Challenges in recruitment of persons with peripheral artery disease for exercise studies

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This article describes feasibility of direct and indirect recruitment methods for exercise studies designed for older adults with peripheral artery disease (PAD). Recruitment of older adults with PAD for participation in exercise studies has been particularly challenging. Age, risk factors, and comorbid conditions affect physical activity in older adults with PAD. Barriers to exercise, such as safety, health, and age-related changes, contribute to lack of participation in exercise studies. Various direct and indirect recruitment approaches and participant responses, along with reasons for nonparticipation, are categorized into participant demographic, community, and research-related barriers. At a cost of $1,330.00, indirect recruitment strategies of social marketing and community outreach resulted in two referrals and no enrollments. Recruitment-site champions and education resulted in no referrals and no enrollments. Direct recruitment approaches such as health system recruitment and referrals paired with flyers resulted in 44 referrals and one enrollment. Only one referral was obtained from a physician practice. Reasons for nonparticipation included lack of follow-up, presence of one or more exclusion criteria, lack of transportation, and comorbid disease burden that limited activity. Community- and research-related barriers included recruitment competition for other studies, budget limitations, lack of recruitment staff, and strict inclusion/exclusion criteria. Successful recruitment of older adults with PAD for participation in exercise clinical trials may require substantial time and budget. Interventions to address identified barriers such as personal attitudes and socioeconomic factors, lack of social support, and lack of transportation, combined with community factors such as rural location, and research study design considerations may facilitate recruitment efforts. (J Vasc Nurs 2018;■:1-10)

Recruitment of older adults is a challenge to ensure adequate sample size and confidence in results of clinical trials. In the United States, adults aged 65 years or older make up approximately 14.5% of the population, and this segment of the population is expected to grow to 21.7% over the next 35 years.[1] Furthermore, 15% of older adults struggle with living independently, and 23% have difficulty with ambulation.[2]

Mobility of older adults can be compounded by the presence of peripheral artery disease (PAD), which can result in significant functional impairment[3–5] and decreased quality of life.[6] For those with PAD, recent clinical guidelines recommend that a supervised walking program be implemented.[7] However, there exist barriers that affect participation in a walking program, including pain while walking, need to rest during the walk, and foot or leg ulcers.[8,9] More generally, adherence to any exercise program is difficult for individuals with PAD because of impaired mobility,[9,10] exertional pain with walking (claudication), presence of comorbidities, environmental factors,[11] and lack of transportation.[12]

Recruitment of older adults with PAD for participation in exercise studies has been particularly challenging. Older adults with PAD typically suffer from additional comorbid conditions. Age, risk factors, and comorbid conditions all affect physical activity of older adults with PAD. As a result, barriers to exercise such as safety, health, and age-related changes contribute to lack of participation in exercise studies.[13] For example, one group of researchers conducting a randomized controlled trial of an exercise intervention in participants with PAD and claudication used several recruitment strategies over 3 years to identify potential participants, but 71% of potential participants were excluded because of unstable cardiac or respiratory conditions, other comorbid conditions, and absence of claudication. Of patients who met inclusion criteria, 26% declined to participate. Ultimately, only 44 participants completed the study.[14] This study illustrates challenges in recruiting older adults with PAD for studies that involve physical activity.

The purpose of this article is to describe barriers to recruitment, resulting in inability to conduct an exercise study for older adults

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with PAD and to analyze feasibility of recruitment techniques for this population. The original study for which participants were to be recruited was a mixed-method randomized two-group technology-enhanced 12-week walking exercise study for persons with PAD and intermittent claudication (IC). Because this was originally designed to be a feasibility study, the goal was to recruit and randomize 40 participants. Unfortunately, because of failure in recruiting participants, the study could not be conducted.

DEFINITION OF RECRUITMENT METHODS

The Feinstein Institute for Medical Research[15] generalized guidelines for two types of research recruitment methods for all ages guided the approaches used in this study. Direct contact approach includes research personnel contacting potential participants by phone or in-person or a referral from a medical doctor who is not part of the research team. The indirect approach to research study recruitment includes word of mouth and printed advertisements (flyers, posters, pamphlets, brochures, newspapers, newsletters, and postcards).

A systematic review of the recruitment methods revealed several categories of recruitment strategies including social marketing, community outreach, referrals, and health system recruitment,[16] primarily indirect methods. A combination of these methods was used in this study. A conceptual framework proposed by Young et al[17] considers participant demographic, community-, and research-related barriers to participation and therefore was used to explain patient nonparticipation challenges.

According to the Young et al[17] conceptual framework, feasibility was investigated of both direct and indirect recruitment strategies used for enrollment in this physical activity study designed for older adults with PAD. Specific aims include (1) to describe the process, revisions in recruitment processes, and associated costs for each recruitment method and (2) to categorize characteristics of patients approached into personal, community-, and research-related barriers.

CONCEPTUAL FRAMEWORK

Young et al[17] introduced a conceptual framework based on the theory of planned behavior (TPB) to explain why rural patients with cardiovascular disease may or may not participate in behavioral modification research. Young et al's[17] conceptual framework further categorizes barriers to research participation using TPB, which helps to understand and predict personal behavior. TPB posits that behavior is directed by three principles: (1) behavioral beliefs (and consequences of action), (2) normative beliefs (expectations of others), and (3) control beliefs (factors that may control the outcome of action—positively or negatively).[18] Similarly, Young et al's[17] framework explains that potential participants are more likely to participate in behavioral modification research if they believe the intervention and its outcome will be beneficial, receive social support, and feel that they have control over the intervention.

Young et al[17] identified four categories of factors that may prohibit a person's participation in research: (1) contextual factors that include personal factors, community factors, and research factors; (2) perceived information and social support that include potential lack of knowledge, understanding, or awareness and lack of provider referrals and social support; (3) participant attitudes; and (4) opportunity to participate, including lack of transportation and lack of technology support. With favorable contextual factors, a person's attitude, adequate information, and social support positively influence his/her desire to enroll in a research study. Then, being presented with the opportunity to participate in a research study, the person's desire changes to engagement in the study.

OVERVIEW OF EXERCISE STUDY

Originally proposed as a longitudinal walking study, the intervention group was to receive walking program education, a Fitbit Zip activity monitor, and social support from a nurse with a goal to improve walking frequency and duration. There were two planned visits: (1) baseline visit for training on the Fitbit Zip activity monitor as part of pretest and baseline data collection and (2) a second visit at the end of the study to collect postintervention data and exit surveys.

The 12-week walking program was to be individualized and based on American College of Cardiology/American Heart Association (2006) recommended walking guidelines for a person with claudication.[7] The intervention was to include a weekly phone call from a nurse to offer social support during the walking program. The self-management model with 5 A's (Ask, Advise, Assess, Assist, and Arrange)[19] was to be used to guide the social support from a nurse, resulting in a personal action plan for the following week. Walking goals for the following week were to be mutually agreed upon by both nurse and patient based on exercise tolerance of the patient.

After consulting with other researchers who successfully recruited for studies involving persons with PAD and recognizing that study protocol might hinder participation because of onsite visits, length of the study, and frequent uploading of data, the study protocol was amended. An institutional review board (IRB) amendment allowed the principal investigator (PI) to make home visits for the baseline and study completion visit. The exercise intervention was also decreased from 12 weeks to 6 weeks in duration. In addition, the requirement of uploading data from the activity monitor was changed from daily to 3-week intervals, including the study completion visit.

Setting/sample

The study was to take place at an urban medical center in central Illinois and was designed to evaluate feasibility of the proposed intervention, participant acceptability, use of technology (activity monitor), and preliminarily the differences between the experimental and control groups. One hundred twenty persons between 50 and 80 years of age seeking care for vascular symptoms with a diagnosis of PAD and IC were to be approached for participation in the proposed walking study. Potential participants had to be willing to participate in a walking program using mobile technology (wearable activity monitor) and have access to a mobile phone or computer with Internet connectivity. Participant eligibility was to be determined by screening ankle-brachial index (ABI) (a noninvasive test that compares systolic pressures in the arms to the ankles). A normal ABI result is 1.00–1.40. ABI results ≤ 0.9 are indicative of arterial insufficiency.[7] Participants would not be enrolled if scores on the Walking Impairment

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