Physical Activity Behavior Change for Older Veterans After Dysvascular Amputation

NCT02738086

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Department of Veterans Affairs	Informed Consent Form	COMIRB APPROVED For Use 21-Dec-2018 20-Dec-2019
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Subject Name: _____ **Date:** _____

Title of Study: Physical Activity Behavior Change for Older Adults after Dysvascular Amputation

Principal Investigator: Cory Christiansen, PT, Ph.D. **VAMC:** 554

VA Investigator: Cory Christiansen, PT, Ph.D. **COMIRB#** 15-1586

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about using mobile health technology to provide an intervention designed to provide lasting physical activity behavior change. The use of home based behavior change methods has successfully improved physical activity in healthy older adults and patients with chronic health conditions, but a mobile health physical activity behavior change intervention has not been studied in people with dysvascular amputation.

You are being asked to be in this research study because you have had a lower limb amputation.

Up to 32 people will participate in the study.

What happens if I join this study?

If you join the study, you will participate in an initial testing session in your home. This testing includes completion of physical function tests and questionnaires (approximately 2 hours). After initial testing, we will randomly assign you to 1 of 2 groups. Based on your group assignment, you will participate in physical activity behavior change intervention; months 1-3 or 4-6.

The study lasts 6 months. Testing will occur at initiation, 3 months and 6 months.

Initial Test Session

Baseline Health and Function Assessment (1/2 hour): This assessment will include a group of questionnaires that will ask questions to assess your mental function, depression, physical function, demographic information and general health. In addition, we will test blood pressures in your arms, examine your residual limb at the amputation site, and record the type of prosthesis you use. We will also review your medical record for documentation of your current medications and blood glucose testing (HBA1c), if you have diabetes.

Tests and Questionnaires (1 ½ hours): You will complete physical function testing and questionnaires that assess physical ability, physical activity, prosthetic limb use, motivation, confidence in performing activity and health status. There are a total of 20 tests. You are free to not answer any questions.

Physical Activity Monitoring: At the initial test session, you will be given an activity monitor that you will wear on a belt around your waist during waking hours for a week. The activity monitor will measure your level of physical activity during the week you wear it. At the end of the week, you will mail the monitor back to the researcher (in a provided, postage paid envelope) or it will be picked up from you by the researcher at your home. You will be given written and verbal instructions on use of the activity monitor before you begin using it.

Weekly Visit Phase

Activity Behavior Change Intervention The activity behavior change intervention will occur during Months 1-3 for GROUP1 and Months 4-6 for GROUP2. The intervention begins with a home visit in which the researcher delivers and outlines the PABC intervention and use of equipment (FitBit wearable sensor (FitBit Inc., Boston MA) and FitBit application on the tablet).
Week 1 will be an accommodation period for you to interact with the equipment and establish baseline activity feedback. After Week 1, weekly video-based interactions between participant and therapist (30 minutes) will occur over 3-months (12 visits) using the mobile-health tablets. The PABC intervention will require you to use the FitBit daily. Your FitBit activity will guide the goals for each week and barriers to reaching goals will be identified. The therapist will guide you in reasoning how to address any identified barriers to activity progression.
Each week will include scripted education delivered by the therapist during the video interaction, on a relevant intervention topic (e.g., fall prevention, monitoring blood sugar and diet relative to increasing activity, etc.) (10 minutes).

No Exercise Attention Control During Months 1-3, GROUP2 will participate in weekly video interactions with a therapist using the mobile-health tablets, in a no-exercise control period. These meetings will provide health and safety education on non-exercise topics pertaining to older Veterans (e.g., fall prevention, diet, medication management, retirement issues, etc.). Physical activity recommendations will not be discussed. Each week will include scripted education on one topic (10 minutes) and a brief period of light upper and lower extremity range of motion tasks led by the therapist with the video interface and participants seated in a chair (20 minutes).

Follow-up Test Sessions

After 3 months of participation in the study, a researcher will come to your house and perform the same group of tests and questionnaires (1 ½ hours) as in the first session. You will be given the activity monitor to wear for another week. As with the first activity monitor test, at the end of the week, you will mail the monitor back to the researcher (in a provided, postage paid envelope) or it will be picked up for you by the researcher at your home.

The final testing session will be at 6 months. This test session will be identical to the 3-month session.

Summary of the Study Activities

The study will last 6 months. Weekly video interactions between you and the therapist will take place throughout the 6-month period, with physical activity behavior change intervention being provided either in months 1-3 or 4-6. Testing will be completed at initiation of study, 3 and 6 months.

What are the possible discomforts or risks?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unforeseeable (unexpected) risks also may occur.

Discomforts you may experience while in this study include delayed onset muscle soreness, fatigue, minor sprains or strains.

Other possible risks include:

- Experiencing falls
- Negative cardiovascular response

We anticipate a negative cardiovascular response to the intervention to be rare, but serious. We do not anticipate the risk of such a response to be higher than regular daily physical activity. In the rare care of a negative cardiovascular response to physical activity, they may manifest in symptoms such as excess fatigue, chest pain and shortness of breath. In such incidence, you should immediately seek medical attention.

There is a risk that people outside of the research team will see your research information. We will do all we can to protect your information, but it cannot be guaranteed.

The study may include risks that are unknown or unforeseeable or unexpected at this time.

Risks of the usual care you receive are not risks of the research and are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about the feasibility of using established physical activity behavior change intervention to improve activity and disability outcomes following dysvascular lower limb amputation. If you decide to take part in this study, it is unknown at this time if the activity behavior change intervention will be more beneficial than the no exercise attention control group.

This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

Who is paying for this study?

This research is being paid for by the VA.

Will I be paid for being in the study?

You will be paid $50.00 for each test visit (3 test visits total) in this study. This will add up to a total of $150.00 if you complete all of the visits. If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

It is important to know that payments for participation in a study are taxable income. Your SSN will be collected and used to report this taxable income to the IRS.

Will I have to pay for anything?

There will be no cost to you for participation in this study. However, some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study. If you decide to participate in this study, you cannot be charged nor your insurance billed, for research-related interventions or procedures that are required by the protocol.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you don't take part or leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get the same kind of medical care outside of the study. Ask your study doctor.

For data already collected prior to withdrawal from the study, the investigator may continue to review the data already collected for the study, but cannot collect further information, except from public records.

Can I be withdrawn from the study?

The study doctor may decide to stop your participation without your permission, if he or she thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?

Every reasonable safety measure will be used to protect your well-being. The Eastern Colorado Health Care System will provide necessary medical care and treatment for any injury that is a result of participation in this study for veterans. Compensation for such an injury may be permitted by applicable federal laws and/or regulations. The VA is not required to provide treatment for injuries in research studies if the injuries are caused by your non-compliance with study procedures.

You should inform your care provider(s) if you decide to participate in this research study. If you have questions about an injury related to the research, call Dr. Cory Christiansen at 303 724-9101.

Who do I call if I have questions?

The researcher carrying out this study at the VA is Dr. Cory Christiansen.

You may ask any questions you have now. If you have any questions later you may call Dr. Cory Christiansen at 303 724-9101. You will be given a copy of this form to keep.

If you have questions regarding your rights as a research subject, concerns or complaints about this research study, please call the Colorado Multiple Institutional Review Board (COMIRB) office at 303-724-1055. This is the Board that is responsible for overseeing the safety of human participants in this study. If you want to verify that this study is approved, please contact the VA Research Office at 720.858.5094.

Who will see my research information?

Taking part in this study will involve collecting private information about you. We will keep all research records that contain your identifiable health information, confidential to the extent allowed by law. Records about you will be kept in locked filing cabinets at the VA, and on password protected computers only accessible to authorized study personnel.

We will try to keep your medical records confidential, but it cannot be guaranteed. Records that identify you (including your medical records and the consent form signed by you), may be looked at or portions of your records copied that identify you by others. These include:

- Federal agencies such as the Food and Drug Administration (FDA), the General Accountability Office (GAO), the Office of the Inspector General, Office for Human Research Protections (OHRP), and the Office of Research Oversight (ORO) that protect research subjects like you, may also copy portions of records about you.

- People at the Colorado Multiple Institution Review Board
- The investigator and research team for this study
- The sponsor (group paying for the study), study monitors or agents for the sponsor
- Officials at the institution where the research is being conducted, and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
- Our local VA Research and Development Committee
- Researchers at UC Denver

Social security numbers are recorded because payment for this study is taxable income. You must submit your social security number in order to receive payment for participation.

Information about you will be combined with information from other people taking part in the study. We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

We will ask you to sign a different form that talks about who can see your research records. That form is called a HIPAA Authorization form. It will mention companies and universities who will see your research records.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study has been completed.

Limited data about you, restricted to questionnaires, performance testing, and activity monitoring data, that is collected as part of this specific VA research study to be placed on the REDCap Instance at the Colorado Clinical and Translational Sciences Institute (CCTSI). This data will be used solely for the purposes defined in this consent form for this specific study. Data collected about me for this study and is placed on the CCTSI REDCap Instance will not be accessed or used for any other study or purpose, and will only be accessed by VA-credentialed personnel. The CCTSI REDCap Instance is a highly secure, nationally-utilized data management system, and it is housed within the highly-secure environment at the University of Colorado.

The HIPAA Authorization form that you will also be asked to sign will state when or if it expires. However, you may withdraw this authorization for use and disclosure of your personal health information by providing written request to the Investigator. If you withdraw the HIPAA Authorization form, the Institution, the Investigator, the research staff, and the research Sponsor will no longer be able to use or disclose your personal health information from this study, except so far as that they have already relied on this information to conduct the study.

Is there other information I need to know?

Scientists at the VAMC work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, the VA may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Would you like to be contacted to participate in future studies?

☐ Yes, I am interested in being contacted to participate in future studies. ____Initials

☐ No, I am not interested in being contacted to participate in future studies. ____Initials

Would you like to limit the type of studies that you are contacted to participate in? If yes, provide additional details.

☐ No

☐ Rehabilitation Research Studies Only

If you would like to be contacted to participate in further studies.

- We will not be storing any health information with your contact information
- We will confirm that you have given us consent to have your data stored for future recruitment
- Researchers on this study protocol will be contacting you for possible participation in future studies.
- You can withdraw consent for participation in future studies at any time by contacting Dr. Cory Christiansen at 303-724-9101

Title of Study:	COMIRB Approval Stamp/Date:
Physical Activity Behavior Change for Older Adults After Dysvascular Amputation	DEC 2 1 2018

Agreement to be in this study

I have read this form or it has been read to me. A member of the research team has explained the study to me and answered my questions. I have been told about the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I have been told that I do not have to take part in this study. My refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law.

In case there are medical problems or questions, I have been told I can call Dr. Cory Christiansen at 303-724-9101 during the day and at 970-310-6394 after hours. If any medical problems occur in connection with this study, the VA will provide the necessary medical care.

I choose to participate in this study. A copy of this consent form will be placed in my medical record.

Subject's Signature: _____ Date:_____

Print name: _____

Consent form explained by: _____ Date: _____

Print name: _____

Witness Signature_____ Date_____

Print Name: _____

Witness of Signature ☐

Witness of consent process ☐