UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title:

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

1.2 Company or agency sponsoring the study:

National Institutes of Health

1.3 Names, degrees, and affiliations of the researchers conducting the study:

Dr. Caroline R. Richardson, M.D., Department of Family Medicine, University of Michigan

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

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 goals, 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.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

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.

3.2 How many people (subjects) are expected to take part in this study?

200 subjects are expected to take part in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

There will be 4 groups with 50 people each. You will be randomized to a group, 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 Ann Arbor 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 with ABI/TBI testing, online surveys, and 6-minute walk 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/contexts	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 until project completion	Access to Internet program for walking & online community until project completion	Receive pedometer Access to Internet program for walking & online community until project completion

Pedometer information

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.

4.2 How much of my time will be needed to take part in this study?

You will visit Ann Arbor 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.

4.3 When will my participation in the study be over?

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

4.4 What will happen with my information and/or biospecimens used in this study?

Your biospecimens and collected information may be shared with the National Institutes of Health.

With appropriate permissions, your samples and collected information may also be shared with other researchers here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

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

1) 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. Data on paper will be stored in a locked filing cabinet in a locked office. Only research staff will have access to study documents.

2) 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.

3) 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.

4) 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.

5) 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.

6) 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.

7) 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.

8) 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.

9) 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.

10) 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.

11) 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.

12) 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.

13) 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.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

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.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

If you choose not to participate, you may talk with your doctor about:

- Attending a PAD rehab program
- Starting your own exercise program
- Medications or surgical options available to treat PAD

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to

leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

There will be no harm to you if you decide to leave the study before it is finished. At no time will your regular evaluation and treatment for your medical concerns be affected by non-participation in this study.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The results of your ABI/TBI test at visit 1 do not confirm that you have PAD and we cannot confirm you have a PAD diagnosis.
- ✓ The researchers believe that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.
- ✓ You display abusive behavior toward the study staff or other participants on the online message boards.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will get $10 after you complete the baseline visit; $30 after you complete the 4-month visit; and finally you will get $100 after you complete the 12-month visit.

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

If we conduct games or contests on the message boards, some participants in the Internet-based arms may win a small prize (value less than $10).

Typically, you are responsible for travel costs associated with getting to and from Ann Arbor for study visits; however if you live more than 300 miles from the University of Michigan, then we will talk with you about possible reimbursement for your expenses. This is only an option if funds are available.

8.3 Who could profit or financially benefit from the study results?

Neither the researchers nor the University of Michigan nor the sponsor have a financial interest in this study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or the proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

- The study website uses up-to-date 128-bit encryption, and requires a username and password to access. Participants can only access their own identified data.
- Electronic study data will be stored on a server that is in a secure location. Data is password-protected and behind the UMHS firewall. Electronic backups will be stored on disc in a locked fire safe in a locked office.
- Data on paper will be stored in a locked filing cabinet in a locked office. Only research staff will have access to these documents.
- Automated emails sent to you from us will not include sensitive information.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results and dental records
- Any records relating to condition, the treatment received, and response to the treatment
- Demographic information
- Personal identifiers

To make this study work, the researchers need to collect and store some information about you, such as your name and address, and information we collect about your health. All the information we store, we gather from you directly or with your permission.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Analyze the results of the study

- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- If you tell us or we learn something that makes us believe that you or others have been or may be harmed, we may be required to report that information to the appropriate agencies.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

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.

9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments

- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:	Dr. Caroline R. Richardson, MD
Telephone:	(734) 936-7507
Email:	caroli@med.umich.edu
Study Coordinators:	Richard Wu
Telephone:	(734) 232-0484
Email:	UM-PAD-Study@med.umich.edu
Mailing Address:	CV Health Studies 2800 Plymouth Road Bldg 16-400 S23 Ann Arbor, MI 48109-2800

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.*

12. SIGNATURES

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____