CONSENT FORM

Title of Research: Physical Activity Daily: An Internet-Based Walking Program for Patients with Peripheral Arterial Disease

UAB IRB Protocol #: IRB-300001012

Principal Investigator: Elizabeth Jackson, M.D.

Sponsor: National Institutes of Health (NIH)

Purpose of the Research

This research study aims to help people with peripheral arterial disease (PAD) and who do not walk much now, to start and continue a walking program. Many studies have shown that walking can reduce the pain that PAD patients feel in their legs when they walk. In some studies, walking has been shown to be as good as or better than medications and surgery for reducing pain with walking (also called claudication). Walking can also help people increase the distance they can walk. We also know that giving people feedback about how much they are exercising can be helpful in getting them to walk more. This study uses pedometers. A pedometer is a small device you wear at your waist that counts steps. It also uses weekly step count goal, and a personalized website with motivational tips and an online message board to increase walking gradually. We are looking to compare an Internet-supported home-based walking program to a home-based program that uses regular phone calls from an exercise specialist.

This study is looking for people who are sedentary, at least 40 years old with lower extremity PAD and regular computer access. This study is not open to people with certain types of PAD or those people with unstable medical conditions.

We plan to enroll 50 subjects here at the University of Alabama at Birmingham (UAB).

Explanation of Procedures

You will be randomized to one of 4 groups, which means you are put into a group by chance (like the flip of a coin). The 4 groups are:

1. Home-based walking program with regular phone calls from an exercise specialist
2. Home-based walking program with Internet support
3. Combined program with both regular phone calls and Internet support
4. Usual care – you will receive the Internet program at the end of your participation

Before you start the study, you will need to have your healthcare provider sign a medical clearance form to be sure it is alright for you to participate. You can download the form at our website or we can send it to you.

Study visits

You will visit UAB 3 times:

1) once at the start of the study
2) once after 4 months
3) once after 12 months

At the first visit we will ask you to sign a copy of this form and we will scan it into your medical record. We will measure your height and weight. You will complete online surveys at each visit.

At *each visit* you will do treadmill testing with Ankle-Brachial Index/Toe-Brachial Index (ABI/TBI) testing, online surveys, 6-minute walk testing, and strength testing:

1) Treadmill with ABI/TBI testing

The treadmill with ABI/TBI testing at the first visit will be used to confirm that you have PAD. For treadmill with ABI/TBI testing we will:

1. Measure your blood pressure in both arms.
2. Measure your blood pressure in either your ankles and/or toes.
3. Have you perform a supervised treadmill test. This test is a standard test used to see how long and how far you can walk. The speed or grade of the treadmill will increase every 2 minutes. We will monitor your heart rate and blood pressure during the test. For the treadmill test at your first visit, we will do an ECG while you are on the treadmill. The ECG involves putting pads on your chest area, arms and legs so we can measure your heartbeats. If you have a lot of hair, we may need to shave you so the pads will stick to your skin.
    - You will walk on the treadmill until you start to feel pain in your legs. We will note the time and distance you walk.
    - You will continue walking until you feel moderate pain and we will stop the test. We will note the time and distance you walk.
    - If you don't have any pain, you will walk until you feel you cannot walk any further.
4. Measure your blood pressure in both arms after the treadmill test.
5. Measure your blood pressure in either your ankles and/or toes after the treadmill test.

2) Online surveys

After you complete treadmill with ABI/TBI testing you will complete online surveys. The surveys will take about 15-30 minutes to complete. You do not have to answer any questions you do not want to.

3) 6-minute walk testing

After you complete the online surveys, you will do a 6-minute walk test. The purpose of the 6-minute walk test is to see how far you can walk in 6 minutes. For the test we will ask you to walk in a hallway and to cover as much ground as possible. We will want you to walk continuously if you can but you can slow down or stop and rest if you need to. The goal is to feel at the end of the test that more ground could not have been covered in the 6 minutes.

Before and after the test we will measure your blood pressure and heart rate. We will also measure the amount of oxygen in your blood. This is a painless test where we clip a small plastic device about the size of a large clothespin on your finger for about 15 seconds. It sends light through your finger and the light that comes out on the other side is measured.

4) Strength testing

We will test 3 different measures of strength: your usual walking speed, your handgrip strength, and your feelings of tiredness. To test your walking speed, we will have you walk at your own comfortable pace for about 15 feet. You will do this 3 times with a little rest break in between each round. To test your handgrip, you will squeeze our handgrip tester as hard as you can for 2-3 seconds. You also do this 3 times with a little rest break in between each test. Finally, we will ask you 2 questions about your feelings of tiredness.

We will assign you to a group at the end of your first visit. You will then do the following:

Month	Group 1	Group 2	Group 3	Group 4
1-4	Walk regularly according to exercise prescription Wear pedometer every day Weekly phone calls with exercise specialist Bi-weekly education modules to promote walking Practice skills learned in modules	Wear pedometer every day Receive weekly walking goals via email Walk regularly according to weekly goals Access to online community of other participants and research staff You can post messages or questions and be eligible to participate in games or contests to promote walking	Everything from Group 1 and Group 2 combined: Wear pedometer & receive weekly walking goals via email Walk regularly according to weekly goals Weekly phone calls with exercise specialist & bi-weekly education modules; practice skills Access to online community & post messages or questions; be eligible to participate in games/contests	Continue with your usual medical care and activities
4	Follow-up testing: repeat treadmill with ABI/TBI testing, online surveys, and 6-minute walk			

Month	Group 1	Group 2	Group 3	Group 4	
4-12	Continue with usual daily activities, including walking Wear pedometer every day		Continue with usual daily activities, including walking Wear pedometer every day Receive weekly walking goals via email Access to online community of other participants and research staff You can post messages or questions	Continue with usual daily activities, including walking Wear pedometer every day Receive weekly walking goals via email Access to online community of other participants and research staff You can post messages or questions	Continue with your usual medical care and activities
12	Follow-up testing: repeat treadmill with ABI/TBI testing, online surveys, and 6-minute walk				
			Access to Internet program for walking & online community for duration of study	Access to Internet program for walking & online community for duration of study	Receive pedometer Access to Internet program for walking & online community for duration of study

<u>Pedometer information</u>

If you are in Group 1, 2 or 3, we will give you a pedometer after your first visit. You will wear it every day for 12 months. The pedometer will record all the walking you do during the day. For the first week, the pedometer will have a sticker over the front of the display. We want you to do your usual activities so we can determine how many steps you currently take each day.

You will download software from the fitbit.com website once. The software will let you upload your steps wirelessly through the USB port on your computer when you are near your computer and connected to the Internet. Your steps will upload to the fitbit.com website but you will not use that website during the study. You will use our study website which will import your steps from fitbit.com.

You will visit UAB 3 times. The first visit will take about 2-½ to 3 hours. The second and third visits will each take about 2 to 2-½ hours.

Your participation in the study will be over in 12 months. The entire study is expected to last 5 years.

Risks and Discomforts

The known or expected risks and what we will do to protect you against these risks are as follows:

Loss of confidentiality (rare)
Any time information about you is collected and stored electronically there is a chance that someone who is not supposed to have access to it will gain access. We store data using the latest security measures.
These measures include an encrypted website that is on a secure, password protected server. Any emails we send you will include only the minimum amount of information needed. These emails will be unencypted which means that the emails can potentially be viewed by unauthorized parties who are not the senders of the intended recipient. Data on paper will be stored in a locked filing cabinet in a locked office. Only research staff will have access to study documents.

Risk related to interaction with other participants (Internet-based groups) (rare)
You may be interacting with other participants on the website. In most cases, this interaction will be to share information, and to give and receive support during the study. You may find something another participant posts to be uncomfortable or unpleasant. If this happens, please let us know. If a participant is demonstrating abusive behavior towards other participants, he or she may be removed from the study.

We will be able to delete and edit posts, as well as lock specific users out of the study website temporarily or permanently.

Risk related to disclosure of personal information on the Internet (Internet-based groups) (infrequent)
Participants in the Internet-based groups will be able to post messages in the online community on the website for other participants to read. If you are in one of these groups, other participants will be able to see the username you choose, as well as any information you enter into your profile and the text of any posts you make on the message boards. It is up to you what information you want to share on the message boards. It is possible you may share some personal information about yourself, and then later change your mind. If you would like something you posted removed, let us know and we can remove it. Prominent warnings will be posted in the public areas of the website in the online community to remind you that it is a semi-public environment.

Risk related to depression or anxiety (rare)
Patients with chronic diseases including PAD have higher risks for depression and/or anxiety. If you feel any psychological distress while completing the online surveys or anytime during the study, you may contact us. We have a phone line that will be answered by study staff during normal business hours. An answering machine will have referral numbers for you to call at other times.

If you report mild, moderate or severe depression in the online surveys, we will contact you and offer a referral for psychiatric evaluation. We will inform your doctor about the results of that survey with your permission. If at any time you feel suicidal, we will refer you for immediate evaluation with your doctor or an emergency psychiatric provider.

Risk related to musculoskeletal injury (infrequent)
Walking programs are much less likely than more vigorous exercise programs to result in minor musculoskeletal injury. However, musculoskeletal injuries can occur even in walking programs. By

gradually increasing the duration and walking speed over the course of several weeks, musculoskeletal injury will be reduced to the minimum level possible.

Risk related to treadmill walking (rare)
You will be walking on a motorized treadmill and there is a risk of falling off the treadmill. By gradually increasing the speed of the treadmill, risk of falling will be reduced to the minimum level possible. At any time, you may stop the treadmill or ask the attending exercise physiologist to stop it for you.

Risk related to your heart (rare)
Patients with PAD may have vascular disease in other parts of their bodies such as their heart. On average, people live longer if they participate in regular physical activity like a walking program. However, it is possible that you will have a problem with your heart during or just after walking. To minimize this risk, we recommend a moderate level or less of exercise (such as walking) rather than a vigorous level of exercise (such as running). Your step count goals and/or PAD rehab sessions are based on your baseline walking level. Your step count goals are gradually increased but may also be decreased each week depending on your prior step counts.

If you currently have heart problems, the risk of starting a walking program may outweigh the benefits. To protect against the risks, before you start a walking program, we will require that you obtain medical clearance from your doctor, who can evaluate your medical condition, and decide whether it is safe and beneficial for you to start a walking program.

Risks related to hydration (rare)
If you are on fluid restriction or diuretics you may have trouble hydrating sufficiently when walking in hot weather. If you are on fluid restriction or diuretics, you will be referred to your doctor for an appropriate hydration plan.

Risks related to breathing (infrequent)
You may experience shortness of breath while walking. This could be a sign of heart problems, but in most cases it is likely to be low fitness. In some cases it could be related to exercise-induced asthma or other lung problems. If you report shortness of breath of unknown cause while walking, you will be referred to your doctor for evaluation and treatment.

Risks related to blood pressure control (infrequent)
Starting an exercise program may lower your blood pressure. If you take medication to lower your blood pressure, you may need to have your blood pressure medication adjusted as you progress in the program. Likewise, if you have poorly controlled blood pressure, you may experience raised blood pressure as you progress in the program. If you report blood pressure symptoms, you will be referred to your doctor for further evaluation and medication adjustments.

Risks related to diabetes (infrequent)
If you have diabetes you may have some specific risks associated with walking, including lowered blood sugar and problems with your feet, such as ulcers or sores. If you have diabetes, you will be provided textual information to teach you about exercising safely with diabetes and will be referred to your doctor for further evaluation and medication adjustments as necessary.

Risks related to leg or buttocks pain (common)

You may have leg or buttock aching, pain or cramps while you are walking. During the treadmill test, you will determine when to stop the test. During the 6MWT, you will determine the intensity of the test and can stop and rest as needed or stop the test before 6 minutes have elapsed if you choose. Research has shown that for PAD patients, pain while walking does not cause physical damage.

Risks related to the ECG (rare)

You may experience minor discomfort similar to removing a bandage when the electrodes are removed. Redness or a mild rash where the electrodes were attached may occur. Redness and/or rash often go away without treatment. To minimize the risks, the pads will be placed and removed by an experienced exercise physiologist. In the case of any ongoing rash or discomfort, you will be referred to your doctor for follow-up.

Risks associated with randomization

You will be assigned to a group by chance, which may prove to be less effective or to have more side effects than the other study group or alternatives.

Risks Associated with each study arm

1. Home-based walking program with regular phone calls from an exercise specialist
    - No specific risks associated with this arm as compared to other arms
2. Home-based walking program with Internet support
    - Risks associated with potential loss of confidentiality due to interactions with other participants and personal information on the internet
3. Combined program with both regular phone calls and Internet support
    - Risks associated with potential loss of confidentiality due to interactions with other participants and personal information on the internet
4. Usual care
    - No specific risks associated with this arm as compared to other arms

Benefits

You may not receive any personal benefits from being in this study. However, you may see improvements in the distance you can walk and a decrease in pain with walking. You may see improvements in blood sugar control (for diabetics), blood pressure control and/or lipid levels. You may have improved weight control (for those who are overweight) and management and/or prevention of chronic disease in general. You may experience an improvement in mood.

Others may benefit from what we learn in this study about designing a sustainable walking program for people with PAD.

Alternatives

Your alternative is to not participate in this research study. This study is not part of your treatment.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- The UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.

National Institutes of Health (NIH)

- The Office for Human Research Protections (OHRP)

The information from the research may be published for scientific purposes; however, your identity will not be given out.

Your consent form will be placed in your medical record at UAB Health System. This may include either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your care within this health system. Your EMR may indicate that you are on a clinical trial and provide the name and contact information for the principal investigator.

If you are receiving care or have received care within this health system (outpatient or inpatient) and are participating in a research study, results of research tests or procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing medical record.

If you have never received care within this health system (outpatient or inpatient) and are participating in a research study, a medical record will be created for you to maintain results of research tests or procedures.

Results of research tests or procedures may be placed in your medical record. All information within your medical record can be viewed by individuals authorized to access the record.

Information relating to this study, including your name, medical record number, date of birth and social security number, may be shared with the billing offices of UAB and UAB Health System affiliated entities so costs for clinical services can be appropriately paid for by either the study account or by your insurance.

Monitors, auditors, the Institutional Review Board for Human Use, and regulatory authorities will be granted direct access to your original medical records for verification of trial procedures and/or data without violating confidentiality.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

You may be removed from the study without your consent if the sponsor ends the study, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study.

Payment for Participation in Research

You will get $10 after you complete the baseline visit; $30 after you complete the 4-month visit if you have one and finally you will get $100 after you complete the 12-month visit for a total of $140. .

You will get a pedometer to keep. If you are in Arms 1, 2 or 3, you will get the pedometer at your first visit. If you are in Arm 4, you will get the pedometer at your 12-month visit.

Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

Payment for Research-Related Injuries

UAB has not provided for any payment if you are harmed because of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Significant New Findings

You will be told by your doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions/Contact Information

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, you may contact Dr. Jackson. She will be glad to answer any question. Dr. Jackson's phone number is 205-975-7123 or 205-934-3411 (24-hour pager).

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

_____

Signature of Participant Date

_____

Signature of Person Obtaining Informed Consent Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF
PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name:_____

UAB IRB Protocol Number: IRB-300001012 _____
Principal Investigator: Elizabeth Jackson, MD
Sponsor: National Institutes of Health

Research Protocol: Physical Activity Daily: An Internet-Based Walking Program for Patients with Peripheral Arterial Disease

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant:_____ Date: _____

or participant's legally authorized representative:_____ Date: _____

Printed Name of participant's representative: _____

Relationship to the participant: _____