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PERIPHERAL VASCULAR DISEASE (WS JONES, SECTION EDITOR)

Decision Aids for Determining Facility Versus Non-Facility-Based Exercise in Those with Symptomatic Peripheral Artery Disease

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Abstract

Purpose of Review This paper sought to provide rationale for determining when a patient with symptomatic peripheral artery disease (PAD) might be referred for home-based versus facility-based exercise therapy.

Recent Findings Multiple randomized controlled studies have embedded supervised, structured exercise therapy as a class IA recommended therapy for those with symptomatic PAD. More recently, there is interest in non-facility-based exercise training as an alternative. The current literature is mixed on the effectiveness of non-facility-based training and is influenced by the amount of contact with clinical staff providing some supervision (e.g., occasional facility-based exercise or coaching phone calls), and the intensity (e.g., performed intermittently by inducing pain or continually and not inducing pain) and frequency (e.g., 12-week common supervised exercise program or those longer than 24 weeks) of exercise. Certainly, the data suggests non-facility-based exercise, while possibly improving walking performance, is inferior to facility-based supervised exercise training. Comprehensive data is lacking on utilization of supervised exercise therapy in those with symptomatic PAD, but is likely <2% of those eligible who participate. This suggests a possible important role for alternatives including non-facility-based (e.g., home, fitness center).

Summary Exercise training in the supervised, facility-based setting appears to be greatly underutilized. Non-facility-based exercise may help to overcome some of the most common barriers to participating in facility-based exercise including those related to motivation, transportation, and proximity. However, facility-based training is considered the gold standard so decisions about allowing a patient to exercise train at home must take into account issues including disease severity, patient motivation and available exercise resources, mobility and balance, cognitive function, and other medical concerns (e.g., symptomatic coronary artery disease or heart failure).

Keywords Symptomatic · Peripheral artery disease · Facility-based · Exercise training

Introduction

Patients with symptomatic peripheral artery disease (PAD) (e.g., claudication) that limits walking performance (i.e., walking time/distance to initial claudication discomfort and maximal tolerable waking time/distance) should be treated with multiple guideline-directed medical therapies including, when indicated, medications, risk factor counseling and control, revascularization, and exercise therapy [1]. Supervised exercise therapy (SET) performed at a medical facility or clinic is considered the gold standard for improving walking performance in those with symptomatic PAD and has a class IA rating based on the highest level of available research evidence [1]. Therefore, when possible, SET should be the preferred mode of delivering exercise therapy. However, the recent SARS-CoV-2 pandemic, combined with an understanding that SET is not widely available throughout the USA, has resulted in clinicians who deliver exercise therapy to consider non-facility-based (i.e., home or community) setting options.

An example of the development of non-facility-based exercise has taken place within cardiac rehabilitation

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(CR). Since inception in the 1970s, through expansion in the 1980s and 1990s, and to today's delivery in more than 800 programs throughout the USA [2], the primary mode of delivery has been in the medical facility setting (i.e., facility-based). These are typically located in hospitals or clinics, with much fewer located in fitness facilities or other non-medical buildings. Estimated participation in cardiac rehabilitation is in the range of <20% for Medicare eligible patients and has remained relatively unchanged over the past 15–20 years [3, 4], to approximately 28% among all eligible patients [2]. Recognizing the underutilization of cardiac rehabilitation (which is a class 1 (strong) or 2a (moderate) ACC/AHA recommendation for many cardiac conditions [5]), the Million Hearts initiative launched an effort to increase participation to 70% of eligible patients [6]. Additionally, there are many programmatic (e.g., quality initiatives, resource development) [7] and research efforts [8] ongoing which are designed to increase CR participation and adherence. As part of these efforts, there has been an emphasis on non-facility-based or hybrid (i.e., part facility and part home or other location) CR delivery. Much of this is done using synchronous audio + video visits where CR staff can supervise one or several patients exercising in a remote setting [9]. In addition to an ongoing NIH funded trial [8], there are many programs offering this mode of CR delivery to Medicare eligible patients during the COVID-19 pandemic. This is primarily due to a temporary allowance of reimbursement for this specific telehealth service by Medicare under their "hospital without walls" program developed in response to the declared public health emergency related to the COVID pandemic (at the time of this writing, it is set to expire on 12/31/2022 or when the public health emergency is over, whichever comes first). This reimbursement allowance for those eligible for cardiac rehabilitation does not apply to those with symptomatic PAD.

For the CR eligible patients, consideration must occur as to which patients might be best suited for non-facility-based CR. Factors related to telehealth accessibility, safety, effectiveness, etc. must be considered to appropriately select these patients. Additionally, traditional facility-based CR participation barriers (e.g., cost, transportation, fear of exercise after cardiac event) should also be part of the decision process. Similar decisions should be assessed and developed for patients with symptomatic PAD who are referred for SET. Can any of these patients be recommended for non-facility-based structured exercise training? This paper explores the effectiveness of non-facility-based exercise training in patients with symptomatic PAD and presents factors that should be considered when recommending patients for non-facility-based exercise training.

Effectiveness of Facility-Based Supervised Exercise Training Versus Non-Facility-Based Training

Supervised, structured exercise therapy is a treatment that is developed and monitored by an exercise professional (e.g., clinical exercise physiologist or a registered nurse with exercise training experience) and provides a designed and organized process of delivering an exercise dose, monitoring for improvement, and adjusting the workload to maximize improvement. This type of exercise training has consistently been shown to improve walking performance in those who have PAD resulting in intermittent claudication [10–12]. For instance, Murphy et al. [12] randomized 111 patients with aortoiliac peripheral disease to either optimal medical therapy (OMT), OMT plus revascularization, or OMT plus SET. SET was performed 3 times per week for 26 weeks with a progressive treadmill walking speed and grade adaptation based on patient walking performance. At 6 months, SET had the greatest improvement in peak treadmill walking time (5.8 ± 4.6 min) versus revascularization (3.7 ± 4.9) and OMT (1.2 ± 2.6).

McDermott et al. [11] reported a significant improvement in 6-min walk distance (33.6 m, 95% CI, 9.4, 57.5) in a supervised exercise group ($n = 53$) compared to a non-exercise control group ($n = 51$). The SET group performed progressive intensity treadmill waking 3 times per week for 6 months while the control group received weekly educational lectures over the same period.

Fakhry et al. [10] randomized 151 patients to either SET or endovascular revascularization. The SET program was 24 weeks in duration and consisted of treadmill walking, twice per week for 30 min per session, with encouragement to walk on their own for 60 min per day following the SET program. The study team reported short (1 year) and sustained (7 years) improvements in graded treadmill walking performance (maximal walking distance) of 1041 m (95% CI 892, 1189) and 975 m (772, 1177), respectively. Durable results were also found for pain-free walking distance (916 m [743, 1090] and 700 m [461, 941]), respectively at 1-year and 7-year follow-up. These improvements were not different versus revascularization. Additionally, several meta-analyses have shown consistent improvements in walking performance associated with SET [13–19] and emerging evidence suggests performing SET following a percutaneous revascularization intervention will maximize results compared to either treatment in isolation [20•].

Non-facility-based exercise is a potential alternative to SET. Structured non-facility-based exercise training has been shown to improve walking performance. Gardner et al. [21] performed a randomized, controlled clinical trial

comparing changes in functionality in patients with symptomatic PAD who performed exercise either in a supervised setting ($n=33$), at home (i.e., non-facility; $n=29$), or neither ($n=30$). The home-based exercise intervention was structured with a goal of similar intensity, frequency, and duration as the supervised group. Notably, to achieve the goal of similar exercise volume, the home-based group planned to exercise 5 min longer than the supervised group because exercise intensity was lower at home. The authors stated it was not their intention to duplicate the supervised program at home and allowed for differences in walking intensity. Patients at home could freely choose their walking pace while those exercising in the supervised setting performed a traditional walk-pain-rest-walk-repeat protocol with incremental increases in intensity as indicated. This study reported no difference in adherence to the exercise training with both groups exceeding 80% attendance. Both groups similarly increased time to pain onset and peak walking time. The author group stated that they remained in regular contact (bi-weekly, 15-min meetings) with the home-based group and monitored their ambulation and provided feedback and that this may be an important factor affecting their results [21].

McDermott et al. [22] evaluated if a wearable activity monitor affected 6-min walk distance after 9 months of intervention (4 weekly exercise visits at medical center in the 1st month; wearable activity monitor for use at home; weekly to bi-weekly coaching calls aimed at structured exercise). This group was compared to a group receiving no onsite exercise sessions or coaching interventions. The primary finding was no difference in 6-min walk distance between the groups after 9 months (−8.9 m, 95% CI, −26.0, 8.2; $p=0.31$).

In a different study, McDermott et al. [23•] compared a low-intensity versus a high-intensity home-based exercise program in 305 patients with symptomatic PAD. The low-intensity group walked without ischemic pain at all times while the high-intensity group was instructed to walk at a pace that elicited moderate to severe pain, although it was unclear if they performed a walk-rest-walk protocol. The goal was to walk five times per week for up to 50 min over a 12-month period. Six-minute walk distance was used to evaluate walking performance change and the between group comparison was −40.9 m (97.5% CI, −62, −21; $p<0.001$) for the low vs. high-intensity group (i.e., the high-intensity group walked ~41 m more). The low-intensity group was not different from a non-exercise control comparator group.

Several meta-analyses have evaluated non-facility-based walking exercise versus supervised exercise. Pymer et al. [24] evaluated 23 studies with 1907 study participants and concluded that home-based exercise was inferior to supervised exercise when maximal walking distance was assessed (139 m difference; 95% CI 45, 232; $p=0.004$). In a sub-analysis of investigations in which monitoring was used in non-facility-based settings, there was equivalent improvement in maximal walking distance (8 m difference; −81, 97; $p=0.86$).

Fokkenrood et al. [25] performed a Cochrane analysis of 14 studies (1202 male and female participants) comparing supervised to non-supervised (defined as structured home-based exercise or walking advice) exercise programs. The supervised setting was superior for improvement at both 3and 6 months of approximately 180 m in maximal treadmill walking distance. Pain-free treadmill walking distance was also improved in the supervised setting. Another Cochrane review compared supervised and home-based exercise [15]. They included 21 studies with a total of 1400 participants where, in general, exercise training was performed on 3 days each week and follow-up at 6 weeks to 2 years. The supervised groups had a 120 and 210-m improvement in maximal treadmill walking distance for SET compared to non-facility-based training and walking advice alone, respectively, at 3 months and were found to be durable at 6 and 12 months. The home-based group did not demonstrate an improvement in walking performance. Interestingly, neither of these reviews found a difference in quality-of-life assessment, but the quality of this evidence was considered low. Finally, Back et al. [26] assessed hospital-based versus home-based versus "go home and walk advice". They analyzed 9 studies (7 randomized controlled and 2 non-randomized controlled trials) and considered the overall quality of the studies as low. Similar to others, they found home-based was less effective for improving maximal and pain-free walking distances. However, they reported that the home-based exercise appeared superior for improvements in daily-life walking ability. They also stated that both hospital-based and home-based structured exercise were superior overall versus walking advice alone.

The general conclusion from these studies is that SET should be used to elicit maximal walking performance improvement. Note that many of the presented studies utilized a longer period of training (often 24 weeks or longer) than the current typical duration of SET in a clinical setting (12 weeks). Treat-Jacobson et al. reported the small mean change in maximal walking distance for 8 studies that used a 12-week training period (79% improvement) versus those using a 24+ week training period (+92%) [27••]. This suggests that longer periods of training produce better improvement, so, when a supervised setting is not a viable option due to either inability to participate or following maximum duration participation, home-based exercise can be a viable option for initial or continued walking performance improvements. However, for maximum benefit, a home-based program should be structured, supplemented with SET when possible, and ideally provide connection to an exercise professional (e.g., phone consultation or coaching, ideally in real-time) as often as possible.

Typical Patients Referred to Supervised Exercise Therapy

There has been only a small amount of evidence published on rates and characteristics of patients with PAD referred for SET. Divakaran et al. [28] reviewed all SET referrals in CMS-enrolled patients during the first year of coverage of SET for patients with symptomatic PAD (June 1, 2017-December 31, 2018). Results showed that of the 129,699 patients diagnosed with claudication, 1735 (1.3%) were enrolled in SET. Of those enrolled, only 5% completed all 36 sessions; sixteen was the median number of sessions completed. Patients referred were predominantly older, white, and male, and less likely to be dually enrolled in Medicaid, indicating higher socioeconomic status. However, there were no differences between referred patients and a matched group of non-referred patients in these characteristics. As would be expected, SET-referred patients had high rates of hypertension, hyperlipidemia, and history of tobacco use, and these were similar to those in the non-referred group. The majority of patients referred lived in the Midwest (48%) and Northeast (16%), with underrepresentation in the South Atlantic and Southern regions of the USA. During the 1-year follow-up period, SET participants were significantly less likely to have surgical or endovascular revascularization compared to those who were not referred (11.9 vs. 15.7% and 2.4 vs. 6.3%, respectively).

The Patient-centered Outcomes Related to Treatment Practices in Peripheral Arterial Disease (PORTRIAT) registry [29] found similar rates (2%) of referral in their US sites during an earlier period (2011–2015) prior to CMS coverage for SET. This contrasts with sites in the Netherlands that averaged 70% referral to SET. It should be noted that SET in the Netherlands has been well established and is covered by health insurance.

One factor related to referral to SET is the lack of available programs and lack of awareness of whether a program is available in the community where a provider practices. This likely influences what we know currently about those referred and participating in SET. Dua et al. [30] surveyed 900 vascular care physicians across the USA regarding SET referral practices. Of the 135 (15%) respondents, 49% had never referred a patient for SET, 30% were not aware that SET was covered by CMS, 52% said that there was not a program available in their practice setting, and 34% did not know if a program was available in their practice community. However, 98% said that they would refer a patient if a program was available.

Determinants of Facility Versus Non-Facility-Based Exercise Training

To date, no study has been conducted that has specifically investigated the appropriateness of facility-based SET compared to non-facility-based exercise programs. Likewise, demographic and clinical predictors of response to facility-based SET compared to non-facility-based exercise therapy programs are not well understood. Given this lack of understanding, a collective decision between the clinician and patient is recommended when deciding if a facility-based SET or non-facility-based exercise program is the most appropriate choice for the treatment of symptomatic PAD. It is well-documented that the clinician-patient relationship plays a key role in the therapeutic process and health service delivery through a unique opportunity for a shared decision-making model [31, 32]. The model has three steps: (a) introducing choice (facility-based SET vs. non-facility-based exercise), (b) describing/detailing the options (i.e., how facility-based SET and non-facility-based programs are implemented, and which of these produce superior results), and (c) helping patients explore preferences and make decisions. Pertaining to the latter, the clinician and patient should evaluate factors that will ultimately affect (1) the safety of the patient and (2) the feasibility of facility-based SET, which will in turn directly influence program compliance and outcomes. Following earlier discussion of the efficacy of facility-based SET and non-facility-based exercise, here we discuss the shared decision-making with a focus on safety considerations and barriers to participation for both rehabilitation options.

Safety

A recent systematic review has now provided safety evidence of home-based exercise programs in persons with symptomatic PAD [33]. In this review, twenty-seven studies were included and totaled 1642 participants completing 147,810 patient-hours of home-based exercise. Four study-related (possibly or likely attributed to exercise intervention) adverse events were reported, three of which were cardiac in origin, giving an all-cause complication rate of one event per 36,953 patient-hours. Three of these events occurred following exercise inducing severe claudication pain (relative to exercise programs encouraging bouts to mild or moderate pain). Each of the three studies [21, 23•, 34] within this systematic review from which the four study-related adverse events occurred utilized

symptom-limited graded exercise tests as part of the screening process. It should be noted that the incidence of adverse events in non-facility-based exercise programs may result in the overestimation of safety due to three factors. First, due to less monitoring used in non-facility-based exercise programs relative to facility-based SET, exercise is often completed at a self-selected pace (despite prescribed intensity), and thus participants may be less likely to experience an exercise-induced event. Likewise, with the infrequent monitoring in most non-facility-based exercise programs, it is plausible that events may not be consistently reported by participants. Lastly, the number of patient-hours reported in this review was calculated based on the number and duration of training sessions prescribed and not those completed.

Despite the limitations in the aforementioned review, the current evidence suggests that non-facility-based exercise is a safe exercise option for people with symptomatic PAD. However, there is currently no guidance for whom non-facility-based exercise might be inappropriate (i.e., relative or absolute contraindications). Currently the most relevant recommendations that might be used are those developed for non-facility-based or hybrid-based cardiac rehabilitation programs [8] and available safety exclusionary criteria from non-facility-based exercise for PAD [22, 23•, 34, 35]. Since many patients with PAD also have a cardiac condition, these recommendations are pertinent. Recent guidance related to safety considerations of hybrid-based cardiac rehabilitation (facility-based [CR] + home-based CR) reveal contraindications for patients who are (1) currently receiving continuous inotropic support, (2) a recent recipient of a mechanical support device (i.e., LVAD), and (3) symptomatic (cardiac symptoms including chest pain and dizziness) at very low workloads (≤2 metabolic equivalents of task) [8]. Likewise, current exclusionary criteria in non-facility-based PAD exercise research protocols often include critical limb ischemia (i.e., foot ulcers, gangrene, ischemic pain at rest), revascularization procedure in the last 3 months, active cancer treatment, angina, NYHA class III or IV heart failure, and inability to walk unaided [22, 23•, 34]. From these, a contraindication list for non-facility-based exercise was established and is reported in Table 1.

If a non-facility-based exercise program is considered by the clinician and patient, the clinician should ensure the following: (1) The patient is screened for comorbidities that may make non-facility-based exercise unsafe or overly challenging (Table 1) thereby making a facility-based SET program the more appropriate option, and (2) a non-weight bearing, symptom-limited graded exercise test is completed in select patients with cardiac-related comorbidities including myocardial infarction in the past 12 months, history of stable angina, heart failure, prior coronary revascularization, prior heart valve repair or replacement, or heart transplant, as recommended for facility-based SET programs [8]. If safety concerns are expressed by the clinician, non-facility-based exercise should not be considered, and facility-based SET should be recommended to the patient and a referral placed.

Table 1 Safety indications to refer to facility versus non-facility-based exercise for rehabilitation of symptomatic PAD

Chronic limb ischemia or CLI (ischemic rest pain, foot ulcer, or gangrene)
Cognitive impairment (i.e., MCI, types of dementia)
Inability to walk unaided
Major gait or motor disturbance (i.e., Parkinson's disease, MS, ataxia) or other reasons for increased fall risk
Recent surgery
Angina/moderate-to-severe coronary artery disease
NYHA class III or IV heart failure
Recent recipient of mechanical support device (i.e., LVAD)
Receiving continuous inotropic support

Safety indications derived from recommendations for hybrid and home-based exercise in cardiac rehabilitation and exclusionary criteria derived from home-based exercise studies in symptomatic PAD

SET supervised exercise therapy, *PAD* peripheral artery disease, *CLI* critical limb ischemia, *MCI* mild cognitive impairment, *MS* multiple sclerosis, *NYHA* New York Heart Association, *LVAD* left ventricular assist device

For patients deemed to be safe to participate in facility or non-facility-based exercise, a discussion of feasibility and barriers to each exercise delivery option should occur as part of the shared decision-making process. Currently, the primary barriers to use of facility-based SET programs include the following: (1) travel (distance to facility-based SET program or lack of transportation), (2) lack of available SET programs (related to #1), (3) lack of patient interest or motivation, and (4) cost of co-pay [28, 30, 36, 37]. With the 2017 CMS National Funding Determination to cover SET for patients with lifestyle-limiting claudication set at ~$57 per session (about 50% of the CR payment), for many facilities, this reimbursement is insufficient to justify funding an independent SET program. Thus, the majority (likely > 80%) of programs are embedded in CR programs [38]. The result of this likely contributes to the barrier of insufficient availability of SET programs for participants. Lack of available SET programs can contribute to travel concerns for all eligible patients. However, even if SET facilities are in relatively close proximity, transportation (e.g., no car, expensive cab service, public transportation not taking someone near a facility) issues can still serve as a common barrier, particularly in urban settings. Due to lifestyle-limiting claudication, eligible patients may find ambulating to transport hubs (i.e., bussing, light rail) to get to a SET facility to be challenging, especially in cold-weather climates. With regard to cost, patients still may have a variable coinsurance fee for each of the 36 SET sessions. For patients to have to pay three times

Table 2 Barriers for facility-based SET and non-facility-based exercise participation for symptomatic PAD

Facility-based SET	Home-based exercise
Lack of available SET programs	Is over-ground walking a feasible option (weather or climate issues, lack of facilities conducive for walking)?
Travel (distance to facility-based SET program or lack of transportation)	Lack of aerobic exercise equipment
Lack of patient interest	Inability or lack of confidence to perform unsupervised exercise rehabilitation for PAD
Financial burden (cost of coinsurance fees, etc.)	Past failures in starting and maintaining an exercise program
COVID-19 fears	
Family or employment obligations that interfere with the available time slots for SET at the desired facility	

SET supervised exercise therapy, *PAD* peripheral artery disease, *COVID-19* coronavirus disease 2019

per week for 12 weeks at a commonly seen 20% coinsurance fee can experience an out-of-pocket cost (~$11.50 per session for up to 36 sessions [$414]) that is too costly to enroll in SET and represents a socio-economical barrier.

Although barriers for participation in facility-based SET are generally well understood, barriers for non-facility-based exercise for treatment of symptomatic PAD are often under recognized. Given that most non-facility-based exercise is performed at home and utilizes over-ground walking, most barriers for this form of exercise involve participation in walking exercise, which include unsafe walking environment conducive to falls, weather issues (heat/humidity and cold extremes), unavailability of seating (for resting), and lack of social support systems [39]. A summary of barriers for participation in facility-based and non-facility-based exercise for symptomatic PAD is presented in Table 2.

The clinician's knowledge of barriers for facility-based and home-based exercise participation should be understood to (1) inform their patient of these barriers (Table 2) and (2) interview their patient to identify if any specific barriers are present. A decision-making tool (Fig. 1) can aid the clinician in guiding patient interviews to determine the appropriate mode of rehabilitation for their patients with symptomatic PAD.

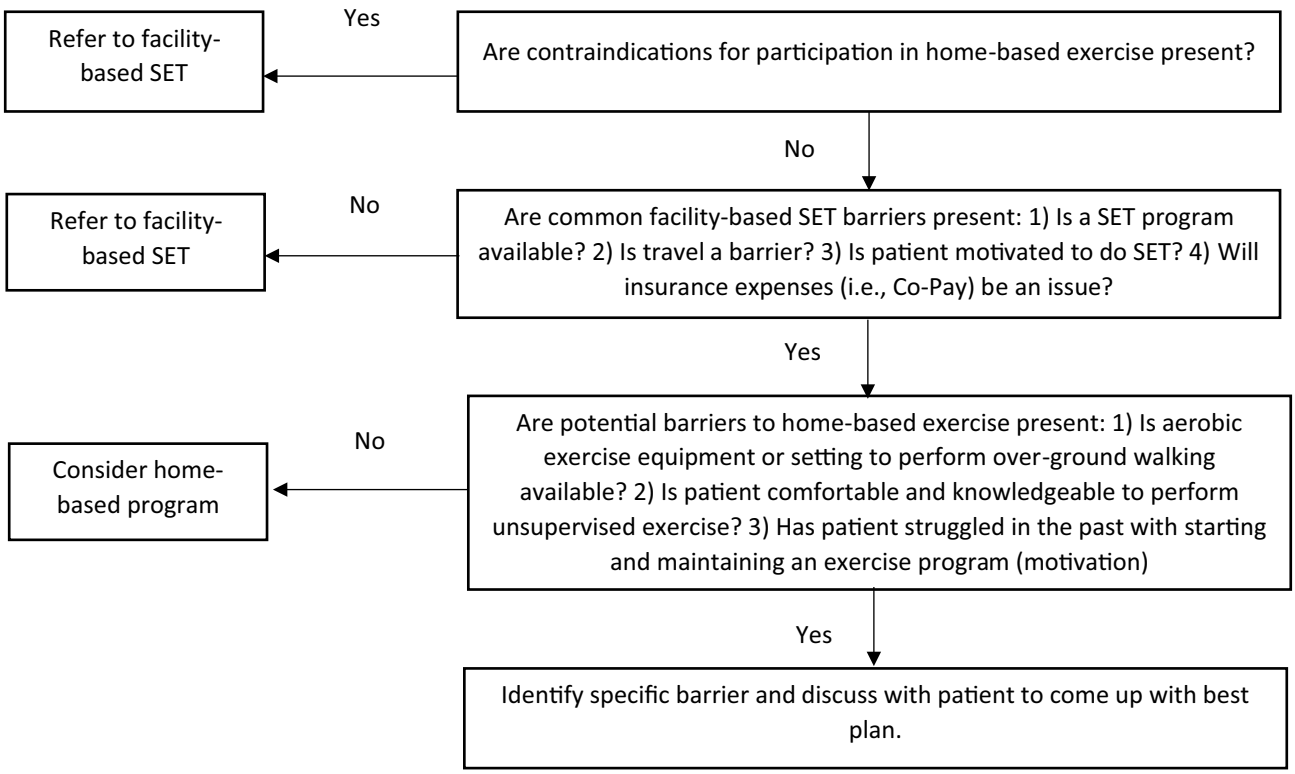

Fig. 1 Shared decision-making tree for determining use of facility-based SET or home-based exercise for PAD

Conclusion

There are a variety of factors to consider when determining the best location for an individual with symptomatic PAD to perform their exercise training. The literature suggests that exercising in a supervised setting will likely yield the best results. However, non-facility-based (primarily home) training can also provide positive results and should be considered when discussing with a patient. One possibility to maximize non-facility-based exercise would be to implement using synchronous telehealth visits (ideally using both audio and video connection) that would allow for real-time supervision. A possible reason for this would be to ensure adherence to the recommendation to stop exercise when claudication pain increases to a mild or moderate level, and to also ensure that progression occurs consistently when indicated. However, the data needed to justify supervised non-facility-based training does not yet exist and thus whether these recommendations would be sufficient in the non-facility-based setting is unknown. For this reason, currently if maximal improvement is desired, a facility-based training model is likely best in most individuals.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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•• Of major importance

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