 (29.5)</td>
<td>37.89 (27.3)</td>
</tr>
<tr>
<td>WIQ speed score (0-100, 100 = best), mean (SD)</td>
<td>36.37 (19.4)</td>
<td>40.03 (24.5)</td>
</tr>
<tr>
<td>WIQ stair climbing score (0-100), mean (SD)</td>
<td>48.65 (27.2)</td>
<td>47.40 (27.8)</td>
</tr>
</tbody>
</table>
### Table 3. Evaluation of Outcomes

<table>
<thead>
<tr>
<th>Outcome Description</th>
<th>Home-Based Exercise n = 99</th>
<th>Usual Care n = 101</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROMIS pain interference score (higher score = worse), mean (SD)(^g)</td>
<td>56.5 (8.4)</td>
<td>56.7 (7.5)</td>
</tr>
<tr>
<td>PROMIS role satisfaction with social roles and activities (higher score = best), mean (SD)(^g)</td>
<td>48.2 (10.0)</td>
<td>48.8 (10.5)</td>
</tr>
<tr>
<td>PROMIS mobility score (higher score = best), mean (SD)(^g)</td>
<td>33.3 (5.3)</td>
<td>33.8 (5.4)</td>
</tr>
</tbody>
</table>

Abbreviations: ABI, ankle-brachial index; PROMIS, Patient-Reported Outcomes Measurement Information System; SF-36, 36-Item Short Form; WIQ, Walking Impairment Questionnaire.

\(^a\) This table was adapted from McDermott et al.\(^1\)

\(^b\) This comparison excluded 34 participants who were eligible based on prior revascularization or other criteria but whose baseline ABI was > 0.90.

\(^c\) Two participants were missing data for myocardial infarction.

\(^d\) One participant was missing data for heart failure.

\(^e\) One participant was missing data for the SF-36 physical component score.

\(^f\) Two participants were missing data for the WIQ distance score at baseline.

\(^g\) The PROMIS measures are based on item response theory and therefore have no defined minimum or maximum value. The lowest and highest scores observed for PROMIS have been 20 and 80, respectively.

### Table 3. Number and Characteristics of Participants At Each Study Site

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total</th>
<th>NU</th>
<th>NYU</th>
<th>MN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomly assigned participants, n</td>
<td>200</td>
<td>143</td>
<td>31</td>
<td>26</td>
</tr>
<tr>
<td>Current smokers, n (%)</td>
<td>56</td>
<td>48 (33.6)</td>
<td>5 (16.1)</td>
<td>3 (11.5%)</td>
</tr>
<tr>
<td>Randomized to intervention group, n</td>
<td>99</td>
<td>71</td>
<td>15</td>
<td>13</td>
</tr>
<tr>
<td>FitBit data available, n (%)(^a)</td>
<td>99</td>
<td>64 (90.1)</td>
<td>12 (80.0)</td>
<td>12 (92.3%)</td>
</tr>
</tbody>
</table>

Abbreviations: MN, University of Minnesota; NU, Northwestern University; NYU, New York University.

\(^a\) FitBit data were available only for participants randomly assigned to the intervention.
Intervention Adherence and Rates of Walking for Exercise

Of participants randomly assigned to the intervention, 92 (93%) attended all 4 on-site visits. Of participants randomly assigned to the intervention, 89% used the FitBit at least once. Scheduled intervention telephone call completion rates were 1295 of 1753 (73.9%). Excluding participants who died or dropped out, intervention call completion rates were 1204 of 1521 (79.2%). Follow-up rates across both study groups were 178 of 200 (89%) at 4.5 months and 182 of 200 (91%) at 9 months.

Primary Outcome

At the 9-month follow-up, adjusting for site, we observed no significant difference in change in 6-minute walk distance between the intervention and usual care groups: from 330.5 m (SD 100.2) to 333.4 m (SD 115.1; within-group change: 5.5 m) in the intervention group vs from 336.2 m (96.6) to 348.2 m (SD 98.1; within-group change: 14.4 m) in the usual care group. The between-group difference in the mean change from baseline to follow-up was –8.9 m (95% CI, –26.0 to 8.2; p = 0.31). Table 4 shows the primary and secondary outcome results.

Secondary Outcomes

The WIQ distance score improved from 38 (SD 29) at baseline to 52.2 (SD 33.5) at 9-month follow-up in the intervention (site-adjusted within-group change: 10.6) and 37.7 (SD 27.1) to 46.1 (SD 30.0) in usual care (site-adjusted within-group change: 4.8) at 9-month follow-up. The between-group site-adjusted difference in the mean change from baseline to follow-up was 5.8 (95% CI, –3.0 to 14.7; p = 0.198; see Table 4).

In the intervention group, the PROMIS pain interference score changed from 56.4 (SD 8.4) to 56.6 (SD 9.0; site-adjusted within-group change: 0.70) at 9-month follow-up. In the usual care group, the PROMIS pain interference score changed from 56.7 (SD 7.5) to 53.4 (SD 8.8; site-adjusted within-group change: –2.8) at 9-month follow-up. The site-adjusted between-group difference in the mean change from baseline to follow-up was 3.5 (95% CI, 1.3-5.8; p = 0.002), indicating a more favorable pain interference score in the usual care group.
We observed no other statistically significant differences between the intervention and the usual care group in secondary outcomes (Table 4).
Table 4. Effects of Home-Based Walking Exercise Intervention on Primary and Secondary Outcomes (N = 200)\textsuperscript{a,b}

<table>
<thead>
<tr>
<th></th>
<th>HBE Baseline (Mean, SD) n = 97</th>
<th>HBE 9-month Follow-up (Mean, SD) n = 97</th>
<th>HBE Change Between Baseline and 9-month Follow-up (Mean, 95% CI) n = 97</th>
<th>UC Baseline (Mean, SD) n = 101</th>
<th>UC 9-month Follow-up (Mean, SD) n = 101</th>
<th>UC Change Between Baseline and 9-month Follow-up (Mean, 95% CI) n = 101</th>
<th>Difference in Change Between HBE and UC at 9-month Follow-up (Mean, 95% CI)</th>
<th>P Value for Difference in Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Six-minute walk distance, m</td>
<td>330.5 (100.2)</td>
<td>333.4 (115.1)</td>
<td>5.5 (–8.7 to 19.7)</td>
<td>336.2 (96.6)</td>
<td>348.2 (98.1)</td>
<td>14.4 (0.5-28.3)</td>
<td>–8.9 (–26.0 to 8.2)</td>
<td>0.31</td>
</tr>
<tr>
<td>WIQ distance score (0-100 scale, 100 = best)\textsuperscript{c}</td>
<td>38.0 (29.4)</td>
<td>52.2 (33.5)</td>
<td>10.6 (3.3-17.9)</td>
<td>37.7 (27.1)</td>
<td>46.1 (30.0)</td>
<td>4.8 (–2.4 to 12.0)</td>
<td>5.8 (–3.0 to 14.7)</td>
<td>0.20</td>
</tr>
<tr>
<td>WIQ speed score (0-100 scale, 100 = best)\textsuperscript{c}</td>
<td>36.7 (19.3)</td>
<td>41.3 (26.4)</td>
<td>4.1 (–1.1 to 9.2)</td>
<td>40.0 (24.4)</td>
<td>43.4 (24.4)</td>
<td>2.9 (–2.3 to 7.9)</td>
<td>1.3 (–5.0 to 7.5)</td>
<td>0.69</td>
</tr>
<tr>
<td>WIQ stair climbing score (0-100 scale, 100 = best)\textsuperscript{c}</td>
<td>49.2 (27.1)</td>
<td>52.2 (32.4)</td>
<td>2.5 (–3.7 to 8.7)</td>
<td>47.4 (27.6)</td>
<td>50.5 (29.4)</td>
<td>2.6 (–3.4 to 8.7)</td>
<td>–0.2 (–7.6 to 7.3)</td>
<td>0.97</td>
</tr>
<tr>
<td>SF-36 physical functioning score (0-100 scale, 100 = best)\textsuperscript{c}</td>
<td>35.8 (9.4)</td>
<td>36.5 (10.8)</td>
<td>0.4 (–1.5 to 2.4)</td>
<td>36.9 (9.0)</td>
<td>39.0 (9.6)</td>
<td>1.8 (0.0-3.7)</td>
<td>–1.4 (–3.7 to 1.0)</td>
<td>0.24</td>
</tr>
<tr>
<td>PROMIS pain interference score\textsuperscript{d}</td>
<td>56.4 (8.4)</td>
<td>56.6 (9.0)</td>
<td>0.70 (–1.1 to 2.6)</td>
<td>56.7 (7.5)</td>
<td>53.4 (8.8)</td>
<td>–2.8 (–4.6 to –1.0)</td>
<td>3.5 (1.3-5.8)</td>
<td>0.002</td>
</tr>
<tr>
<td>PROMIS role satisfaction score\textsuperscript{d}</td>
<td>48.5 (9.9)</td>
<td>48.2 (9.7)</td>
<td>–0.1 (–2.4 to 2.1)</td>
<td>48.8 (10.4)</td>
<td>50.4 (10.3)</td>
<td>1.7 (–0.6 to 4.0)</td>
<td>–1.8 (–4.6 to 1.0)</td>
<td>0.20</td>
</tr>
<tr>
<td></td>
<td>HBE Baseline (Mean, SD) n = 97</td>
<td>HBE 9-month Follow-up (Mean, SD) n = 97</td>
<td>HBE Change Between Baseline and 9-month Follow-up (Mean, 95% CI) n = 97</td>
<td>UC Baseline (Mean, SD) n = 101</td>
<td>UC 9-month Follow-up (Mean, SD) n = 101</td>
<td>UC Change Between Baseline and 9-month Follow-up (Mean, 95% CI) n = 101</td>
<td>Difference in Change Between HBE and UC at 9-month Follow-up (Mean, 95% CI) n = 95</td>
<td>P Value for Difference in Change</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>--------------------------------</td>
<td>-----------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------</td>
<td>----------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>PROMIS mobility score(^d)</td>
<td>33.3 (5.3)</td>
<td>33.0 (6.3)</td>
<td>−0.3 (−1.3 to 0.7)</td>
<td>33.8 (5.3)</td>
<td>33.1 (5.9)</td>
<td>−0.7 (−1.7 to 0.3)</td>
<td>0.4 (−0.8 to 1.7)</td>
<td>0.47</td>
</tr>
<tr>
<td>ActiGraph physical activity data (activity units)(^e)</td>
<td>112 445 (67 129)</td>
<td>111 767 (72 263)</td>
<td>−494 (−13 110 to 12 123)</td>
<td>115 069 (71 988)</td>
<td>112 669 (70 318)</td>
<td>−2,427 (−13 439 to 8 585)</td>
<td>1,934 (−14 872 to 18 740)</td>
<td>0.82</td>
</tr>
</tbody>
</table>

Abbreviations: HBE, home-based exercise; PROMIS, Patient-Reported Outcomes Measurement Information System; SF-36, 36-Item Short Form; UC, usual care; WIQ, Walking Impairment Questionnaire.

\(^d\)This table was adapted from a table in McDermott et al.\(^1\) The within-group difference is adjusted for sites (ie, it is an average of the difference across sites). Therefore, this value may not be the same as the arithmetic difference between average follow-up distance and average baseline distance, which were not adjusted for sites.

\(^e\)Missing data were imputed for each outcome measurement.

\(^f\)The WIQ and SF-36 scores range from 0 to 100, and 100 is the best possible score.

\(^g\)The PROMIS measures are based on item response theory and therefore have no defined minimum or maximum value. The lowest and highest scores observed for PROMIS have been 20 and 80, respectively.

\(^h\)The ActiGraph physical activity data are shown in activity units and should be interpreted as relative comparisons between the intervention and control group only.
Exploratory Analyses

In the intervention group, the 6-minute walk distance changed from 330.0 m (SD 99.8) to 339.0 m (SD 113.7; site-adjusted within-group change: 9.8 m) at 4.5-month follow-up. In the usual care group, the 6-minute walk distance changed from 336.2 m (SD 96.6) to 335.7 m (SD 104.2; site-adjusted within-group change: 0.0 m; 95% CI, –12.6 to 12.7) at 4.5-month follow-up. The site-adjusted between-group difference in the mean change from baseline to follow-up was 9.8 m (95% CI, –6.2 to 25.7; p = 0.231). We observed no statistically significant between-group differences in the mean change from baseline to follow-up between the intervention group and usual care group for any other outcomes at 4.5-month follow-up (Table 5). Table 5 shows the exploratory outcome results for change in study outcomes at 4.5-month follow-up.
Table 5. Change in Study Outcomes at 4.5 Month Follow-up by Group$^{a,b}$

<table>
<thead>
<tr>
<th></th>
<th>HBE Baseline (Mean, SD) $n = 98$</th>
<th>HBE 4.5-month Follow-up (Mean, SD) $n = 98$</th>
<th>HBE Change Between Baseline and 4.5-month Follow-up (Mean, 95% CI) $n = 98$</th>
<th>UC Baseline (Mean, SD) $n = 101$</th>
<th>UC 4.5-month Follow-up (Mean, SD) $n = 101$</th>
<th>UC Change Between Baseline and 4.5-month Follow-up (Mean, 95% CI) $n = 101$</th>
<th>Difference in Change Between HBE and UC at 4.5-month Follow-up (Mean, 95% CI)</th>
<th>$P$ Value for Difference in Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Six-minute walk distance</td>
<td>330 (100)</td>
<td>339 (114)</td>
<td>10 $(-4$ to $23)$</td>
<td>336 (97)</td>
<td>336 (104)</td>
<td>0 $(-13$ to $13)$</td>
<td>10 $(-6$ to $26)$</td>
<td>0.23</td>
</tr>
<tr>
<td>WIQ distance score$^c$</td>
<td>37.7 (29.4)</td>
<td>46.6 (31.0)</td>
<td>6.4 $(0.8-12.1)$</td>
<td>37.7 (27.1)</td>
<td>45.5 (30.4)</td>
<td>5.3 $(-0.1$ to $10.6)$</td>
<td>1.2 $(-5.5$ to $7.8)$</td>
<td>0.73</td>
</tr>
<tr>
<td>WIQ speed score$^c$</td>
<td>36.4 (19.4)</td>
<td>44.0 (26.2)</td>
<td>9.3 $(4.0-14.7)$</td>
<td>40.0 (24.4)</td>
<td>42.4 (25.0)</td>
<td>4.0 $(-1.0$ to $9.1)$</td>
<td>5.3 $(-1.0$ to $11.6)$</td>
<td>0.10</td>
</tr>
<tr>
<td>WIQ stair climbing score$^c$</td>
<td>49.0 (27.0)</td>
<td>56.3 (30.6)</td>
<td>8.5 $(2.7-14.3)$</td>
<td>47.4 (27.6)</td>
<td>51.9 (26.8)</td>
<td>5.7 $(0.1-11.3)$</td>
<td>2.8 $(-4.2$ to $9.7)$</td>
<td>0.43</td>
</tr>
<tr>
<td>SF-36 physical functioning score$^c$</td>
<td>35.7 (9.4)</td>
<td>36.7 (11.6)</td>
<td>0.4 $(-1.7$ to $2.6)$</td>
<td>36.9 (9.0)</td>
<td>38.3 (9.8)</td>
<td>0.9 $(-1.1$ to $2.9)$</td>
<td>$-0.4$ $(-3.0$ to $2.1)$</td>
<td>0.73</td>
</tr>
<tr>
<td>PROMIS mobility score$^d$</td>
<td>33.3 (5.3)</td>
<td>32.4 (5.6)</td>
<td>$-0.7$ $(-1.5$ to $0)$</td>
<td>33.8 (5.3)</td>
<td>33.2 (5.7)</td>
<td>$-0.4$ $(-1.1$ to $+0.4)$</td>
<td>$-0.3$ $(-1.3$ to $0.6)$</td>
<td>0.47</td>
</tr>
<tr>
<td>PROMIS pain interference score$^d$</td>
<td>56.5 (8.4)</td>
<td>54.5 (9.4)</td>
<td>$-2.1$ $(-3.8$ to $-0.4)$</td>
<td>56.7 (7.5)</td>
<td>54.5 (8.7)</td>
<td>$-2.3$ $(-3.8$ to $-0.7)$</td>
<td>0.2 $(-1.8$ to $2.2)$</td>
<td>0.84</td>
</tr>
<tr>
<td></td>
<td>HBE Baseline (Mean, SD) n = 98</td>
<td>HBE 4.5-month Follow-up (Mean, SD) n = 98</td>
<td>HBE Change Between Baseline and 4.5-month Follow-up (Mean, 95% CI) n = 98</td>
<td>UC Baseline (Mean, SD) n = 101</td>
<td>UC 4.5-month Follow-up (Mean, SD) n = 101</td>
<td>UC Change Between Baseline and 4.5-month Follow-up (Mean, 95% CI) n = 101</td>
<td>Difference in Change Between HBE and UC at 4.5-month Follow-up (Mean, 95% CI)</td>
<td>P Value for Difference in Change</td>
</tr>
<tr>
<td>-------------------------</td>
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<td>------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>ActiGraph activity count per day</td>
<td>n = 92</td>
<td>n = 92</td>
<td>n = 92</td>
<td>n = 95</td>
<td>n = 95</td>
<td>n = 95</td>
<td>−14 670 (−57 273 to 27 933)</td>
<td>0.50</td>
</tr>
<tr>
<td></td>
<td>111 940 (66 937)</td>
<td>129 933 (91 290)</td>
<td>11 310 (−23 193 to 45 813)</td>
<td>115 069 (71 988)</td>
<td>147 904 (188 997)</td>
<td>25 980 (−8761 to 60 720)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: HBE, home-based exercise; PROMIS, Patient-Reported Outcomes Measurement Information System; SF-36, 36-Item Short Form; UC, usual care; WIQ, Walking Impairment Questionnaire.

* This table was adapted from a table in McDermott et al.1 Within-group and between-group differences adjust for study site. Therefore, results may not be simply sums of differences.

* Missing data were imputed for each outcome measurement.

* The WIQ and SF-36 physical functioning score are measured on 0-to-100 scales, where 100 = best.

* The PROMIS measures are based on item response theory and therefore have no defined minimum or maximum value. The lowest and highest scores observed for PROMIS have been 20 and 80, respectively.
Among the 97 participants randomly assigned to the intervention who did not die during the study, we observed no difference in change in 6-minute walk distance among those who dropped out of the study intervention (n = 9) vs those who did not drop out (n = 88). From 332 to 337 m among those who did not drop out of the study intervention (within-group change: 8.5 m [95% CI, –8.6 to 25.7]) from 318 to 302 m among those who dropped out of the study intervention (within-group change: –12.4 m [95% CI, –71.7 to 46.9]) The difference in change between the 2 groups was 21 m (95% CI, –38.5 to 80.4; p = 0.49). In prespecified exploratory analyses, among participants randomly assigned to the intervention, those who viewed their data more often on the study website achieved significantly greater improvement in 6-minute walk distance at 9-month follow-up compared with those who viewed their data less frequently (see Table 6).

In prespecified exploratory analyses, among participants randomly assigned to the intervention, we observed no difference in change in 6-minute walk distance at 9-month follow-up according to whether participants engaged in a group call or website activity. For participants who did not engage in a group call or group website interaction (n = 8), site-adjusted within-group change was –2.6 m (95% CI, –64 to 56). For participants who engaged in a group call or group website (n = 89), site-adjusted within-group change was 7.4 m (95% CI, –9.9 to 25). The difference is 10.0 m (95% CI, –52 to 72; p = 0.92).
Table 6. Change in 6-Minute Walk Distance According to Frequency of Website Visits and Frequency of Wearing FitBit\textsuperscript{a}

<table>
<thead>
<tr>
<th></th>
<th>Tertile 1  \ n = 29</th>
<th>Tertile 2  \ n = 29</th>
<th>Tertile 3  \ n = 30</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Frequency of visiting study website</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in 6-min walk distance at 9-mo follow-up, m</td>
<td>−11 (95% CI, −39 to 17)</td>
<td>6.0 (95% CI, −18 to 51)</td>
<td>23 (95% CI, 0.80-67)</td>
<td>0.017</td>
</tr>
<tr>
<td><strong>Frequency of wearing FitBit</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in 6-min walk distance at 9-mo follow-up, m</td>
<td>14 (95% CI, −10 to 39)</td>
<td>2.0 (95% CI, −23 to 7)</td>
<td>9.0 (95% CI, −17 to 34)</td>
<td>0.750</td>
</tr>
<tr>
<td><strong>Total steps recorded by FitBit</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in 6-min walk distance at 9-mo follow-up, m</td>
<td>−8.1 (95% CI, −31.9 to 15.8)</td>
<td>16.5 (95% CI, −9.7 to 42.7)</td>
<td>18.6 (95% CI, −4.6 to 41.9)</td>
<td>0.0921</td>
</tr>
<tr>
<td><strong>Average steps per day recorded by FitBit</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in 6-min walk distance at 9-mo follow-up, m</td>
<td>−4.8 (95% CI, −28.8 to 19.3)</td>
<td>10.5 (95% CI, −15.7 to 36.8)</td>
<td>19.6 (95% CI, −3.9 to 43.0)</td>
<td>0.126</td>
</tr>
</tbody>
</table>

\textsuperscript{a}The sample size was the same for all outcomes.
Post Hoc Exploratory Analyses

In post hoc exploratory analyses, we observed no statistically significant interactions for response to the intervention, indicating that no subgroups of people with PAD (characterized by older age, female sex, white race, greater PAD severity, or other characteristics) responded significantly better to the intervention than did individuals without that characteristic. $P$ values for interaction terms for each subgroup analyzed are shown in Figure 3.

In post hoc exploratory analyses, of the 106 participants who either reported the onset of leg symptoms during the SMWT or did not develop leg symptoms during it, those randomly assigned to the intervention had a 17.7-m (95% CI, −20.2 to 55.6) improvement in pain-free walking distance during the SMWT, relative to the usual care group ($p = 0.356$).

Of the 200 participants randomly assigned, 31 had participated in a previous trial with the principal investigator. We detected no statistically significant interactions between having participated previously in a randomized trial with the principal investigator and displaying a response to the intervention. When these 31 participants were excluded from the primary analyses, the change in 6-minute walk distance between the intervention and usual care groups was −2.8 m (95% CI, −23.5 to 17.9; $p = 0.505$). Thus, results did not change when the participants who had been part of a previous trial were excluded from analyses.

In post hoc exploratory analyses, we observed no differences in changes in sedentary-light, light-moderate, moderate-vigorous, or vigorous activity between the 2 groups (data not shown).
Figure 3. Change in response to the home-based walking exercise intervention by participant characteristics

Abbreviations: LCL, lower confidence limit; UCL, upper confidence limit.

*This figure was adapted from a previously published figure. General linear models were run for 80 imputed data sets, separately. The MI analyze procedure in SAS was used to combine results from the 80 models. Data were not imputed for 2 participants who died during follow-up testing.
In post hoc exploratory analyses, participants randomly assigned to the intervention reported greater increases in walking exercise frequency at 3-month follow-up and at 6-month follow-up compared with usual care (see Table 7). However, we observed no statistically significant difference in reported walking exercise frequency at 9-month follow-up (Table 7). We observed no changes in number of minutes walked for exercise between the 2 groups at any time point (Table 7).
### Table 7. Changes in Participant-Reported Walking Exercise Frequency

<table>
<thead>
<tr>
<th>Walking exercise frequency, n</th>
<th>HBE Baseline (Mean, SD)</th>
<th>HBE Follow-up (Mean, SD)</th>
<th>HBE Change Between Baseline and Follow-up (Mean, SD of Change)</th>
<th>UC Baseline (Mean, SD)</th>
<th>UC Follow-up (Mean, SD)</th>
<th>UC Change Between Baseline and Follow-up (Mean, SD of Change)</th>
<th>Difference in Change Between HBE and UC (Mean, 95% CI)</th>
<th>P Value for Difference in Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-mo follow-up, per week</td>
<td>1.7 (2.9)</td>
<td>3.7 (2.5)</td>
<td>2.0 (3.7)</td>
<td>1.5 (2.1)</td>
<td>2.2 (3.0)</td>
<td>0.7 (2.5)</td>
<td>1.3 (0.4-2.3)</td>
<td>0.005</td>
</tr>
<tr>
<td>6-mo follow-up, per week</td>
<td>1.7 (2.9)</td>
<td>4.3 (6.8)</td>
<td>2.8 (7.3)</td>
<td>1.5 (2.1)</td>
<td>2.4 (3.5)</td>
<td>0.9 (3.3)</td>
<td>1.9 (0-3.8)</td>
<td>0.05</td>
</tr>
<tr>
<td>9-mo follow-up, per week</td>
<td>1.7 (2.9)</td>
<td>3.5 (4.2)</td>
<td>1.9 (5.0)</td>
<td>1.5 (2.1)</td>
<td>2.3 (2.9)</td>
<td>0.8 (2.9)</td>
<td>1.1 (−0.2 to 2.4)</td>
<td>0.09</td>
</tr>
<tr>
<td>Minutes walked for exercise per week</td>
<td>70 (81.2)</td>
<td>70 (82.0)</td>
<td>70 (81.2)</td>
<td>81 (81.2)</td>
<td>81 (81.2)</td>
<td>81 (81.2)</td>
<td>23.3 (−9.9 to 56.4)</td>
<td>0.17</td>
</tr>
<tr>
<td>3-mo follow-up</td>
<td>40.6 (65.6)</td>
<td>41.1 (109.4)</td>
<td>58.5 (100.8)</td>
<td>40.6 (65.6)</td>
<td>61.6 (86.8)</td>
<td>21.0 (80.3)</td>
<td>58.0 (−227.2 to 111.2)</td>
<td>0.50</td>
</tr>
<tr>
<td>6-mo follow-up</td>
<td>40.6 (65.6)</td>
<td>47.3 (103.7)</td>
<td>61.6 (86.8)</td>
<td>40.6 (65.6)</td>
<td>40.6 (65.6)</td>
<td>148.5 (724)</td>
<td>107.8 (708.4)</td>
<td>0.081</td>
</tr>
<tr>
<td>9-mo follow-up</td>
<td>40.6 (65.6)</td>
<td>59.8 (111.7)</td>
<td>40.6 (724)</td>
<td>40.6 (65.6)</td>
<td>107.8 (708.4)</td>
<td>−58.0 (−227.2 to 111.2)</td>
<td>107.8 (−227.2 to 111.2)</td>
<td>0.50</td>
</tr>
</tbody>
</table>

*This table was adapted from a table in McDermott et al. One participant had extreme outlier values; when this participant was excluded from analyses, results did not substantially change.
Serious Adverse Events

Fifty-five serious adverse events (SAEs) occurred in 23 participants randomly assigned to the intervention and 23 occurred in 15 participants randomly assigned to usual care ($p = 0.091$ for comparison of mean number of SAEs per participant between groups; Table 8a). All SAEs represent either hospitalizations or deaths; therefore, there were a total of 55 hospitalizations or deaths. Table 8a shows the reason for the SAEs by number. Table 8b shows the reason for SAEs by number of participants who experienced each SAE.

Table 8a. Number of Serious Adverse Events

<table>
<thead>
<tr>
<th>Category of SAE</th>
<th>Trial Assignment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Home-Based Exercise</td>
</tr>
<tr>
<td>Cancer</td>
<td>1</td>
</tr>
<tr>
<td>Cardiovascular event</td>
<td>13</td>
</tr>
<tr>
<td>Chest pain</td>
<td>4</td>
</tr>
<tr>
<td>Death</td>
<td>2</td>
</tr>
<tr>
<td>Elective surgery</td>
<td>2</td>
</tr>
<tr>
<td>Fall</td>
<td>1</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>4</td>
</tr>
<tr>
<td>Infection</td>
<td>4</td>
</tr>
<tr>
<td>Lower extremity PAD event</td>
<td>6</td>
</tr>
<tr>
<td>Neurologic</td>
<td>3</td>
</tr>
<tr>
<td>Pulmonary event</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>13</td>
</tr>
<tr>
<td>Total</td>
<td><strong>55</strong></td>
</tr>
</tbody>
</table>

Abbreviation: PAD, peripheral artery disease; SAE, serious adverse event.
Table 8b. Number of People Experiencing Each Serious Adverse Event

<table>
<thead>
<tr>
<th>Category of SAE</th>
<th>Trial Assignment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Home-Based Exercise</td>
<td>Usual Care</td>
</tr>
<tr>
<td>Cancer</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Cardiovascular event</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Chest pain</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Death</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Elective surgery</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Fall</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Infection</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Lower extremity PAD event</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Neurologic</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Pulmonary event</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td><strong>No. of patients experienced any SAE</strong></td>
<td><strong>23</strong></td>
<td><strong>15</strong></td>
</tr>
</tbody>
</table>

Abbreviation: PAD, peripheral artery disease; SAE, serious adverse event.

*aThis table was adapted from a table in McDermott et al.1

bNumbers in this row are not the summations of the numbers in the categories, because people could have SAEs in different categories.

Two deaths occurred, both in the intervention group: one due to critical limb ischemia and sepsis and one due to metastatic cancer. Neither was considered related to study participation. Adverse symptoms experienced during the trial are shown in Table 9. Participants were asked about these symptoms once a month through questionnaire administration.
### Table 9. Adverse Symptoms by Group

<table>
<thead>
<tr>
<th>Adverse Symptom</th>
<th>Home-Based Exercise n = 95, n (%)</th>
<th>Usual Care n = 101, n (%)</th>
<th>Total N = 196, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest discomfort during activity or exercise</td>
<td>16 (16.8)</td>
<td>27 (26.7)</td>
<td>43 (21.9)</td>
</tr>
<tr>
<td>Dizziness or generalized weakness during activity or exercise</td>
<td>39 (41.1)</td>
<td>39 (38.6)</td>
<td>78 (39.8)</td>
</tr>
<tr>
<td>Experienced more difficulty than usual during exercise</td>
<td>43 (45.3)</td>
<td>51 (50.5)</td>
<td>94 (48.0)</td>
</tr>
<tr>
<td>Shortness of breath during activity or exercise</td>
<td>45 (47.4)</td>
<td>48 (47.5)</td>
<td>93 (47.4)</td>
</tr>
<tr>
<td>No. of participants reporting any of above events</td>
<td>69 (72.6)</td>
<td>74 (73.3)</td>
<td>143 (73.0)</td>
</tr>
</tbody>
</table>

*Data represent the number of people reporting each adverse symptom. Rates are different from those in Tables 8a and 8b because those tables report reasons for hospitalization. Participants were asked about the presence of adverse symptoms during monthly telephone calls.*
DISCUSSION

In people with PAD, a home-based exercise intervention of telephone coaching combined with a wearable activity monitor did not improve 6-minute walk distance at 9-month follow-up compared with usual care. The usual care group reported greater improvement in pain interference with daily activities compared with the intervention group at 9-month follow-up. We observed no significant differences in other secondary outcomes, including the PROMIS mobility score, PROMIS satisfaction with social roles and activities, WIQ scores, quality of life, or ActiGraph-measured physical activity.

Potential Explanations for Lack of Efficacy of the Intervention

Several potential explanations exist for the lack of intervention benefit in this trial. First, for behavioral interventions, remote coaching is less potent than in-person visits.43 Second, because of feedback from patients with PAD, this trial used a wearable activity monitor; however, the wearable monitor measured activity continuously throughout the day, whereas the intervention was designed to increase discrete episodes of walking exercise each day. This mismatch between the wearable device measurement and the exercise recommendations might have encouraged participants to increase overall activity level, which has not been shown to improve walking endurance in people with PAD, rather than increase walking exercise specifically, which has been shown to improve walking endurance in people with PAD. Third, monthly telephone counseling calls during the final 4.5 months of the intervention might have been too infrequent. Fourth, individuals with PAD who are interested in home-based exercise that does not require ongoing medical center visits may be less committed than individuals who agree to take part in supervised exercise.

Additional characteristics of this trial should be noted. First, improvement in pain interference in the usual care group may reflect that attempts to exercise in the intervention group resulted in greater ischemic leg symptoms. Observational studies have suggested that some patients with PAD limit their activity to avoid ischemic leg symptoms, which may reduce pain interference with daily activities.6,45 Second, consistent with prior observational studies
and randomized trials, most participants with PAD in this trial did not have classical claudication symptoms. In this trial, results did not differ according to the presence or absence of intermittent claudication symptoms. Third, the higher rate of hospitalizations in the intervention group was not statistically significant, but it does suggest the possibility that an exercise program in people with PAD may increase health care sought for symptoms related to exercise such as chest discomfort, shortness of breath, or other discomfort. Greater interaction with the health care system may result in increased hospitalization rates; further study is needed. Fourth, the FitBit did not record minutes engaged in exercise, which would have provided more information to the coach about the participant’s behavior. This might have increased participant accountability to the coach, thereby increasing the potency of the intervention.

**Interpretation of Results Relative to Those of Prior Studies**

Results reported here should not be construed as evidence that home-based walking exercise is not effective for people with PAD. In randomized clinical trials, behavioral interventions of home-based exercise interventions that included periodic visits to the medical center achieved large meaningful improvements in the 6-minute walk distance in people with PAD.16-18

The primary difference between these previous randomized trials and the HONOR trial is that previous trials required ongoing regular visits to the medical center throughout the trial (ranging in frequency from once per week to once per month). In contrast, in this trial no visits to the medical center occurred after the first month of the intervention. Contact after the first month of the intervention consisted of telephone calls with the coach. Another difference between previous trials and the HONOR trial is that previous trials compared the intervention against an attention control group, which received either stretching exercises or group education classes.16-18 In contrast, the HONOR trial compared the intervention with usual care. It is possible that participants randomly assigned to usual care in the HONOR trial decided to
conduct some walking exercise activity on their own, because they realized that they were not receiving any intervention from a study of home-based walking exercise.

Results in Table 7 support the hypothesis that those randomly assigned to usual care increased their walking exercise frequency and the total number of minutes walked for exercise, compared with baseline. However, because investigators did not objectively measure walking exercise activity in the usual care group, this statement is speculative. Characteristics of people in the previous home-based walking exercise trials in patients with PAD were reasonably similar to those of participants in the current trial regarding age, sex, race, prevalence of diabetes mellitus, BMI, and PAD severity. Therefore, our finding that our intervention did not increase home-based walking exercise activity is more likely related to the nature of the intervention than to the characteristics of the study participants.

**Generalizability of the Findings**

Based on the recruitment methods used, results are likely generalizable to people whose walking ability is limited by PAD and who are interested in participating in a walking exercise program that can be completed at home. Methods of recruitment were specifically intended to identify people with PAD who were interested in improving their walking ability with a home-based exercise intervention. During recruitment and again before randomization, we specifically asked participants whether they were willing to attend study visits and walk for exercise 3 to 5 days per week for the 9-month study duration. Potential participants not willing to commit to the study requirements, including regular walking exercise, were excluded prior to randomization. Participants in the HONOR trial were comparable with those in a previous home-based walking exercise trial in PAD participants in terms of disease severity, age, leg symptoms, proportion of women and minorities, and comorbidity prevalence. Because participants with atypical exertional leg symptoms as well as those who reported no exertional leg symptoms participated in this trial, results are generalizable to PAD participants who do not have classical symptoms of intermittent claudication.
Implementation of Study Results

Because results of the HONOR trial were negative (ie, the intervention did not significantly improve primary or secondary outcomes), this particular intervention is not recommended for adoption in typical care settings; however, results will inform future home-based walking exercise trials (see Future Research).

Subpopulation Considerations

No subgroups of people with PAD, defined by age, sex, race, PAD severity, BMI, and other comorbidities, responded to the home-based walking exercise intervention. Lack of greater or lesser responsiveness to an exercise intervention among patients with specific characteristics is consistent with prior successful randomized trials of exercise in people with PAD; however, it is also true that the study did not have statistical power to definitively evaluate the effect of the intervention in each individual subgroup. The trial lacked the statistical power to determine the intervention’s effectiveness in individual subgroups of patients with PAD.

Limitations

This study has limitations. First, we did not collect data on location of PAD (aorto-iliac vs superficial femoral). Second, there were multiple secondary outcome measures and no adjustment for multiple comparisons. Third, participants in the intervention adhered to 79% of scheduled intervention calls, which might have been insufficient to achieve the intervention’s goals. Fourth, telephone calls to measure walking exercise behavior in the usual care group every 3 months might have been insufficient to measure uptake of exercise activity. Fifth, the study did not include a run-in, which might have resulted in inclusion of participants who were not fully committed to the requirements of the intervention. Sixth, we did not collect or record quantitative data during aim 1; rather, results were obtained from participant feedback and a summary was recorded in writing. Seventh, it is possible that participants anticipated the regular telephone calls from the study coach (in the intervention group) or from study staff (in the intervention and usual care groups) and increased their walking exercise activity during the
weeks leading up to the anticipated calls. Eighth, the multiple imputation method assumed that missing data were missing at random; it is possible that missing data were not missing at random.

An additional finding was the large standard deviation of the SMWT in the population. The sample size calculation assumed a standard deviation of 51 to 69 m for the 9-month change in 6-minute walk distance. The observed standard deviation was 71 m. The following considerations regarding this large standard deviation should be noted: First, the large standard deviation in the population suggests that, to detect a statistically significant but small difference, the sample size needed to be larger. Second, the main conclusion of the study is the point estimate of the between-group difference in the mean change, –8.9 m (95% CI, –26 to 8.2). Our results show that there was not a statistically significant difference based on the preset criterion for statistical significance. Our results also show that we have confidence that the true difference, if it is nonzero, is still between –26 and 8.2 m. In summary, any true benefit is likely below 8.2 m. If there is a true benefit, it is not likely to represent a clinically meaningful difference.

Future Research

Future research is needed to identify an effective and durable home-based exercise intervention that minimizes visits to the medical center but effectively increases walking endurance in people with PAD. Based on previous research and the HONOR trial results, future studies of home-based walking exercise in this population should include more contact with PAD participants and should consider requiring occasional return visits to the medical center to reinforce the intervention.
CONCLUSIONS

This randomized clinical trial of 200 participants with PAD was designed to determine whether a PAD patient-centered home-based exercise program improves walking ability, physical function, pain, and social functioning, compared with usual care. Patients with PAD contributed to the overall design of the study, including characteristics of the intervention, which relied on telephone coaching and a wearable activity monitor; however, the intervention did not improve walking performance at 9-month follow-up in people with PAD. These results do not support home-based exercise interventions without ongoing periodic on-site visits to improve walking performance in people with PAD.
REFERENCES


ACKNOWLEDGMENTS

We thank the patient members of our advisory committee for their contributions to the HONOR study: John Sullivan; Barbara Sullivan; Eugene Pergament, MD, PhD; Lynn Crawford; Iter Vartan; and Roberta Ashley.
# Appendix Table of Contents

## The HONOR Study

**PCORI Award Number:** CER-1306-02719

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<tr>
<td>Usual Care Manual</td>
<td>9</td>
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<td>10</td>
</tr>
<tr>
<td>Session 2</td>
<td>14</td>
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<tr>
<td>Session 3</td>
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<td>Session 4</td>
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<tr>
<td>HONOR Phone Coaching Checklist</td>
<td>36</td>
</tr>
<tr>
<td>HONOR Study Website</td>
<td>38</td>
</tr>
</tbody>
</table>
1. Overview of proposed home-based walking exercise intervention

The intervention focuses on home-based walking exercise and consists of two phases. Phase I (weeks 1-4) involves four on-site weekly visits to an exercise facility, where participants will meet their coach and a small group of participants to learn how to use the Fitbit activity monitor, to discuss and practice behavioral skills necessary for long-term adherence to home-based exercise, to develop a sense of social provisions, and to get started on their home exercise program. Phase II (weeks 5-36) is entirely home-based and includes a) use of the Fitbit for self-monitoring and access to the HONOR website, b) regularly scheduled telephone calls from the study telephone coach to monitor and support participants’ home exercise activity, and c) the participants involvement in remote activities with other participants via telephone and electronic communication.

2. Phase I of the intervention (weeks 1-4; detailed manuals for sessions 1-4 are provided separately).

Our home-based exercise intervention begins with four on-site visits, one per week, to an exercise facility. The first 2 visits occur individually with the coach and the remaining 2 visits take place in a small group format. During these weekly on-site visits, the coach will teach PAD patients to use the Fitbit to self-monitor their exercise activity. The coach will help PAD patients learn and practice behavioral skills including goal-setting, self-monitoring, and managing exertional leg pain during walking exercise. PAD participants will engage in some walking exercise activity at the weekly center visits in Phase I. This will enable them to have guided experience with the goals and challenges posed by walking with the onset of ischemic leg pain. Walking exercise will be individualized according to the participant’s ability. In general, participants will be asked to begin walking five days weekly for 15 minutes each day. Participants will be asked to increase their walking time (i.e. time spend engaged in walking exercise) by approximately 5 minutes each week until the participant achieves 50 minutes of walking per exercise session, five days weekly. Following the walking activity, small group meetings will be held to discuss specific topics and engage in group in social problem solving. A collaborative relationship will be encouraged between each patient, the coach, and their group. The coach will begin contacting patients weekly by telephone during Phase I (in addition to the
weekly on-site visits) and will remain in contact with them via regularly scheduled telephone calls during Phase II (see below). PAD participants will be scheduled in groups of about 3-8 participants for the weekly on-site sessions in Phase I. This provides patients an opportunity to meet and bond with others who have PAD.

As detailed in the weeks 1-4 manuals, participants will be asked to use the website in weeks 1-4.

3. Phase II of the intervention (weeks 5-36).

After Phase I, participants will transition to Phase II of the intervention. Phase II does not involve on-site visits to the exercise center or face-to-face contact with their group. PAD participants will continue using the Fitbit to track their home-based exercise, and they will communicate with the coach by both telephone and electronic communication. Between weeks 5-9, the coach will call PAD participants once per week. Between weeks 10-17, the study coach will call PAD participants every other week. Between weeks 18-36, the study coach will call PAD participants once per month. However, the coaches will check the website bi-weekly to ensure exercise adherence. If participants’ exercise activity drops below 10% for 2 consecutive weeks of what they have been doing for the past 2-months (excluding illness and travel), the coach will make additional contact via website and telephone, so that the coach can offer additional help and ensure adherence to the home-based exercise program. Thus, remote coaching via regular telephone calls will be individualized. PAD patients will continue to use the Fitbit throughout Phase II. Output from the Fitbit monitor will be visible to both the coach and the patient throughout Phase II on the participant’s computer or tablet. If participants do not own a computer or tablet, they will be loaned a tablet for the duration of the study so that they can track their progress based on the Fitbit recorded data.

Participants will remain in contact with their group by telephone and by way of the study website. The website will be constructed to be interactive, allowing postings from individual study participants.

4. Our home-based exercise intervention focuses on walking.

Our exercise intervention focuses on walking exercise for several reasons. First, our focus groups of PAD patients informed us that walking exercise is preferred by most people with PAD. PAD patients consistently told us that walking exercise is easily accessible because they can walk outdoors, in the hall corridors of their apartment buildings, or even around perimeter of their home basement. Second, PAD patients told us that walking exercise allows them to specifically focus on improving their walking. PAD patients believe that walking exercise will specifically help them overcome their walking difficulty. Third, supervised walking exercise is known to improve walking performance in PAD patients and is the only form of exercise currently recommended by practice guidelines for patients with PAD (1-6). Table 1 summarizes feedback from PAD patients and healthcare providers that justifies our plan to have our exercise intervention focused on walking.
Table 1. Feedback from PAD patients and healthcare providers about walking exercise.

<table>
<thead>
<tr>
<th>Summary of key messages about walking exercise from PAD patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Walking exercise allows patients with PAD to practice and improve upon their walking difficulties</td>
</tr>
<tr>
<td>• Walking exercise is accessible: patients can walk outside their home and start walking.</td>
</tr>
<tr>
<td>• PAD patients know that walking is good for them.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Summary of key messages about walking exercise from healthcare providers.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Healthcare providers are aware of practice guidelines recommending walking exercise for PAD patients.</td>
</tr>
<tr>
<td>• Healthcare providers, based on available evidence, believe that walking exercise is the best type of exercise for PAD patients, but want help getting PAD patients to exercise.</td>
</tr>
</tbody>
</table>

5. Using the Fitbit to motivate PAD patients to adhere to home-based exercise

Our preliminary data show that PAD patients find the Fitbit highly motivating. A figure of the Fitbit and the uploaded data from the Fitbit are shown in Figures 1a and 1b, respectively. The Bluetooth mechanism automatically uploads Fitbit data on a home computer or tablet when the participant walks within 10 feet of the device. Each individual’s activity data are visible on-line to both the PAD participant and the coach. In addition, patients are provided with summary updates on their overall group performance and on the progress of study in general. The study coach will view each participant’s exercise data once weekly. During the regularly scheduled telephone calls with study participants, the coach will use the uploaded Fitbit data to provide feedback and reinforcement to each participant. If participants do not have access to a Fitbit compatible mobile device, computer, or internet they will be provided with them for the duration of the study. All borrowed devices will be returned at the end of the study.

**Figure 1a. Fitbit (zip model) shown next to quarter**

**Figure 1b. Uploaded Fitbit data from PAD participant**

*Figure 1 Legend.* Figure 1a shows the Fitbit (zip model) adjacent to a quarter. Figure 1b shows uploaded data from a PAD participant in our pilot study. As shown in Figure 1b, the y axis shows number of steps and the x-axis shows time. As shown in Figure 1b, this PAD participant was extremely inactive when he was not exercising.

6. Telephone calls from the coach.

Each contact by the coach with each participant in the intervention will have a structured format. Adherence to this format (treatment fidelity) will be monitored by the coach using a check-list, completed at the end of each weekly participant contact. In addition, for quality control purposes, each telephone coaching session will be audiotaped and a randomly selected ten
percent subset will be reviewed by an independent rater. The components of each session are as follows:

a) *Greet participant- small talk.* The coach will open the call by checking in with the participant and see how they are generally doing and whether there are any major changes in their lives that are affecting them positively or negatively.

b) *Checking in:* Review use of the fitbit and exercise. This information will include the total number of exercise sessions and the time spent engaged in exercise per session. This will be reviewed in the context of the walking exercise goals established during the prior contact with the coach. The coach will review whether the participant met their exercise goals. The coach will discuss with the participant any barriers encountered to walking exercise activity and strategies to overcome them. Potential barriers we may encounter, based on our experience, include leg pain and discomfort during exercise, adverse weather affecting the ability to walk outdoors, and inter-current illness that interferes with exercise behavior. The coach will also ask about successes. When appropriate, suggestions posted by others will be raised. The coach will ask participants, as appropriate, whether concepts/ideas from individual participants might be posted on the study website.

c) *Discuss use of website.* The coach will discuss the use of the website with the participant including logging exercise and posting to the message board. The coach will discuss with the participant any difficulty using the website. The coach will check to ensure the participant is using the website to track their progress.

d) *Setting goals:* The coach will help the participant set walking goals for the coming week(s). These goals will be entered into the website by the coach and will serve as a reference for the next telephone coaching call.

e) *Wrap-up/conclusion- mindful reflection and wrap-up/conclusion with focus on successes and challenges.* The coach will use this time to set up a future coaching call. If applicable, the coach will discuss a relevant group call to discuss a specific topic this participant is dealing with.

7. **Coach training and certification.**

Prior to beginning the intervention, the coach will receive training by co-investigators and behavioral experts, Drs. Rejeski and Spring. The study coach will be an exercise physiologist or a health interviewer who completes training with investigators Drs. Rejeski and Spring. The study coach will read the study intervention manuals prior to training. Training will be on-site and include an overview of the conceptual background for the intervention, information about PAD-related ischemic leg pain, optimal exercise programs for PAD, and basic tenets of social cognitive theory and methods demonstrated to successfully achieve behavior change. The coach will role-play telephone counseling sessions, receiving immediate feedback. Management of “difficult” participants and challenging scenarios will be reviewed. After completing training, the interventionist will perform telephone counseling calls with three mock participants. A certification checklist will be used to ensure that the interventionist adheres to the study protocol (see Table 2).
8. Monitoring the coach’s fidelity to the study intervention.

The coach will use a checklist (shown in Table 2) to guide each telephone coaching call. All telephone contacts with participants will be audiotaped. A ten percent subsample will be reviewed each quarter by study investigators (Drs. McDermott/Spring/Rejeski) to ensure fidelity to the intervention. Feedback will be provided to the coach. When the coach deviates from the protocol, the coach will be re-trained and certified.

Table 2. Study Checklist Components for Monitoring Fidelity to the Study Intervention.

<table>
<thead>
<tr>
<th>Component</th>
<th>Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Checking in- adherence to entering exercise activity.</td>
<td>X</td>
</tr>
<tr>
<td>2) Adherence to exercise goals.</td>
<td>X</td>
</tr>
<tr>
<td>3) Discuss use of website.</td>
<td>X</td>
</tr>
<tr>
<td>4) Discuss group call participation.</td>
<td>X</td>
</tr>
<tr>
<td>5) Discuss challenges encountered with solutions to overcome them.</td>
<td>X</td>
</tr>
<tr>
<td>6) Discussion of My Action Plan (MAP).</td>
<td>X</td>
</tr>
<tr>
<td>7) Wrap-up, conclusion.</td>
<td>X</td>
</tr>
</tbody>
</table>

9. Weekly group telephone calls with other PAD patients.

Some PAD patients have told us that interactions with other PAD patients are supportive and motivating. Therefore, we will hold telephone conference calls, led by the study coach, during which PAD patients will have opportunity to interact with other PAD participants via the group telephone call. All participants randomized to the intervention will be provided with a dial-in number that they can dial into if they choose. There will be one topic/group call per month that participants can choose to dial into. Each topic will be offered at least two times per month to help ensure that participants are available to participate. The coach will present a topic of interest related to PAD and/or exercise during each group telephone calls. Topics will include walking in extreme weather conditions, novel patient-centered methods to manage walking related leg pain, goal-setting, self-monitoring, and other topics that are likely to help PAD participants adhere to their home-based walking exercise program. In addition, there will be page on the study website that will be used to allow participants to post useful strategies and accomplishments related to home exercise adherence. Both the telephone calls and the on-line system will provide PAD participants with the opportunity to share successes and challenges regarding exercise.

10. Intervention summary.

Table 3 provides a summary of the components of the HONOR intervention.
<table>
<thead>
<tr>
<th>Intervention components</th>
<th>Phase I (weekly on-site visits, weeks 1-4)</th>
<th>Phase II (entirely home-based, weeks 5-36)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coaching</td>
<td>Participants will meet and bond with the coach during weekly on-site meetings.</td>
<td>Participants will communicate with the coach remotely via telephone and website.</td>
</tr>
<tr>
<td>Fitbit self-monitoring</td>
<td>Participants will learn to use the Fitbit to track their exercise and use of the m-Health app. They will learn to upload the data for online viewing.</td>
<td>Participants will use the Fitbit for self-monitoring of their exercise activity.</td>
</tr>
<tr>
<td>Goal setting</td>
<td>Participants will be taught to record walking exercise goals, reviewing them in person with the coach each week.</td>
<td>Coaches and participants will discuss walking exercise goals during each telephone call. The goals will be entered by the study coach on the website during the telephone call.</td>
</tr>
<tr>
<td>Group support from other PAD patients</td>
<td>PAD participants will have opportunity to meet and bond with other PAD participants.</td>
<td>We will hold optional weekly group telephone calls and provide an on-line system to post strategies/accomplishments. The telephone calls will be co-led by the coach and a participant.</td>
</tr>
<tr>
<td>Website</td>
<td>PAD participants will be asked to enter their exercise data and post comments.</td>
<td>PAD participants will be asked to enter their exercise data and post comments.</td>
</tr>
</tbody>
</table>

Each intervention component in Table 3 was selected because of feedback we received from PAD patients. a) Coaching. PAD participants have indicated that they need a coach to be accountable to. They need to know that someone is checking on them b) Fitbit self-monitoring. In our pilot testing, PAD patients were overwhelmingly enthusiastic about the Fitbit as a motivational tool to promote home-based exercise; c) Goal-setting. It is well-documented that goal setting helps people achieve behavior change (8-10). In addition, PAD patients tell us that they needed accountability to adhere to regular exercise. Goal setting combined with coaching will help ensure that patients achieve this accountability; d) Group support. Some PAD patients tell us that they find interactions and support from other PAD patients motivating. Therefore, PAD patients will have opportunity to meet and bond with other PAD patients during the on-site weekly visits in Phase I. PAD participants will have opportunity to network with other PAD patients in the weekly group telephone session in Phase II. e) Website. The website will help with self-monitoring and group support.
REFERENCES

PAD participants randomized to usual care will not receive any study interventions. They will receive usual care from their own physicians. Thus, the usual care group will represent typical practice currently available to patients with PAD. To minimize loss to follow-up and to allow meaningful comparisons between the intervention and usual care group in this randomized trial, participants in the usual care group will be contacted by telephone once per month to inquire about serious adverse events, such as hospitalizations. These monthly telephone calls will last for about 5 to 10 minutes. Every three months, the telephone interview of participants in the usual care group will be slightly longer and will include additional questions (compared to the monthly telephone call). These additional questions will assess changes in exercise behavior and activity level.

Participants randomized to usual care will return for follow-up testing at nine-month follow-up. An incentive of $25.00 has been budgeted to help maximize follow-up rates for all participants, including those randomized to the usual care group.
The HONOR Study
Home-Based Walking Intervention for PAD
ON SITE SESSION #1:
Individual Session with Participant

Date: ____________________
Coach: ____________________
Participant Name: ____________________

How does the participant prefer to be addressed (first name, Mr./Ms., etc): ____________________

Accommodation Needs: □ low vision □ hearing impairment
Resides with: ____________________

Welcome to the HONOR Study.

Objectives
In this session the interventionist will:
• Discuss structure of the HONOR physical activity program (provide website link)
• Introduce patient to use of the Fitbit, including the study website
• Establish activity goals for first week and enter walking goals onto the study website.
• Provide dates for additional one-on-one session and 2 group exercise sessions

A. Greeting / your background & role in HONOR / introduction of other intervention staff

B. Program Overview-Provide a brief overview of the program while completing a 10 minute walk with participant.

“The HONOR Study is designed to help individuals with PAD improve their physical function and prevent physical disability. We expect this will improve your walking ability and overall health. This is an exciting study and it is has been made possible with the financial support of the Patient-Centered Outcomes Research Initiative (PCORI).
Briefly review the how the intervention is structured: Refer to FITT Model at end of packet

C. HONOR Technology Training and Practice
   a) Fitbit: The interventionist will describe what the Fitbit is and what it does, how to take care of the device, and how to transmit data from Fitbit to the website. They should practice putting the Fitbit on, taking it off, and syncing the device with their computer to transmit data. They should demonstrate that they know how to log onto the website and can understand the information displayed on the website.

   If the participant has a laptop or smartphone, download the software for them. If the participant does not have their computer at the visit, review download instructions with them and then ask them to demonstrate on the study laptop.

   1. ☐ Set up fitbit account and fitbit. If they do not have an email address, help them create a Gmail account to use for this study. Record the participant’s fitbit account information on page 2 of their manual (if manual needed). If they had an account last time, reuse this account.

       Email:___________________________________________

       Password:_______________________________________

   2. ☐ Explain that the previous process only needs to be done once. Show the participant how they can log out of the site.

   3. ☐ Explain how frequently we will need the participant to sync the device.

   4.  SYNC and LOG IN- Check when participant completes:

       ☐ Opens up Fitbit main menu
       ☐ Clicks “Sync Now”
       ☐ Device syncs

       ☐ Show the participant how to wear the fitbit. They wear it all day but they can take it off to sleep and shower. The fitbit is not waterproof.

       ☐ Show the participant how to see their steps/distance/calories burned for the day on the device screen. Tell the participant that the device resets at midnight but stores the data from previous days.

   b) HONOR website
1.☐ Set up HONOR account and link to fitbit. Record username and password on their website page.
   Email:________________________________________
   Password:____________________________________
2.☐ Show participant how to log in to the site and view their walking
3.☐ Show participant how to record walking on different days.
4.☐ Ask the participant to go to the website and log in to their account.
5. Goal Setting
   ☐ Discuss RPE and/or pain when walking with the participant.
   ☐ Help the participant set walking targets for the first week of the intervention (complete online form for this).

D. Assignments for next week: ask the participant to do the following in the next week or before their next session
   1. If not already done, download the fitbit software on your home computer
   2. Post on the group message board
   3. Log any exercise into the HONOR website

E. Session Close Out

Is there anything else that we can do to help you be successful in this program?

Do you have any questions that we can answer for you?
It was a pleasure to meet you and we look forward to seeing you next time.
Thank you for coming in today.
Confirm next appointment day and time and location.
FITT Model (Frequency, Intensity, Time, Type)

- **Frequency**: We would like you to walk for exercise at least 5 times per week. (Explain the concept of shaping behavior.)
- **Intensity**: We will ask you to exercise at a moderate intensity using the below exertion scales or until you reach a level of moderate discomfort in your legs, whichever applies. (Share the scale that applies to each person and explain how it should be used.)
- **Time**: This exercise program is customized to you, but eventually we would like you to get to the point where you can walk without stopping, or stop less frequently and only briefly each time you exercise. We would like you to begin by aiming to walk for exercise for a total of 15 minutes or more, not including rest time, and then work your way up to walking up to 50 minutes per session.
- **Type**: The physical activity program will include walking since type of exercise has shown to be ideal for persons with PAD.
The HONOR Study
Home-Based Walking Intervention for PAD

ON SITE SESSION #2:
Individual Session with Participant

Date:_______________
Coach: _________________
Participant Name: ____________________________
How does the participant prefer to be addressed (first name, Mr./Ms., etc): ____________________________
Accommodation Needs:  □ low vision   □ hearing impairment
Resides with: ________________________________________

Welcome to the HONOR Study.

Objectives

In this session the interventionist will:

- Build a **collaborative relationship** with the participant
- Discuss the participant’s **past exercise experiences, motives/incentives for exercise**, intended outcomes, and factors that may inhibit and facilitate participation
- Provide **dates for 2 group exercise sessions** & review their purpose
A. **Phase I of Collaborative Discussion:** Open-ended questions should be used to elicit information about participants and allow them to talk about the issues that are most important to them.

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>1.</strong> How did you decide to enroll in the HONOR Study?</td>
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</tr>
<tr>
<td><strong>2.</strong> What benefits do you hope to achieve from the HONOR Study?</td>
<td></td>
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<tr>
<td><strong>3.</strong> What has been your past experience with physical activity/exercise programs?</td>
<td></td>
</tr>
<tr>
<td><strong>4.</strong> If previously active, then ask: “What happened? Did you like being active? What benefits did you experience? Was there anything negative about the experience? Why did you stop?”</td>
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</tbody>
</table>
### B. Barriers/Facilitating Factors

<table>
<thead>
<tr>
<th>Conflict from other commitments/personal issues</th>
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</thead>
<tbody>
<tr>
<td>Are there any barriers that may get in the way of your participating fully in the HONOR Physical Activity Program such as talking care of a spouse or other family member, volunteer or paid work, health issues, or current physical symptoms?</td>
</tr>
<tr>
<td>If yes, how do you think these barriers might conflict with your walking exercise goals?</td>
</tr>
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</table>

<table>
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<tr>
<th>Neighborhood environment</th>
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<tbody>
<tr>
<td>Do you think your neighborhood will have a positive or negative influence on your being physically active at home?</td>
</tr>
<tr>
<td>If negative, how do you think your neighborhood could conflict with your walking exercise goals?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Family and Friends</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you think your family and friends will be positive, negative or really won't care about your being physically active at home?</td>
</tr>
<tr>
<td>If negative or won’t care, how do you perceive this might affect your motivation to walk for exercise?</td>
</tr>
</tbody>
</table>
Your Doctor

Do you think your family physician is positive, negative or really doesn't care (a rating of 0) about your participation in the Physical Activity Program?

If negative or won’t care, how do you perceive this might affect your motivation to walk for exercise?

C. How confident are you that you will be able to do what we are asking you to do? Do you have any concerns about sticking to a walking exercise program?

D. Personal Goals and Concerns--It is very important to discuss personal goals and concerns regarding physical activity participation in the HONOR study. Goals should be generated by the participant and consistent with his/her abilities.

- **Long Term Goals** (e.g., improve health, walk further without pain, decrease medication)

  Considering everything in your life at the present time, how much do you value these goals?

- **Short term goals** (e.g., walk for 15 minutes per day for 5 days per week).
**E Session Close Out**

Is there anything else that we can do to help you be successful in this program?

Do you have any questions that we can answer for you?

It was a pleasure to meet you and we look forward to seeing you next time.
Thank you for coming in today.
Confirm next appointment day and time and location.
Session Objectives:

- Check-in
- Review of the Fitbit & other Tools
- The Group Experience: Use of the Website

“The world is so empty if one thinks only of mountains, rivers & cities; but to know someone who thinks & feels with us, & who, though distant, is close to us in spirit, this makes the earth for us an inhabited garden.”

- Johann Wolfgang von Goethe
Checking-in

- The Importance of Awareness
- Accountability to Yourself & Others
- Reflecting on Success
- Social Problem Solving

Please list some of your successes/challenges/ideas to share with the group.

**My successes/challenges/ideas:**

- _________________________________
- _________________________________
- _________________________________
- _________________________________
- _________________________________
- _________________________________
- _________________________________
Challenges/Experience with Using the Fitbit

Challenges/Experience/Tips:

• __________________________________________________________________________

• __________________________________________________________________________

• __________________________________________________________________________

• __________________________________________________________________________
1. It is designed with the help of patients like you who have PAD and is being funded by the Patient-Centered Outcomes Research Initiative (PCORI).

2. We depend upon your active involvement in this project. Those of us here in this room, the study investigators, and other participants in the study have come together as a community to try to figure out how to improve quality of life for individuals with PAD. Everyone’s full engagement is necessary for these efforts to be successful.

The program has organized all of these contributions to provide help in a variety of ways:

- **Offering Guidance:**
  - Coach interactions
  - Optional weekly group conference calls with other participants
  - Website postings

- **Helping to Gain Confidence in Your Function:**
  - Sharing and reflecting on your personal successes
  - Optional weekly group telephone conference calls with other participants in the HONOR community
  - Sharing in and celebrating the successes of the entire HONOR community on the website

- **Feeling Connected:**
  - Regular individual calls with your coach
  - Interactive use of the study website to stay in contact with the HONOR community
• **Resources for Difficult/Challenging Times:**
  o Your coach
  o Dr. McDermott and other study investigators
  o Helpful tips from fellow participants
  o Optional weekly group telephone conference calls with other HONOR participants

• **Part of a Larger Whole:** A national effort to help fight the physical disability that is caused by PAD

• **Commitment to Helping Others:**
  o Join group calls to support others and help them figure out how to overcome barriers
  o Post experiences/tips on the website
  o Accumulate activity to increase the entire HONOR community’s accomplishments

**A Tour of the Website**
Your coach will lead the group through the study website.
My Commitment to the Study

- I will wear the Fitbit daily and monitor my progress.
- I will enter my minutes walked on the study website at least once per week.
- I will be available for and actively participate in the individual telephone calls with the coach.
- I will visit the study website weekly to review helpful hints/experiences from participants.
- I will contribute a comment or question on the website at least once per month.
- I will participate in at least one optional group telephone conference call with other participants to see if this is something I find useful.

_________________________________  __________________________________
Participant’s Initials               Coach’s Initials
Mindful Reflections

◆ How will you achieve your walking exercise goals this week?

_________________________________________________________
_________________________________________________________
_________________________________________________________

This Week’s Physical Activity Goals

1. Follow my HONOR study walking plan for this week:

   ◆ My walking exercise goals:

   _____ days per week       _____ minutes per session

2. Use my Fitbit and the study website as directed.

3. If you had trouble meeting your goals last week, what will you do differently this week to try to meet them?

   _______________________________________________________
   _______________________________________________________
   _______________________________________________________
HONOR On-Site Session 4

Peripheral Artery Disease and Exercise & Moving Forward: Staying on a path to Success

Session Objectives:

- Peripheral Artery Disease and Exercise
  - Checking-in & Review of the participant’s progress on the study website
  - An overview of how PAD causes walking difficulty.
  - Dealing with the discomfort of exercise-induced discomfort/pain from PAD

- Moving Forward
  - Share strategies for keeping yourself on track to achieve your personal health goals
  - Create a plan to keep yourself motivated to engage in regular exercise
  - Brainstorm ways to ensure success for the remainder of the study

―Henri L. Bergson

―Prince Gautama

―Siddharta

“To exist is to change, to change is to mature, to mature is to go on creating oneself endlessly.”

―Henri L. Bergson
Checking-in

Ideas/experiences to share with others:

• ______________________________________

• ______________________________________

• ______________________________________

• ______________________________________

Challenges/Tips on Using the Fitbit and

Challenges/Tips:

• ______________________________________

• ______________________________________

• ______________________________________

• ______________________________________
Why Your Legs Hurt When You Walk

Peripheral arterial disease (PAD) reduces blood flow to muscle tissues in the legs because of blocked leg arteries. Blood brings oxygen to our muscles, which is essential for normal muscle function. When we walk, we need more oxygen for our muscles. When we don’t get all of this oxygen, the result is pain in the legs with walking.

PAD occurs when cholesterol deposits called “atherosclerotic plaque” accumulate in the arteries of the legs. The picture below shows plaque buildup in the iliac artery near the pelvis, although blockages can occur anywhere in the leg arteries. The blockage prevents blood flow to the lower leg, decreasing the oxygen supply to the muscles and resulting in classic leg symptoms called intermittent claudication.

Risk Factors for PAD:
- Cigarette smoking
- Diabetes
- Obesity
- High blood pressure
- High cholesterol

People with PAD who exercise are able to:
- Walk further
- Reduce leg pain during walking
- Improve overall cardiovascular health
- Prevent physical disability
Using Exercise to Your Advantage

Research has shown that walking is the most effective exercise for people with PAD.

Here are the characteristics of walking exercise that have been shown to be most beneficial for people with PAD:

- Walk for exercise **5 days each week**.
- Walk for a minimum of **15 minutes each session**, not including rest time.
- Increase your walking activity to up to **50 minutes per session** over time.
- Walk **beyond the onset of leg pain or discomfort**. When the discomfort is too great, rest until your leg discomfort improves.
- **Resume walking** once discomfort subsides.

While discomfort or pain in the legs is to be expected, pain that occurs elsewhere in the body is an indication to stop. For example, shortness of breath or pain in the chest, arms, neck, or throat could be a sign of insufficient blood flow to the heart. If you experience this type of pain, stop exercising and report it to your physician immediately.
A Little Background on Pain and PAD

No one enjoys experiencing pain or discomfort. It is common to feel threatened and frustrated by pain, causing you to stop the activity that is the source of your discomfort. Most individuals will do everything they can to avoid situations that cause pain. For example, it makes sense to withdraw your hand from the handle of a pan that feels hot.

However, sometimes it is beneficial to tolerate pain or discomfort in order to achieve greater results over time. Let’s think about runners competing in an Olympic event. When runners train, they often experience fatigue and even some discomfort in their joints or muscles. If they were to retreat from the pain by decreasing their activity and reducing their efforts, they would not experience an improvement in their performance. Instead, runners will adapt and develop ways to manage their discomfort in order to accomplish their goals. They must accept the pain and persist through the discomfort, becoming more fit in the process.

PAD creates a similar situation of “no pain, no gain”. However, discomfort caused by PAD occurs with less effort and is more consistent. As we have noted, it is common to feel threatened by pain. The natural response of the body is to respond to the threat by quitting the activity that causes the pain, in your case the pain that occurs with walking. Our emotional response to the pain may be anxiety and frustration, causing our minds to tell us that it’s just not worth the effort—eventually leading to the decision to minimize walking or to stop altogether.

Yet similar to an Olympic runner, it is important not to let the pain get in the way of your ultimate goal—in your case, increasing your activity and walking greater distances with less discomfort. The decision to stop walking can have serious consequences for your health. The less walking you do, the faster your heart, muscles, and other systems of the
body will decline. Not only does this put you at risk for developing chronic diseases such as heart disease and diabetes, but it also makes you vulnerable to physical disabilities that can threaten your independence.

We feel it is important for you to know that the physical sensations in your legs during periods of physical activity are normal for patients with PAD and should not be taken as evidence that physical activity is bad for you. Research has consistently shown that PAD patients who are active have better outcomes and are less likely to decline, despite the discomfort. Like an Olympic runner, you can learn to accept the pain and persist through the discomfort. Your desire for success can ultimately lead to great rewards for your health, your independence, and your overall quality of life!

**Strategies for Success**

Use the following space to reflect on the past four weeks. What tools (the study website, coach telephone calls, participant group conference calls, Fitbit) seem most important and useful for you? Is there anything we could do to make the tools better for you? Think about what has worked best to keep you motivated and focused on your physical activity goals. How do you feel about your walking program? If you have had any difficulties meeting your walking goals, what helped you manage them and stay motivated? Think about what you have learned about yourself during this process.
Please write your thoughts below. We will ask you to share your successes/thoughts with the group when you are done.

**My successes/thoughts:**

- ________________________________
- ________________________________
- ________________________________
- ________________________________
- ________________________________
- ________________________________
Holding Yourself Accountable to Your Own Success

Your coach will help to hold you accountable to meet your weekly walking goals. However, eventually, you must learn how to become accountable to YOURSELF.

To increase your accountability, ask yourself these questions:

- Do I feel confident using the Fitbit, setting weekly walking goals, recording my walking activity, and using the study website? Am I committed to using these tools fully? What will I do to help me stay aware of the barriers that may cause me to lapse?

- How will I know if I am not meeting my walking goals? What action should I take if this occurs?

- How will I motivate myself to continue to meet my walking goals?

Knowing the answers to these questions will help you to continue taking positive steps toward your personal goals.
Planning for a Healthy Future

Now that you have answered these questions, you are ready to write your own plan to help keep you on the path to success.

Think about:

1. What helps me stay motivated to meet my walking goals?

2. Who is in my support system that I can rely on to help me stay motivated?

3. What is my plan to monitor my progress?

Write down some of your ideas below.

My HONOR Plan

I plan to do the following in order to improve my walking ability and increase my commitment to the program:

_________________________________________
_________________________________________
_________________________________________
_________________________________________
_________________________________________
_________________________________________
Mindful Reflections

◆ What are your experiences like when you walk for exercise? Do you ever reflect on how fortunate you are to be able to walk?
◆ How will you implement your walking exercise goals this week?

This Week’s Physical Activity Goals

1. Follow my HONOR study walking plan for this week:
   ◆ My walking exercise goals:
     _____ days per week   _____ minutes per session

2. Use my Fitbit and the study website as directed.

3. If you had trouble meeting your goals last week, what will you do differently this week to try to meet them?

____________________________________________________________________
HONOR Telephone Coaching Checklist

Participant ID: __________ Coach Initials: ________ Date of call: ________

Call Number

Call Attempts:

<table>
<thead>
<tr>
<th>Attempt</th>
<th>Date</th>
<th>Time</th>
<th>Outcome: No answer, left message, emailed etc</th>
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</thead>
<tbody>
<tr>
<td>1.</td>
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</table>

Checklist: check off items that are complete, make notes in the margin or under additional comments.

☐ Greet participant- small talk
☐ Check in
☐ Discuss walking exercise activity and use of Fitbit and website:
  o Is the Fitbit working? Any issues with syncing, logging in?
  o Discuss Adherence to goals from previous call (open-ended; e.g., How have you been doing with your PA since we last spoke?)
  o What’s working? Where are you exercising? (Note. Jot down any website worthy comments/experiences)
  o Reinforcement and positive follow-up (intrinsic rewards; that is great! Ask question: How does it make you feel?)
  o Discuss RPE/Claudication (pain, symptoms, intensity)
  o Setting goals with participant
  o Coach enters goals for next week/bi-weekly/month
☐ Discuss and reinforce the use of the website
  o Discuss accessing website; things you found interesting this week
  o Discuss logging in activity ( how often are you logging in ?)
  o Encourage posting on message board and directly to coach
  o Ask the participant if it is OK to share their successes or how they overcame challenges on the message board for others to see (increase engagement in website)
  o Discuss graphs and achievement bar in adherence
Discuss struggles/barriers and potential solutions (try to get them involved in coming up with solutions with you facilitating the process); perhaps you can point to something on the website.

Wrap up/conclusion and update participants on progress of the trial

Set up future call

Remind the participant of the upcoming group call

Adverse Event:
Did the participant spontaneously or in conversation report an adverse event or other new health problem?

☐ Yes ☐ No

Participant: ________________________  DOB: ___________  Date: ___________
ID Number: _________________
Date of Randomization: ____________
Date of SAE: _________________
Type of SAE: ___ Hospitalization _ Death __Significant disability
If hospitalization, is the participant still hospitalized?
Participant’s phone number (s): ______________________________
Physician/Phone #: ______________________________
Detailed description of adverse event:

Was the PI contacted?
☐ Yes ☐ No  Date contacted: ___________
Method used for contact:

Was the Project Manager contacted?  Date contacted____
Method used for contact _______________
☐ YES  ☐ NO

Additional Comments:
EXAMPLE WEBSITE IMAGES from the HONOR Study
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Disclaimer:
The [views, statements, opinions] presented in this report are solely the responsibility of the author(s) and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute® (PCORI®), its Board of Governors or Methodology Committee.

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https://www.pcori.org/research-results/2014/effectiveness-home-based-exercise-program-walking-ability-patients-peripheral