Effectiveness of Group Walking Sessions for Increasing Activity in People With Peripheral Arterial Disease (The Group Oriented Arterial Leg Study [GOALS])

This study is ongoing, but not recruiting participants.

Sponsor:
Northwestern University

Collaborator:
National Heart, Lung, and Blood Institute (NHLBI)

Information provided by (Responsible Party):
Mary McDermott, Northwestern University

ClinicalTrials.gov Identifier:
NCT00693940

First received: June 5, 2008
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History of Changes

Purpose

Lower extremity peripheral arterial disease (PAD) is a disease in which fatty build-up, or plaque, accumulates in the arteries of the legs. People with lower extremity PAD often experience leg pain while walking, which is caused by reduced blood flow to the legs. Regular walking has significant benefits for people with blood flow problems in their legs, but previous studies have shown that most men and women with PAD do not walk for exercise on a regular basis. A group home-based walking program may help people with PAD to walk more often and improve their lower extremity functioning. This study will evaluate the effectiveness of a home-based group mediated cognitive behavioral (GMCB) exercise program in helping people with lower extremity PAD to increase their walking frequency and improve their lower leg functioning.

Condition	Intervention	Phase
Peripheral Vascular Diseases Cardiovascular Diseases	Behavioral: Group mediated cognitive behavioral (GMCB) sessions Other: Health education sessions	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Single Blind (Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Increasing Activity in Peripheral Arterial Disease

Resource links provided by NLM:

MedlinePlus related topics: Exercise and Physical Fitness Peripheral Arterial Disease Vascular Diseases

U.S. FDA Resources

Further study details as provided by Northwestern University:

Primary Outcome Measures:

- 6-minute walk test at 6 month follow-up [Time Frame: Measured at baseline and Month 6 follow-up] [Designated as safety issue: No]

Secondary Outcome Measures:

- Treadmill walking performance [Time Frame: Measured at baseline and Month 6 follow-up] [Designated as safety issue: No]
- Health-related quality of life measures [Time Frame: Measured at baseline, Month 6, and Month 12 follow-up] [Designated as safety issue: No]
- Physical activity levels [Time Frame: Measured at baseline, Month 6, and Month 12 follow-up] [Designated as safety issue: No]
- 6-minute walk test at Month 12 follow-up [Time Frame: Measured at Month 12 follow-up] [Designated as safety issue: No]

Estimated Enrollment: 200
Study Start Date: June 2008
Primary Completion Date: December 2012 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 Participants will receive treatment with group mediated cognitive behavioral sessions.	Behavioral: Group mediated cognitive behavioral (GMCB) sessions GMCB will include weekly group exercise sessions, lasting approximately 60 to 75 minutes each for a 6 month period. During these sessions, participants will be asked to exercise by walking around a track. There will also be a group discussion, led by a facilitator, who will help participants find ways to increase the frequency of their walking exercise at home. After completing the GMCB sessions, which will last about 6 months, participants will be telephoned regularly by a study coordinator for another 6 months.
Active Comparator: 2 Participants will receive treatment with health education sessions.	Other: Health education sessions Health education will include weekly educational sessions on a health-related topic, lasting approximately 60 minutes each. After completing the health education sessions, which will last about 6 months, participants will be telephoned regularly by a study coordinator for another 6 months.

Detailed Description:

Lower extremity PAD affects between 10% and 15% of people over the age of 65. A person's risk for PAD increases with age but can also be raised by smoking or having diabetes, high blood pressure, high cholesterol, or heart disease. PAD symptoms may include leg pain, foot or toe wounds, and a noticeably lower temperature in the lower legs than in the rest of the body. The specific functional impairments caused by PAD symptoms are associated with increased risks of disability, nursing home placement, mobility loss, hospitalization, and mortality. Supervised exercise rehabilitation programs have been shown to improve walking ability in people with PAD. However, few people with PAD have access to supervised exercise rehabilitation programs because of costs and difficulty traveling to the exercise facility. Home-based exercise programs may be more beneficial than supervised programs in improving lower extremity functioning in people with PAD, but more information is needed to support the effectiveness of at-home rehabilitation. This study will compare the effectiveness of a home-based GMCB exercise program versus general health education sessions in helping people with lower extremity PAD to increase their walking frequency and improve their lower leg functioning.

Participation in this study will last 12 months. The primary outcome will be measured at 6 month follow-up. All participants will undergo a baseline 6-minute walk test on a treadmill and an electrocardiogram (ECG). They will also provide information on their physical activity levels. Participants will then be assigned randomly to receive GMCB sessions or health education sessions. Both groups will attend weekly sessions of their assigned treatment for a 6 month period. During the GMCB sessions, participants will be asked to exercise by walking around a track. There will also be a group discussion, led by a facilitator, who will help participants find ways to increase the frequency of their walking exercise at home. Each GMCB session will last approximately 60 to 75 minutes. Health education sessions will last 60 minutes and will cover health-related topics.

After completing approximately 6 months of treatment, participants in both groups will be telephoned regularly by a study coordinator: they will receive telephone calls every other week during Months 6 to 9 of follow-up and monthly during Months 9 to 12 of follow-up. Participants will be asked to return for follow-up testing at Month 6 and Month 12; outcomes measured at Month 6 are highest priority.

Eligibility

Ages Eligible for Study: 25 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Have PAD
- Potential participants with a resting ABI greater than or equal to 0.91 and less than or equal to 1.00 at their baseline visit will be eligible if their ABI drops by at least 20% after the heel-rise test. Potential participants with a resting baseline ABI greater than 0.91 who do not meet criteria for inclusion based on the heel-rise test can be eligible if they have data from a certified non-invasive vascular laboratory that demonstrates presence of lower extremity ischemia. However, more evidence than an abnormal PVR from the non-invasive vascular laboratory is required (for example, a toe brachial index pressure less than 0.60). Finally, potential participants who do not meet the above criteria for inclusion will be eligible if they have an angiogram demonstrating greater than 50% stenosis on one or more lower extremity arterial vessels.

Exclusion Criteria:

- Below or above knee amputation
- Wheelchair confinement
- Uses a walking aid other than a cane (e.g., walker)
- Unable to return to the medical center at the required visit frequency
- Greater than Class II New York Heart Association heart failure or angina (symptoms at rest or with minimal exertion)
- Any increase in angina pectoris symptoms during the 6 months before study entry or angina at rest
- Presence of a foot ulcer
- Lower extremity revascularization or major orthopedic surgery during the 3 months before study entry
- Heart attack or coronary artery bypass grafting during the 3 months before study entry
- Major medical illnesses, including treatment for cancer (except non-melanoma skin cancer) during the 12 months before study entry
- Planned lower extremity revascularization within the 12 months after study entry
- Current participation in another clinical trial
- Walking for exercise at a level comparable to that targeted in the study's intervention
- Completion of a cardiac rehabilitation program within 3 months before study entry
- Coronary ischemia during exercise, defined as ST segment depression greater than 1 mm during the baseline exercise treadmill test, with or without associated chest discomfort
- Left-bundle branch block or significant ST-T wave changes on the baseline ECG without a perfusion stress test, demonstrating no reversible ischemia within the 3 months before study entry
- Stopping during the treadmill exercise stress test because of chest pain, shortness of breath, hip or knee arthritis. These individuals will be interviewed by the principal investigator and will be excluded only if it is determined that their walking performance (based in part on the treadmill test) is limited by a comorbidity other than leg ischemia.
- Unable to walk at least 50 feet without stopping during the 6-minute walk test
- Stopping during the 6-minute walk test for symptoms other than ischemic leg symptoms
- Mini-Mental Status Examination (MMSE) score of less than 23 or psychiatric illness
- Failure to complete a study run-in period
- Parkinson's disease
- Requires oxygen with exertion.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00693940

Locations

United States, Illinois

Northwestern University Feinberg School of Medicine
Chicago, Illinois, United States, 60611

Sponsors and Collaborators

Northwestern University

National Heart, Lung, and Blood Institute (NHLBI)

Investigators

Principal Investigator: Mary M. McDermott, MD Northwestern University

More Information

No publications provided by Northwestern University

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

McDermott MM, Liu K, Guralnik JM, Criqui MH, Spring B, Tian L, Domanchuk K, Ferrucci L, Lloyd-Jones D, Kibbe M, Tao H, Zhao L, Liao Y, Rejeski WJ. Home-based walking exercise intervention in peripheral artery disease: a randomized clinical trial. JAMA. 2013 Jul 3;310(1):57-65. doi: 10.1001/jama.2013.7231.

Responsible Party:	Mary McDermott, Principal Investigator, Northwestern University
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Health Authority:	United States: Federal Government

Keywords provided by Northwestern University:
Peripheral Arterial Disease
PAD

Additional relevant MeSH terms:

Cardiovascular Diseases	Atherosclerosis
Vascular Diseases	Arteriosclerosis
Peripheral Vascular Diseases	Arterial Occlusive Diseases
Peripheral Arterial Disease	

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TO TOP

For Patients & Families | For Researchers | For Study Record Managers

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