

Recruiting participants with peripheral arterial disease for clinical trials: Experience from the Study to Improve Leg Circulation (SILC)

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Objective: To describe the success of diverse recruitment methods in a randomized controlled clinical trial of exercise in persons with peripheral arterial disease (PAD).

Methods: An analysis of recruitment sources conducted for the 746 men and women completing a baseline visit for the study to improve leg circulation (SILC), a randomized controlled trial of exercise for patients with PAD. For each recruitment source, we determined the number of randomized participants, the rate of randomization among those completing a baseline visit, and cost per randomized participant.

Results: Of the 746 individuals who completed a baseline visit, 156 were eligible and randomized. The most frequent sources of randomized participants were newspaper advertising (n = 67), mailed recruitment letters to patients with PAD identified at the study medical center (n = 25), and radio advertising (n = 18). Costs per randomized participant were \$2750 for television advertising, \$2167 for Life Line Screening, \$2369 for newspaper advertising, \$3931 for mailed postcards to older community dwelling men and women, and \$5691 for radio advertising. Among those completing a baseline visit, randomization rates ranged from 10% for those identified from radio advertising to 32% for those identified from the Chicago Veterans Administration and 33% for those identified from posted flyers.

Conclusion: Most participants in a randomized controlled trial of exercise were recruited from newspaper advertising and mailed recruitment letters to patients with known PAD. The highest randomization rates after a baseline visit occurred among participants identified from posted flyers and mailed recruitment letters to PAD patients. (*J Vasc Surg* 2009;49:653-9.)

Men and women with lower extremity peripheral arterial disease (PAD) have greater functional limitations and faster rates of functional decline compared with persons without PAD.¹⁻³ Few interventions have demonstrated efficacy in improving functional limitations in persons with PAD. Randomized controlled clinical trials are needed to identify new therapies to improve functional limitations and prevent functional decline in persons with PAD. However, several clinical trials of participants with PAD have had difficulty achieving recruitment goals.⁴⁻⁶ In addition to their functional limitations, persons with PAD are often older and may have more comorbid diseases compared with persons without PAD.¹ This report describes our experience recruiting PAD participants for a randomized controlled clinical trial in Chicago, Ill. The clinical trial aimed to determine whether distinct types of supervised exercise training improve functional performance in PAD partici-

pants with and without intermittent claudication symptoms. We expect that our experience will provide helpful information for investigators seeking to recruit PAD patients into clinical trials.

METHODS

Study overview

The institutional review boards of Northwestern University, Catholic Health Partners Hospital, Evanston Northwestern Hospital, Rush Medical Center, University of Illinois-Chicago, the Jesse Brown Veterans Administration (VA) Hospital in Chicago, and Mt. Sinai Hospital in Chicago approved the protocol. Participants gave written informed consent. The funding source played no role in the design, conduct, reporting of the study, or decision to submit the manuscript.

Participants were recruited for a randomized controlled clinical trial, the study to improve leg circulation (SILC), designed to determine whether supervised resistance training and a supervised walking exercise program, respectively, improve functional performance compared with an attention control group in persons with PAD with and without classical symptoms of intermittent claudication. After completing baseline testing and a 2-week exercise run-in period, participants were randomized to supervised sessions (ie, supervised treadmill exercise, supervised strength training, or a control group) for 6 months. The run-in consisted of three treadmill exercise sessions and three strength training sessions scheduled over a 2-week period and was designed to identify and exclude potential participants not

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Competition of interest: none.

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fully committed to study participation. Potential participants who did not complete their six sessions within 3 weeks were excluded. Participants received up to \$170 for study participation: \$50 after completing half of their assigned group sessions and \$60 after completing 6-month and 12-month follow-up testing, respectively. We aimed to have 150 participants complete 6-month follow-up testing.

The recruitment period was between April 1, 2004 and January 15, 2008. Recruitment sources of all randomized participants were systematically monitored. Beginning November 17, 2005, recruitment sources were ascertained by asking participants how they learned of the study when their baseline appointment was scheduled. Prior to November 17, 2005, participants were asked how they learned of the study after they were randomized.

Recruitment methods

Not all recruitment sources were used throughout the entire recruitment period. Newspaper advertising, radio advertising, and mailed recruitment letters to patients with PAD identified from Northwestern medical center were employed throughout the recruitment period. Additional methods added during the recruitment period included presentations at Chicago community centers and churches, advertising on Chicago Transit Authority buses and trains, and mailed recruitment postcards to Chicago area residents age 65 and older. Recruitment sources that did not result in randomized participants, such as advertising on the Chicago Transit Authority and presentations at specific community centers, were not further pursued.

Recruiting patients with established PAD from Chicago medical centers. Potential participants were identified from among lists of patients who were diagnosed with PAD in noninvasive vascular laboratories of Chicago-area hospitals and from PAD patients in relevant clinics (vascular surgery, cardiology, general medicine, geriatrics, and endocrinology). This method was employed first at Northwestern and subsequently at other Chicago-area medical centers (Rush Medical center, University of Illinois-Chicago, Jesse Brown Veterans Administration, Mt. Sinai Hospital, St. Joseph's Hospital, and Evanston Northwestern Hospital). Once permission to contact these PAD patients was obtained from the patient's physician, a letter was mailed to the patient describing the study and inviting the patient to call the study's voice-mail line to indicate whether they were interested in participation. If no telephone response was received, up to four mailings were sent at 3-week intervals. Study staff telephoned PAD patients who did not respond to mailings. PAD patients currently participating in other research studies by the same investigative team at Northwestern were not contacted about SILC.

Advertising. Most newspaper advertisements were placed in the Chicago Sun Times (circulation = 312,274) and the Chicago Tribune (circulation = 541,663). Newspaper advertisements were approximately 3.5 × 7 inches in size and were typically placed on pages 2 to 4 of the front section. Radio advertisements were placed on classical

(WFMT), jazz, news (WGN), public radio (WBEZ), and polka music radio stations. Three sets of television advertisements were run at monthly intervals on a local Chicago religious cable television program (WJYS), with a viewership of 3.5 million households. The first two sets of advertisements consisted of 1-minute advertisements that were run four to five times daily for 8 days. The third set of advertisements consisted of 1-minute advertisements that were run one to two times daily for 13 days. Advertisements were posted in Chicago Transit Authority buses and trains.

Mailed postcards to community dwelling residents age 65 and older. Lists of community dwelling men and women age 65 and older in Chicago and the surrounding suburbs were purchased from a local mailing list service. Postcards describing the study were mailed to approximately 72,000 Chicago-area residents age 65 and older. Interested potential participants were asked to call our study voice mail line.

Community outreach. Ankle-brachial index screening was offered at a local church, to identify potentially eligible participants. Lectures about PAD, including information about SILC, were given at community centers that targeted older persons and were sponsored by the Chicago Department on Aging.

Life line screening. Two thousand letters inviting participation in SILC were mailed by Life Line Screening to Chicago-area residents who participated in the Life Line Screening program and had an ABI consistent with PAD. Mailed letters provided a telephone number for potential participants to call about the study.

Miscellaneous. Flyers advertising the study were posted at Chicago hospitals (Northwestern, Rush, University of Illinois, Jesse Brown VA), Chicago-area senior centers, and relevant clinical practices (vascular surgery offices, cardiology clinics, geriatric clinics, and general medicine clinics) at participating medical centers. These flyers were typically colored and 8.5 × 11 inches in size (see [Appendix I](#), online only). PAD participants who completed research studies at Northwestern University and indicated interest in participating in additional research studies were contacted 3 months after completing the previous study and invited to participate.

Measuring recruitment method costs

Financial statements for the grant funding SILC were used to sum expenditures on the recruitment sources (such as advertising) that were measurable. Costs per randomized participant were calculated for methods that incurred a direct charge and resulted in at least two randomized participants. Life Line screening costs included costs of preparing and mailing the recruitment letters.

Inclusion and exclusion criteria

The inclusion criterion was an ankle-brachial index (ABI) ≤ 0.95. Exclusion criteria are shown in [Table I](#). Exclusion criteria were selected because they were likely to prevent the individual from full participation in the interventions; they interfered with our ability to collect com-

Table I. Reasons for exclusion among participants completing a baseline appointment in the study to improve leg circulation

<i>Category of exclusion criterion</i>	<i>Exclusion criteria</i>
Criteria selected because they may interfere with the participant's ability to participate fully in the study interventions (n = 107).	Dementia (n = 6) Above or below knee amputation (n = 1). Critical limb ischemia or foot ulcers (n = 6). Nursing home residence or extreme frailty (n = 8). Inability to walk on a treadmill (n = 5). Inability to speak English (n = 1). Unable/unwilling to come to the medical center three times weekly (n = 57). Failure to complete six run-in exercise sessions in three-weeks (n = 23).
Criteria selected because they may influence study outcomes independently of study participation (n = 14).	Major surgery or a myocardial infarction during the previous three months (n = 2). Major surgery planned during the next year (n = 12). Current participation in other clinical trials (n = 0).
Criterion selected because it limited a potential participant's ability to respond to the intervention (n = 14).	Participant is already exercising at a level comparable to that offered by either exercise arm of the trial (n = 14).
Criteria selected because they indicate that study participation may be unsafe (n = 38).	Unstable angina (n = 6). Baseline stress test consistent with coronary ischemia or indeterminate for presence of coronary ischemia (n = 32).
Miscellaneous exclusion criterion (n = 156)	Walking limited by a condition other than leg ischemia (n = 24). Baseline SPPB = 12 (n = 123). Poorly controlled blood pressure (n = 9)

plete data; they might prevent the participant from improving their functional performance in response to the interventions; they could alter functional performance independently of the exercise intervention; or they indicated that a new exercise program might not be safe. Participants whose walking performance was primarily limited by a reason other than ischemic leg symptoms were excluded.

Ankle-brachial index measurement

Detailed ABI methods have been reported previously and are summarized briefly here.⁷ A hand-held Doppler probe (Nicolet Vascular Pocket Dop II; Nicolet Biomedical Inc, Golden, Colo) was used to obtain systolic pressures in the right and left brachial, dorsalis pedis, and posterior tibial arteries.^{8,9} For each leg, the ABI was calculated by dividing the mean of the dorsalis pedis and posterior tibial pressures by the mean of the brachial pressures.⁸ Participants with an ABI > 0.95 in both legs were excluded.

Treadmill walking performance

Maximal treadmill walking distance and distance to onset of ischemic leg symptoms were measured using the Gardner-Skinner protocol.¹⁰ Treadmill testing also identified potential participants with coronary ischemia for whom initiating an exercise program may not be safe. Therefore, participants whose baseline exercise stress test indicated possible coronary ischemia during exercise were excluded and referred to their physician for follow-up. Some of these participants completed additional stress testing with imaging under their physician's care. If this subsequent stress test demonstrated absence of coronary ischemia, the participant was allowed to return to the study.

Functional performance measures

Six-minute walk. Following a standardized protocol,^{1,2,11,12} participants walk up and down a 100-foot hallway for 6 minutes after instructions to cover as much distance as possible. Participants who stopped during the 6-minute walk test for a symptom other than ischemic leg symptoms (such as shortness of breath or chest pain) were excluded.

Short physical performance battery. The short physical performance battery (SPPB) combines data from usual-paced 4-meter walking velocity, time to rise from a seated position five times, and standing balance. Individuals receive a zero score for each task they are unable to complete. Scores of one to four are assigned for remaining tasks, based upon quartiles of performance for over 6000 participants in the Established Populations for the Epidemiologic Study of the Elderly.^{13,14} Scores are summed to obtain the SPPB, (range 0 to 12).^{13,14} Participants with a baseline SPPB of 12 were excluded. More detailed information about SPPB scoring is provided in [Appendix II](#), online only.

Repeated chair rises. Participants sit in a straight-backed chair with arms folded across their chest and are timed standing five times consecutively as quickly as possible without using their arms.^{13,14}

Standing balance. Participants were asked to hold three standing positions for 10 seconds each: standing with feet together side-by-side and parallel (side-by-side stand), standing with feet parallel with the toes of one foot adjacent to and touching the heel of the opposite foot (semi-tandem stand), and standing with one foot directly in front of and touching the other (tandem stand).^{13,14} Scores range from zero (unable to hold the side-by-side stand for 10 seconds)

to four (able to hold the full tandem stand for 10 seconds).^{13,14}

Four-meter walking velocity. Walking velocity was measured with a 4-meter walk performed at “usual” pace. Participants were instructed to walk at their usual pace, “as if going down the street to the store”.^{13,14}

Comorbidities

Comorbidities were assessed using patient report with questionnaires administered by trained, certified data collectors. Using previously established methods, for each comorbidity, participants were asked, “Has your doctor ever told you that you have . . .”.¹⁵ Comorbidities assessed included angina, diabetes, history of myocardial infarction, pulmonary disease, hypertension, and congestive heart failure.

Other measures

Height and weight were measured, and body mass index (BMI) was calculated as weight (kilograms)/square of height (meters²). Cigarette smoking history was determined by patient report.

Statistical analyses

Descriptive statistics were used to provide mean characteristics of study participants and randomization rates among those completing a baseline visit. χ^2 testing was used to compare the statistical significance of differences in randomization rates across recruitment sources.

RESULTS

Of 746 potential participants who completed a baseline visit, 261 did not meet our inclusion criterion of $ABI \leq 0.95$. Of the remaining 485 individuals completing a baseline visit, 329 met an exclusion criterion (Table I), leaving 156 eligible, randomized participants.

The most frequent reason for exclusion among participants with a baseline $ABI \leq 0.95$ was a baseline SPPB score of 12 ($n = 123$) (Table I). Unwillingness to return to the medical center three times weekly for exercise sessions was the second most common reason for exclusion ($n = 57$). Of the 24 participants excluded because their walking was limited by a condition other than PAD, 16 were primarily limited by dyspnea, two were limited by knee pain, two had foot drop, one was primarily limited by back pain, one had polio, one had a spinal injury, and in one case the limiting condition was not recorded.

Characteristics of the 156 randomized participants are shown in Table II. The average age of participants was 70.6 years \pm 10.3 and the average ABI was 0.61 \pm 0.17. Participants included 52% women and 40% African-Americans.

Randomized participants came from 15 distinct sources (Fig 1). The five most common recruitment sources were newspaper advertisements ($n = 67$), mailed letters to patients with documented PAD identified at Northwestern medical center ($n = 25$), radio advertisements ($n = 18$), bulk mailings to community dwelling Chicago-area resi-

Table II. Characteristics of randomized participants ($n = 156$)

Characteristic	Mean value
Age (SD)	70.6 y (10.3)
ABI (SD)	0.61 (0.17)
BMI (SD)	30.2 (6.8) kg/m ²
Male	48%
African American	40%
History of myocardial infarction	22%
Angina	12%
Heart failure	14%
Hypertension	82%
Diabetes mellitus	44%
SPPB score (0-12, 12 = best)	8.7 (2.4)
Six-min walk	316.2 (87.7) m
Maximum treadmill distance	370.2 (215.7) m
Initial treadmill distance	151.6 (119.3) m

SD, Standard deviation; ABI, ankle-brachial index; BMI, body mass index; SPPB, short physical performance battery.

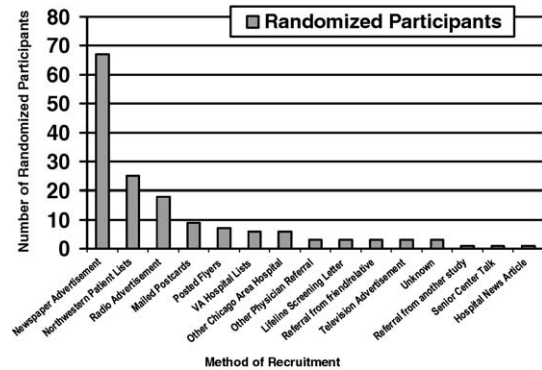


Fig 1. Recruitment sources of randomized participants ($n = 156$).

dents age 65 and older ($n = 9$), and posted flyers ($n = 7$) (Fig 1). Twelve randomized patients were identified from mailed letters to patients with documented PAD at medical centers other than Northwestern, including six identified from the Jesse Brown VA hospital. There were no statistically significant differences in randomization rates from each recruitment source ($P = .92$).

The highest responses to newspaper advertisements in the Chicago Sun Times and the Chicago Tribune came from advertisements located within the first four pages of the newspaper. Newspaper advertisements placed in other sections, such as the health or women’s sections, yielded few calls. Mailed recruitment letters to 2000 local Life Line Screening participants with a low ABI yielded approximately 80 telephone calls and 18 scheduled baseline visits. Three of these were ultimately randomized. Only one participant was randomized from community outreach programs. Advertisements on Chicago Transit Authority buses and trains resulted in no randomized participants.

Most recruitment sources yielded similar rates of randomized patients among participants completing a baseline

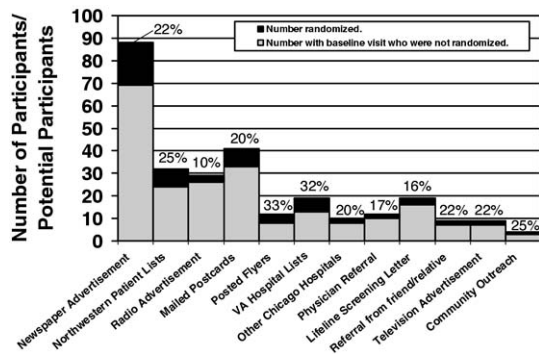


Fig 2. Percent of participants randomized among those completing a baseline visit according to recruitment source (n = 156). *Data were collected after November 16, 2005 when the number of baseline visits per recruitment source was systematically tracked.

visit (Fig 2). However, among those completing a baseline visit, only 10% of individuals identified from a radio advertisement were randomized.

Table III shows recruitment sources for two of the most frequently encountered reasons for exclusion. Newspaper advertisements and mailed recruitment letters were the most frequent recruitment sources for patients excluded because of an ABI > 0.95 or an SPPB of 12. Many patients responding to newspaper advertisements did not have documented PAD. Potential participants with risk factors and symptoms of PAD were invited to schedule a baseline visit and undergo ABI measurement to determine eligibility. Some potential participants with a history of PAD who were contacted with a recruitment letter had undergone lower extremity revascularization or had poorly compressible lower extremity arteries, resulting in ABI values > 0.95 at their study visit.

Table IV shows average cost per randomized participant in a subset of randomization sources. Radio advertising had the highest cost per randomized participant, while Life Line Screening had the lowest cost per randomized participant.

DISCUSSION

Fifteen distinct recruitment sources were enlisted to enroll 156 participants in a randomized controlled clinical trial of exercise in persons with PAD. Sixty-five percent of randomized participants were identified from two sources: newspaper advertisements and mailed recruitment letters to patients with PAD identified from Chicago medical centers. Presentations at community outreach programs for senior citizens, with or without ABI screening, yielded few randomized participants. No randomized participants were identified from advertisements in Chicago Transit Authority buses and trains.

Recruitment methods were employed with varying frequency. We tended to re-use the most successful recruitment methods. However, decisions made by study investigators regarding when and how to recruit participants are

likely to have influenced the success of specific recruitment methods. Unmeasured characteristics may also have influenced the recruitment experience in SILC. For example, the protocol allowed payment of up to \$85 per day for transportation to on-site study sessions. This transportation benefit may have favorably influenced participation of some randomized subjects. In addition, higher recruitment rates of PAD patients from Northwestern Memorial Hospital and the Northwestern-affiliated Jesse Brown VA compared with other Chicago-area hospitals are likely related to the fact that the principal investigator was based at Northwestern University.

To our knowledge, no prior manuscripts have described recruiting experiences for clinical trials of patients with PAD. A previous letter-to-the-editor described the recruitment experience of the Exercise vs Angioplasty in Claudication Trial (EXACT) of participants with PAD, a multicenter, randomized-controlled clinical trial designed to compare lower extremity balloon angioplasty with best medical therapy and supervised exercise in persons with PAD.⁴ EXACT was terminated early because of failure to recruit sufficient numbers of PAD participants. EXACT investigators identified potential participants from primary care physician referrals, but did not use any additional recruitment sources. In the present study, using multiple recruitment sources was essential to achieving recruitment goals.

Previous reports about recruiting individuals without PAD for randomized clinical trials underscore the potential impact of exclusion criteria on the ability to enroll participants. This phenomenon was observed in EXACT⁴ and in the present study. Our decision to exclude potential participants with a baseline SPPB score of 12 resulted in exclusion of 123 men and women who otherwise may have been eligible for this trial. However, our exclusion criterion of failure to complete the exercise run-in period is likely to have reduced study drop-out rates.

This study has limitations. First, SILC was a randomized controlled clinical trial of exercise therapies in patients with PAD. Some features of this trial, such as the requirement that participants be willing to attend exercise sessions three times weekly at the medical center, may not be applicable to clinical trials testing medications or revascularization procedures in patients with PAD. Secondly, we did not systematically collect information on recruitment sources of excluded participants for the first 19 months of recruitment. Third, it is conceivable that some participants may have been identified and recruited by more than one source. This phenomenon may have enhanced the effectiveness of recruitment sources that represented a participant's second or third exposure to study information. Fourth, we did not keep track of the number of flyers placed or the number of telephone calls received in response to an advertisement when the telephone call did not result in a baseline visit. Finally, this study was conducted in Chicago, and findings may not be entirely applicable to other communities in the United States.

Table III. Recruitment sources for all excluded participants and for potential participants excluded because of ineligible ankle-brachial index or short physical performance battery scores

Recruitment sources	All excluded participants (number/percent)	Participants excluded due to ABI > 0.95 (number/percent)	Participants excluded due to SPPB score = 12
Newspaper advertisement	69 (24.7%)	28 (28.3%)	20 (32%)
Mailed recruitment letters	45 (16.1%)	14 (14.1%)	11 (17.7%)
Bulk mail postcard	33 (11.6%)	13 (13.1%)	4 (6.4%)
Radio advertisement	26 (9.3%)	10 (10.1%)	7 (11.3%)
Life Line screening letter	16 (5.7%)	3 (3%)	3 (4.8%)
Physician referral	10 (3.9%)	1 (1%)	4 (6.5%)
Posted flier	8 (2.9%)	3 (3%)	2 (3.2%)
Another study participant	7 (2.5%)	4 (4%)	2 (3.2%)
Television advertisement	7 (2.5%)	5 (5%)	0 (0%)
Northwestern PAD recruitment database	6 (2.2%)	2 (2%)	2 (3.2%)
Senior center presentation.	3 (1.1%)	2 (2%)	1 (1.6%)
Catholic church bulletin	1 (0.36%)	1 (1%)	0 (0%)
Chicago transit authority advertisement.	1 (0.36%)	0 (0%)	0 (0%)
Unknown	27 (9.7%)	13 (13.1%)	6 (9.7%)
Total	279 (100%)	99 (100%)	62 (100%)

ABI, Ankle-brachial index; SPPB, short physical performance battery; PAD, peripheral artery disease.

Table IV. Recruitment method costs per randomized participant

Recruitment method	Cost per randomized participant
Radio advertisement	\$5691
Mailed postcards to community dwelling men and women age 65 and older	\$3931
Television advertisement	\$2750
Newspaper advertisement	\$2369
Life Line screening	\$2167

Costs estimated based on billing data and number of participants recruited from each source.

In conclusion, successful recruitment of patients with PAD for randomized controlled clinical trials may require multiple recruitment sources. Newspaper advertisements placed in the first four pages of major newspapers and direct mailings to patients with established PAD identified from local hospitals were the most successful recruitment methods for SILC. Information about successful recruitment strategies is necessary to ensure sufficient enrollment in clinical trials involving patients with PAD, in order to identify therapies that improve functional performance and prevent functional decline in persons with PAD.

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AUTHOR CONTRIBUTIONS

Conception and design: MM, KD, AD, PA, MC
Analysis and interpretation: MM, KD, AD, PA, MK, MC
Data collection: KD
Writing the article: MM, KD
Critical revision of the article: MM, KD, AD, PA, MK, MC
Final approval of the article: MM, KD, AD, PA, MK, MC

Statistical analysis: AD
Obtained funding: MM
Overall responsibility: MM

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

APPENDIX I, online only.

RECRUITMENT LETTER
Improving Functioning in Peripheral Arterial Disease
Northwestern University Feinberg School of Medicine

2/23/06

[patient address]

Dear [patient],

I am writing to see if you would be willing to participate in an important research study. We are studying the ability of certain types of exercise to improve walking in patients with blood flow problems to the legs. Your physician at Northwestern, Dr. _____, told me that you might be willing to help us with this research project.

If you are eligible for this study, you would be assigned by chance to one of three study groups: a) walking exercise with a trainer; b) leg strengthening exercise with a trainer; c) nutrition group sessions with a dietician. The study lasts for one year. During the first six months you would come down to Northwestern medical center for your participation. During the second 6 months, we will help you continue your exercise or nutrition activities at home.

If you choose to participate and if you are eligible for the study, you will be scheduled for an initial appointment at Northwestern Memorial Hospital. This appointment will take approximately 2.5 to 3.0 hours. During this visit you will be interviewed about your health history. Your blood flow will be measured by comparing the blood pressure in your legs to the blood pressure in your arms. Your walking speed, balance, and leg strength will be measured and you will be asked to complete an exercise stress test.

All exercise and education sessions will be provided free of charge. Study-related transportation and parking will be paid for. If you complete the entire study you will receive \$170.

A research assistant will be contacting you by telephone to discuss whether you want to be in the study. If you are interested in participating, please call (312) 695-2394

If you do not want to be called, please leave a message at (312) 695-2394, and we will not bother you.

Sincerely,

Mary McDermott, MD

**Template used for flyers, newspaper
advertisements and mailed bulk
postcards**

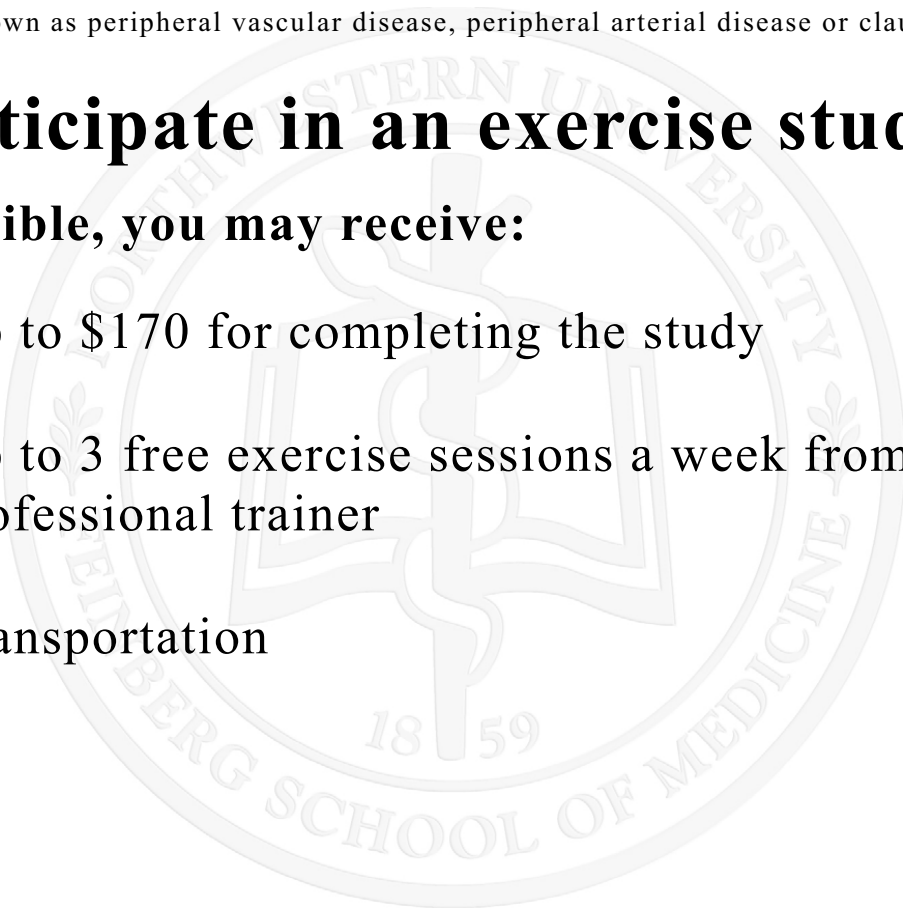
Do you have arterial blood flow problems to your legs?

Also known as peripheral vascular disease, peripheral arterial disease or claudication

Participate in an exercise study!

If eligible, you may receive:

- Up to \$170 for completing the study
- Up to 3 free exercise sessions a week from a professional trainer
- Transportation





Study in Leg Circulation (SILC)
Northwestern University Feinberg School of Medicine

**For more information,
call us at 312-695-2394**

Principal Investigator: Mary McDermott, MD

IRB # 344-008

SCRIPT FOR RADIO ADVERTISEMENT

Do you have poor blood flow to the legs?

Doctors at Northwestern University's Feinberg School of Medicine are conducting a Research Study on adults with poor **arterial** blood flow to their legs.

Most participants will meet with an exercise trainer 3 times a week. The study will focus on ways to improve walking ability.

Candidates must have documented **arterial** blood flow problems to the legs.

Eligible participants are paid up to \$170. Transportation provided.

Call 3 1 2 - 6 9 5 - 2 3 - 9 4. 3 1 2 - 6 9 5 - 2 3 - 9 4. That's 6 9 5 - 2 3 - 9 4.

APPENDIX II online only.

Criteria for scoring the short physical performance battery (SPPB)*

<i>Components of the SPPB</i>	<i>SPPB score</i>	<i>Criteria for the score</i>
Repeated chair rises	0	Unable
	1	≥ 16.7 s
	2	13.7-16.6 s
	3	11.2-13.6 s
	4	≤ 11.1 s
Standing balance	0	Unable to perform the side-by-side stand.
	1	Unable to hold the semi-tandem stand for 10 s.
	2	Held the semi-tandem stand for 10 s, but held the tandem stand for < 3 s.
	3	Held the semi-tandem stand for 10 s and held the tandem stand for ≥ 3 s but < 10 s.
Walking velocity	4	Able to hold the tandem stand for 10 s.
	0	Unable to walk 4 m..
	1	< 0.46 m/s
	2	0.47-0.64 m/s
	3	0.65-0.82 m/s
4	≥ 0.83 m/s	

*From Guralnik JM, Ferrucci L, Pieper CF, Leveille SG, Markides KS, Ostir GV, et al. Lower extremity function and subsequent disability: Consistency across studies, predictive models, and value of gait speed compared with the short physical performance battery. *J Gerontol A Biol Sci Med Sci* 2000;55:M221-31.