

From the Society for Vascular Surgery

Use of an app-based exercise therapy program including cognitive-behavioral techniques for the management of intermittent claudication

Oliver O. Aalami, MD,^a Judith Lin, MD MBA,^b Dasha Savage, MD,^a Vy Ho, MD,^a Daniel Bertges, MD,^c and Matthew Corriere, MD,^d *Stanford, CA; Ann Arbor, MI; and Burlington, VT*

ABSTRACT

Objective: Clinical practice guidelines recommend supervised exercise therapy (SET) as first-line therapy for patients with peripheral artery disease (PAD) and intermittent claudication (IC). The Society for Vascular Surgery Appropriate Use Criteria for IC deems exercise therapy (ET) as appropriate for all patients with IC. However, compliance with recommendations for the use of ET is often poor owing to the lack of availability, patient travel requirements, and cost. Results of home-based ET programs have been mixed with a trend toward improved results with more frequent patient engagement. The feasibility, use, and effectiveness of a 12-week app-based structured ET program using cognitive-behavioral therapy (CBT) techniques for IC was evaluated.

Methods: Patients with PAD confirmed by an abnormal ankle-brachial index or toe-brachial index and IC were recruited prospectively to participate in Society for Vascular Surgery SET, a 12-week app-based ET program. Participants performed home 6-minute walk tests, completed quality-of-life surveys, received education options via micro learning courses (eg, What is PAD?, Exercise, and Nutrition), and ongoing health coaching using CBT techniques. They were instructed to record at least three 30-minute ET walks a week using their personal mobile phones. Programming also included daily doses of health education, coaching, and reminders sent via text message.

Results: One hundred thirty-nine patients (37% women; mean age, 65 years) were enrolled across 20 institutions (44% offered in-person ET programs). One hundred twenty patients (86%) completed the program. Participants recorded 201,163 minutes of walking 8,013,520 steps with the ET program, completing a total of 5049 SET walks. Nineteen enrolled participants (14%) became inactive because they either paused (14 participants: medical reasons, travel, or other) or withdrew (5 participants: security concerns, lack of motivation). Ninety-two percent of patients met their stated CBT specific, measurable, achievable, relevant, and time-bound goals. Freedom from intervention at 6 months was 92% and 69% at 12 months.

Conclusions: Deployment of a 12-week app-based ET program for PAD incorporating CBT was feasible in achieving 86% program completion and effective at meeting guideline recommended activity goals. Ninety-two percent of participants achieved their CBT specific, measurable, achievable, relevant, and time-bound goals. The use of ET was increased by virtue of offering this program at institutions that did not offer ET. (*J Vasc Surg* 2022;■:1-6.)

Keywords: Peripheral artery disease; Intermittent claudication; Exercise therapy; Supervised exercise therapy; SET; Digital health; Cognitive-behavioral treatment; CBT; Appropriate use criteria; Remote monitoring

Exercise therapy (ET) is a Grade 1, Level A recommendation for patients with peripheral artery disease (PAD) and intermittent claudication (IC). In-person supervised ET (SET) programs have demonstrated freedom from

intervention of up to 83% at 5 years.¹ The 2022 Society for Vascular Surgery (SVS) appropriate use criteria for IC deems ET as appropriate for all patients with IC.² If available, SET programs consist of three sessions weekly over

From the Division of Vascular Surgery, Stanford University School of Medicine, Stanford^a; the Division of Vascular Surgery, Michigan State University School of Medicine, Ann Arbor^b; the Division of Vascular Surgery, University of Vermont School of Medicine, Burlington^c; and the Division of Vascular Surgery, University of Michigan School of Medicine, Ann Arbor.^d

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Correspondence: Oliver O. Aalami, MD, Division of Vascular Surgery, Stanford University, 780 Welch Rd, CJ350, Palo Alto, CA 94304 (e-mail: aalami@stanford.edu).

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a 12-week period in a hospital outpatient setting. Patients are guided by trained exercise physiologists and protocols often use treadmills.³ Distribution of education content is required at the time of referral. In addition, traditional programs require direct supervision by a physician, physician assistant, nurse practitioner, or clinical nurse specialist. Despite the documented benefits of SET, its use is extremely poor. In a 2020 national survey, only 49% of vascular specialists had yet to refer a patient to a SET program. Compounding the challenge of use are lack of program availability, patient multiweekly travel requirements to a facility, cost, and low reimbursement, among others.⁴ The Center for Medicare and Medicaid Services issued National Coverage Determination in 2017 for Medicare beneficiaries with IC; however, reimbursement was limited to facility fees and did not cover the required physician fees.⁵

Home-based ET program alternatives, which offer greater patient convenience at a lower cost, have been evaluated for many years.⁶ Approaches and the results of randomized controlled trials have been mixed. Gardner et al⁷ showed increased claudication onset time and peak walking time in patients wearing ankle pedometers asked to walk three times a week to near maximal claudication, compared with control patients. The HONOR trial failed to show a significant benefit in 6-minute walk test (6MWT) or patient-reported outcomes in patients given a Fitbit Zip activity tracker in combination with intermittent telephone coaching.⁸ The LITE Trial by McDermott et al⁹ demonstrated significant improvements in 6MWT distance in patients randomized to the high-intensity group (induce maximal ischemic pain after 5 minutes of walking) supported with weekly coaching and instructed to walk 50 minutes, 5 days a week. These studies demonstrate a trend toward improved outcomes with greater patient engagement and higher intensity and duration walking session recommendations.

The feasibility, use, and effectiveness of a 12-week app-based structured ET program with in-app activity tracking, health education, and access to live in-app health coaches who administered ongoing support and cognitive-behavioral therapy (CBT) techniques was evaluated.

METHODS

Patients with PAD confirmed by an abnormal ankle-brachial index or toe-brachial index and IC were recruited nationally across multiple sites to participate in a 12-week app-based structured ET program pilot. A cross-platform smartphone application named SVS SET (Cell-Ed, Inc., Palo Alto, CA) was developed in partnership with the SVS Health Information Technology Committee, which was available for download on both the Apple iOS app store as well as the Google Play store. Local institutional privacy and security approvals as well as

ARTICLE HIGHLIGHTS

- **Type of Research:** Multicenter prospective pilot study
- **Key Findings:** A home-based, mobile phone administered exercise therapy (ET) program using cognitive-behavioral techniques for patients with intermittent claudication was able to achieve guideline recommended engagement, modest improvement in home 6-minute walk test and patient reported outcomes for health education and physical activity. Ninety-two percent of cognitive behavior-derived specific, measurable, achievable, relevant, and time-bound goals were achieved and freedom from intervention at 6 and 12 months was 92% and 69%.
- **Take Home Message:** More accessible and lower cost digital health approaches to ET for patients with PAD and intermittent claudication could play a role in addressing the wide supervised ET utilization gap faced today.

institutional review board approvals were obtained as warranted.

Clinics either (1) screened patients and provided lists of eligible patients, or (2) referred patients directly to the program while in their offices. Patients who were referred received flyers with instructions to download the application and an associated clinic code. Coaches contacted patients who were only screened to assist with enrolling. The app starts with an in-app consent for the ET program. The assessment bundle then follows where participants are asked to complete the distance component of the Walking Impairment Questionnaire (miniWIQ) (exact questions asked can be found in the [Supplementary Materials](#) [online only]), an assessment of how informed they feel, an assessment of how able they are to do the things they want to do, and finally a phone-based 6MWT.⁹ This assessment bundle is repeated at weeks 6 and 12.

Multilingual health coaches made contact with participants via in-app texting in week 1 of the program to establish rapport. Participants are matched to the same coach for the entire 12 weeks. The CBT included three telephone interview sessions administered at weeks 1, 6, and 12. The coaching support throughout the 12-week program was administered entirely via call and text exchanges and included motivational interviews, solution focused. Specific, measurable, achievable, relevant, and time-bound (SMART) goal setting, habit-building practices, and adaptive objection handling, in addition to overall championship and support. Participants are encouraged to set three SMART goals. Recorded by the coach, they use patients' stated goals to encourage program adherence and change management, with minimum check-ins once a week via text or phone call.

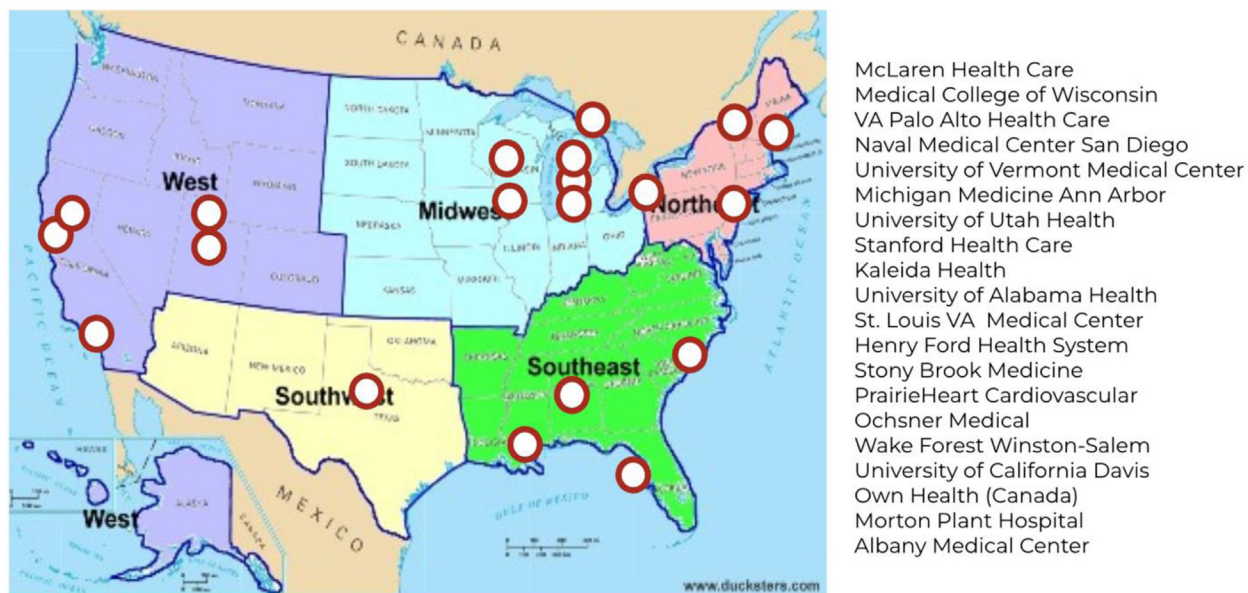


Fig 1. Map of the United States showing the geographic distribution and list of the 20 sites where participants were enrolled.

Health education available 24/7 was based on a unique audio-text micro learning and certification approach via three in-app courses titled, (1) What is PAD?, (2) Exercise, and (3) Nutrition, that require patient response and confirmation of understanding (created by Cell-Ed, Inc. and the SVS). In addition, patients receive one minute long audio 'daily dose' text message links (86 total, one for each day of the 12-week program) as an additional way to receive content, coaching, and activity nudging. Although participants are introduced early on to the concepts of ischemic pain, the formation of collateral circulation, and the benefits and safety of walking up to and even through claudication pain, the information is delivered at a reading, comprehension and digital literacy level accessible even at lower levels (eg, levels 1 and 2 of the Program for the International Assessment for Adult Competencies [PIAAC], 2022). To help participants quantify their symptoms, they were introduced to the claudication pain scale in a similarly accessible way: (1) no pain, (2) pain or discomfort begins, (3) mild pain or discomfort, (4) moderate pain, and (5) severe pain. The correlation between PAD and smoking and the importance of smoking cessation is emphasized in the What is PAD? course.

ET sessions were called SET walks. These sessions are initiated on a participant's mobile device to collect steps, time, and distance walked from the embedded mobile device sensors. At the end of each walk, participants were asked how many times they stopped. Participants were coached to perform SET walks 5 days a week for at least 30 to 60 minutes. They were instructed to

perform high-intensity walks, which were defined as walk-rest intervals where participants would walk up to a claudication pain scale of 4 or 5 before resting.

The 6-month and 12-month follow-ups for a subset of participants included the miniWIQ, the informed assessment, the able to assessment, a likelihood to recommend question, an inquiry into any vascular surgical interventions, and an inquiry into any lasting habit changes.

RESULTS

Two hundred seventy-nine (279) patients were screened or referred from September 2020 to August 2021 from 20 unique sites across the United States (Fig 1). Of these, 127 patients (45%) were not eligible (27% did not respond to three texts or calls, 9.6% did not have the proper device, 5.3% expressed no motivation to participate, and 3.2% had a medical reason not to participate). One hundred fifty-two (54%) of those screened were referred successfully to the SVS SET program and 91% (139 participants) were successfully enrolled (completed in-app consent) (Fig 2). Thirty-seven were women and the mean age was 65 (range, 40-94 years).

Of the participants who were enrolled successfully, 120 (86%) were engaged with the 12-week SVS SET program. Engagement included (1) performing SET walks, (2) completing educational programming, (3) engaging with health coaches, (4) and/or listening to the daily doses. Nineteen enrolled participants (14%) became inactive because they either paused (14 participants;

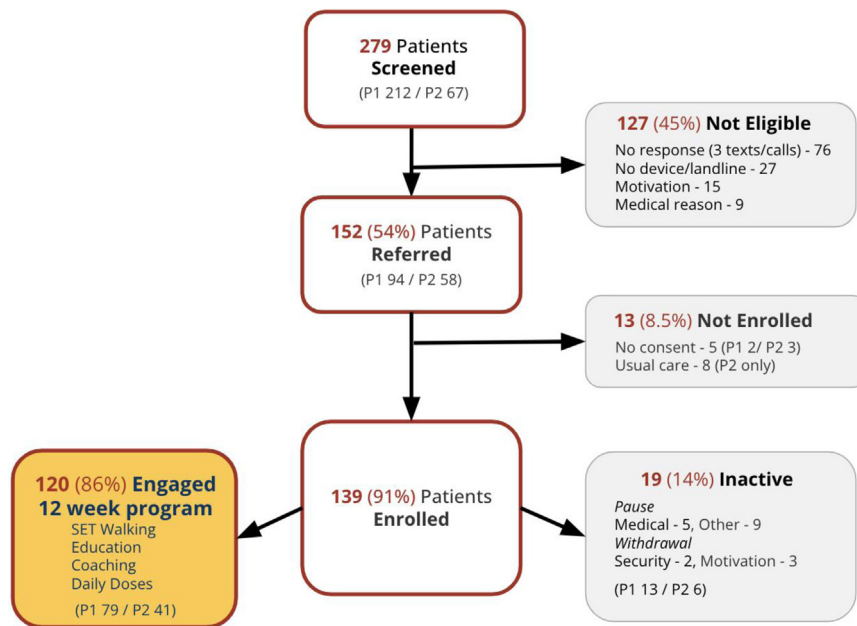


Fig 2. Patient flow chart showing total screened patients, not eligible, not onboarded, onboarded, inactive, and engaged participant breakdown.

medical reasons, travel, other) or withdrew (5 participants: security concerns, lack of motivation).

Participants recorded 201,163 minutes of walking 8,013,520 steps with the ET program, completing a total of 5049 SET walks. The average number of recorded SET walks per patient was 38.2 (3 per week). The average time walked per SET Walk was 39.5 minutes.

The baseline miniWIQ (distance score 0-100) was 41.4 and increased to 43.0 at 3 months ($P = .732$). Six-month scores increased to 78.4 (25 participants; $P < .05$) and 12-month scores were 74.8 (59 participants; $P < .05$) (Fig 3, A). When asked how informed participants were about PAD and their symptoms at baseline, the average was 5.7 out of 10.0 at baseline and 7.9 out of 10.0 at 12 weeks ($P < .05$) (Fig 3, B). When asked about their ability to do what they want to do the average baseline was 4.6 out of 10.0 at baseline and 6.5 out of 10.0 at 12 weeks (Fig 3, C).

Participants set 248 total open-ended SMART goals. These goals can be categorized into those for (1) more hobbies, improved quality of life, and independence (50.8%), (2) longer sustained walking or activity with less pain (29%), (3) creating an exercise schedule to meet goals (10.9%), and (4) other (remain employable, have better health, lose weight, avoid surgery) (9.3%) (Fig 3, A). Ninety-two percent (229 participants) met their goals by the end of the 12-week program. There was an 8.6% increase in patients who achieved longer sustained walking or activity with less pain.

The 6-month follow-up surveys were completed by 26 participants, of which 81% reported that the SVS SET program resulted in lasting habit changes, 92% not requiring any vascular surgical procedures, and 96%

recommending the SVS SET program to others. The 12-month follow-up surveys were completed by 35 participants, of whom 71% reported the SVS SET program resulting in lasting habit changes, 69% not requiring any vascular surgical procedures, and 94% recommending the SVS SET program to others (Table). Surgical interventions included a common femoral endarterectomy with lower extremity stenting, three isolated lower extremity stenting procedures, and three bypass procedures.

Of the 20 sites, only 44% offered in-person SET. One hundred percent of the sites enrolled at least one patient to the SVS SET program (mean of five per site).

DISCUSSION

The evaluation of a 12-week app-based structured ET program enhanced with CBT delivered by health coaches demonstrated 86% engagement in participants successfully enrolled with the average participant meeting recommended ET guideline frequency and duration (3/week and >150 minutes/week). An improvement of 55% in the 6MWT was documented, in addition to a 2.2% increase in self-reported health education and 92% CBT SMART goal achievement. Many prior studies evaluating home-based ET programs have been published with mixed results. The SVS SET program was designed to incorporate learnings from the successful LITE Trial by increasing coaching engagement and recommending high-intensity walking regimens.¹⁰

CBT exercise interventions were first described in McDermott et al's successful GOALS study, where home-based, group-mediated interventions were performed for patients

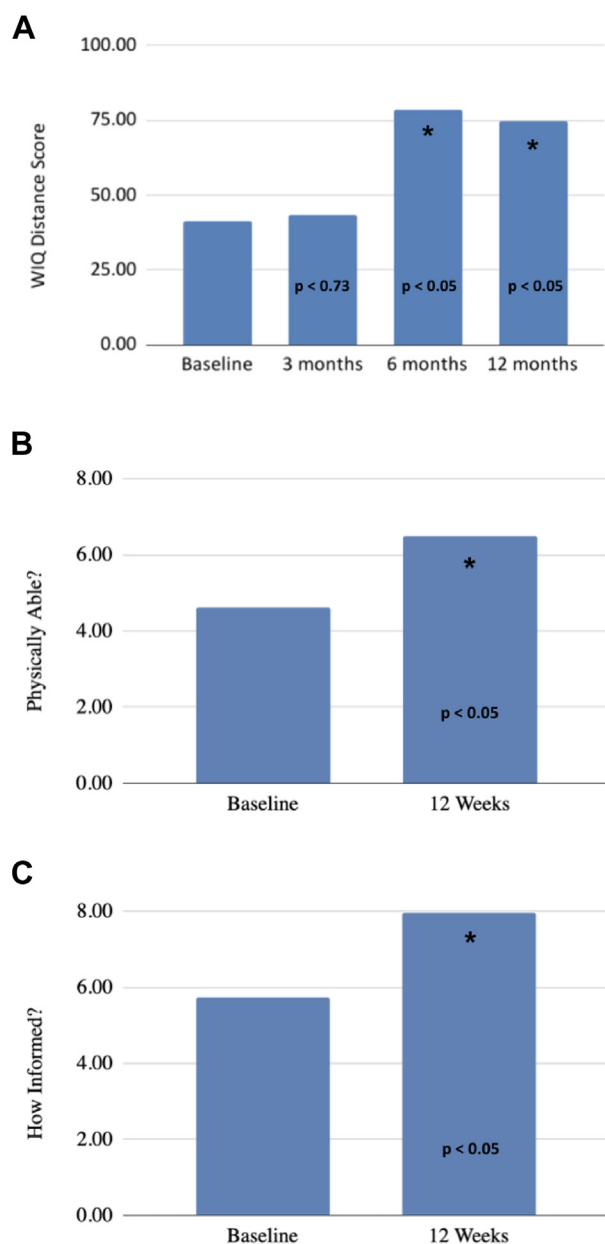


Fig 3. Patient-reported outcomes. The miniWIQ or distance component of the WIQ survey was used for physical activity (A). No significant difference was noted at 12 weeks ($P = .73$), however there was a significant difference noted at both 6 and 12 months ($P < .05$). A significant difference was noted when asked how physically able participants are to do the things they want to do on a scale of 1 to 10 at 12 weeks ($P < .05$) (B), and how informed they felt about their condition at 12 weeks ($P < .05$) (C).

with claudication.¹¹ Remote, health coach-mediated CBT has become widely implemented in digital health applications where behavior change is needed to successfully manage chronic medical conditions.¹²⁻¹⁴ This pilot study is the first to evaluate smartphone-mediated CBT with health coaches to drive behavior change in patients with symptomatic PAD and claudication.

Table. Long-term follow-up survey responses at 6 months ($n = 26$) and 12 months ($n = 35$)

	6-Month follow-up ($n = 26$), %	12-Month follow-up ($n = 35$), %
Lasting habit changes	81	71
Likelihood to recommend	96	94
Freedom from intervention	92	69

When addressing program accessibility, of the 279 patients with PAD screened for eligibility (cold called patients and those referred by physicians from office), 27% did not respond to texts or calls, 9.7% did not have a device (as mentioned elsewhere in this article), 5.3% were not motivated to participate, and 11.3% could not participate because of medical reasons. Once referred, an additional five patients did not complete the consenting process. It could be inferred that a total of 11.5% of the originally screened patients could or did not participate because of a potential lack of access to technology or smart phone usability.

There was a significant difference in enrollment success between patients who were identified via chart review and received a cold call from coaches versus being referred directly by their provider. When including all-comers, the enrollment rate was 50%. Direct referral from a provider increased enrollment to 81%. A screen of referred patients for responsiveness, motivation, device availability and compatibility, and health fitness enrollment success increased to 91%. The use of an exercise program was increased from 44% (sites which offered in-person SET) to 100% (mean enrollment of five participants per site). Simply offering a home-based alternative when otherwise not available increases use.

Prior studies have used wearables (eg, Fitbit Zip and Step-Watch ankle device) to track overall activity; however, challenges remained to associate specific bouts of activity with an ET session or with device connectivity and data uploading.^{7,8} The SVS SET program relies on embedded smartphone sensors and connectivity to track and transmit exercise session activity, and this process requires a smartphone application. This required participants to have a smartphone and created challenges for those with poor digital literacy. To aid with the accessibility of health education content an engaging audio-text micro training approach was used and delivered at a reading, comprehension, and digital literacy level accessible even at lower levels (eg, levels 1 and 2 of the Program for the International Assessment for Adult Competencies [PIAAC], 2022).¹⁵

Study limitations include comprehensive patient demographic information. Socioeconomic, racial, or other medical comorbidity data were not obtained. This factor

is especially pertinent when assessing access to smartphones. In addition, we did not collect the medical management status of each patient (eg, aspirin and/or statin use). To assess site-specific use robustly, a randomized controlled trial would be beneficial.

The utilization of ET for patients with claudication remains a great challenge. The SVS treatment guidelines and the 2022 SVS appropriate use criteria for IC recommend ET as first-line therapy for all patients. Of the 20 sites that participated in this pilot, only 44% had either a dedicated SET program or used their cardiac rehabilitation programs to provide ET for claudicants. This means the majority of patients do not have access to dedicated ET programs. Digital health solutions are ideal to meet the Institute for Healthcare Improvement's Triple Aim framework to (1) improve the patient experience, (2) improve the health of populations at scale, and (3) decrease costs. The SVS SET program was able to provide ET in all sites that participated; of those participants who enrolled, 86% engaged with the program.

Reimbursement does not exist for home-based ET programs. There are reimbursement codes for remote monitoring; however, these codes do not cover the cost of a comprehensive ET program. Category III CPT codes have been approved for health and well-being coaching; however, no national coverage exists for these codes as of yet.

CONCLUSIONS

A home-based, mobile phone-administered ET program using CBT for patients with IC was able to achieve guideline-recommended engagement. Modest improvements in 6MWT and patient-reported outcomes for health education and physical activity were reported. CBT was effective in patients with claudication who engaged as demonstrated by SMART goal achievement of 92%. These preliminary data are promising for a lower cost, more scalable alternative to in-person SET. Further evaluation of the use and effectiveness needs to be evaluated more broadly in a randomized controlled trial. A significant deterrent to the widespread implementation of home-based, mobile phone-administered ET programs remains a lack of reimbursement.⁴

AUTHOR CONTRIBUTIONS

Conception and design: OA, JL, VH, DB, MC
 Analysis and interpretation: OA, JL, DS, VH
 Data collection: OA, JL, DS, DB, MC
 Writing the article: OA, JL, DS, VH, DB, MC
 Critical revision of the article: OA, JL, DS, VH, DB, MC
 Final approval of the article: OA, JL, DS, VH, DB, MC
 Statistical analysis: OA, DS, VH
 Obtained funding: OA
 Overall responsibility: OA

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Additional material for this article may be found online at www.jvascsurg.org.

SUPPLEMENTARY MATERIAL (online only).

1) miniWIQ Survey Question

During the last week, how far did you walk with ease?

- a) 50 feet (3 car lengths)
- b) 150 feet (1/2 block)
- c) 300 feet (1 block)
- d) 600 feet (2 blocks)
- e) 900 feet (3 blocks)
- f) 1500 feet (5 blocks)

The score is calculated by dividing the selected feet in answer chosen by the total possible (1500) and

multiplying by 100 to get a percent. We added reference 8, which describes this and will also add this detail in a supplement for the article.

- 2) The "informed" question reads: "On a scale of 1-10 (1-being not at all informed about how to lower symptoms of PAD and 10 fully informed) how informed do you feel?" Answers are a single digit on a Likert scale of 1-10.
- 3) The "able to" question reads: "On a scale of 1-10 (1-not being physically able to do what you want to do and 10 being physically able to do the things you want to do) where are you on this scale now?" Answers are a single digit on a Likert scale of 1-10.