Walking Exercise Sustainability Through Telehealth for Veterans with Lower-Limb Amputation

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Subject Name: _____ **Date:** _____

Title of Study: Walking exercise sustainability through telehealth for Veterans with lower-limb amputation

Principal Investigator: _Cory Christiansen, PT, PHD _____ VAMC: 554_____

VA Investigator: ___Cory Christiansen, PT, PhD _____ COMIRB#__22-0702__

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.

Key Summary Information About this Study

You are being invited to take part in a research study that is being funded by a Veterans Administration grant. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

What is the Study About and How Long Will it Last?

By doing this study, we hope to learn more about sustaining exercise activity in Veterans with lower limb amputations. Your participation in this research will last 18 months.

What are Key Reasons You Might Choose to Volunteer for this Study?

With minimal risk, you may benefit immediately from the educational experience of interacting with the investigators who are highly interested in supporting sustained, life-long walking exercise to improve acute and long-term physical function after lower limb amputation. You may also benefit from the telerehabilitation sessions which reduce commonly experienced access barriers to rehab sessions.

What are Key Reasons You Might Choose Not to Volunteer for this Study?

There is no direct benefit to your health for participating in this study.

Do You Have to Take Part in the Study?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you chose not to volunteer.

What if you Have Questions, Suggestions, or Concerns?

The person in charge of the study is Dr. Cory Christiansen, Principal Investigator, at the Eastern Colorado Health Care System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is:

Dr. Cory Christiansen
University of Colorado Physical Therapy Program
Mail Stop C244
Aurora CO 80045
303.724.9101

Why is this study being done?

This study plans to learn more about sustaining exercise activity in Veterans with lower limb amputations.

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

Other people in this study

Up to 115 people from your area will participate in the study.

Up to 115 people around the country will be in the study.

What happens if I join this study?

If you join the study, you will be randomly selected (like the flip of a coin) to be in one of two groups. You will be asked to complete 1 set-up visit, 2 annual telehealth multidisciplinary team telehealth sessions, 6 individual sessions, 6 peer group sessions, and 3 testing sessions. You will wear an activity monitor throughout the study. You will use the VA Annie App. You may be asked to wear a Fitbit. You may be asked to participate in up to 2 focus groups.

All telerehabilitation and testing visits will be conducted by study team members through VA Video Connect. You may access VA Video Connect from your own device (tablet or laptop).

- Your set-up meeting will occur 4 weeks prior to your annual telehealth session. Your set-up meeting will include a study overview, telehealth equipment instruction, and training on technology components of the study, such as the ActiGraph and the Annie App.

- Your annual multidisciplinary team telehealth sessions consist of a reviewing your medical history, psychosocial and environmental barriers, assessment of prosthetic fit and function, and physical evaluation, and care planning.

- You will be asked to wear an ActiGraph activity monitor on your waist throughout your participation in the study to keep track of your step count.

- You will be asked to complete 3 testing sessions: one each at baseline, at 6 months, and at 18 months. During these testing sessions you will be asked to complete physical function testing and questionnaires. Questionnaires will be completed online or via VA Video Connect. These questionnaires will include questions about physical health, your prosthesis, and your mobility. You will be provided a link to the questionnaires. It will take approximately 15-20 minutes to complete the questionnaires. You are free to skip any questions that you prefer not to answer.

- You may be asked to participate in up to 2 focus group interviews.

- If you are randomized into the EXP group, you will have integrated conventional telehealth care with exercise self-management training. You will have 6 30-minute individual sessions with an interventionist, which will focus on behavior-change techniques to promote sustained walking exercise.

    - The EXP group you will have 6 peer group sessions (one every 3 months), offered by the VA Regional Amputation Center, in which you will be encouraged to create 1 walking exercise goal and 1 Whole Health goal. Discussion will focus on peer support in attaining sustained exercise.

    - The EXP group will also receive real-time step count feedback throughout the study by a wrist-worn Fitbit. The Fitbit will be yours to keep.

    - The EXP group will also receive messages from the Annie App promoting exercise self-management.

- If you are randomized into the CTL group, you will have 6 30-minute individual telehealth sessions with an interventionist who will provide education on general health topics such as falls, wound care, sock ply, pain information, wellbeing, and sleep.

    - The CTL group will have 6 peer group sessions (one every 3 months) which will include peer discussions on the education topics.

    - The CTL group will receive messages from the Annie App.

    - After you have completed the study, you will be given a Fitbit to keep.

This research study is expected to take approximately 4 years. Your individual participation in the project will take 18 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 unexpected risks also may occur.

Discomforts you may experience while in this study include muscle pain, fatigue, minor sprains or strains, or falls. You will receive education on the expected side effects and methods to reduce fall risk prior to beginning the intervention.

Other possible risks include breach of confidentiality. Breach of confidentiality is rare, but serious. Only the minimum necessary data will be collected, and only authorized study personnel will have access to the data.

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.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in the 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 sustaining exercise activity in Veterans who have lower limb amputations.

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 sponsored by a Veterans Administration Merit Grant.

Will I be paid for being in the study?

You will be paid $50.00 for each testing visit in this study. The total amount possible to be paid to you is $150.00 if you complete all of the testing 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 testing visits you have completed. You will not be paid for the 2 team telehealth sessions, 6 individual sessions, or 6 peer group sessions. You will be paid by direct deposit.

It is important to know that payments from 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.

If you leave the study, we will stop collecting information. The investigator may continue to review the data already collected prior to your leaving the study but will not collect any further data.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission, if the study doctor 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 VA Eastern Colorado Health Care System (ECHCS) will provide necessary medical care and treatment for any injury that is a result of participation in this study for veterans, in accordance with applicable federal regulations (38 CFR 17.85). 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.

If you have an injury while you are in this study, you should call Dr. Christiansen immediately. His phone number is 303.724.9101. Emergency and ongoing medical treatment will be provided as needed.

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, concerns, or complaints later you may call Dr. 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 or if you would like to obtain information or offer input, please contact the VA Research Office at 720.857.5092

How will my private information be protected?

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 on password protected servers accessible only to authorized study team members.

Identifiers might be removed from the identifiable private information or data that are collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

We will include information about your study participation in your medical record.

A description of this clinical trial will be available on http: 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.

Audio Recordings

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize voice recording(s) to be made of you by the study team while you are participating in this study. You also authorize disclosure of the voice recording to Transcription Outsourcing, LLC. The said voice recording is intended for the following purposes: research.

The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may

be entitled. You may at any time exercise the right to cease being recorded, and may rescind your consent for up to a reasonable time before the voice recording is used.

While this study is being conducted, you will not have access to your research related health records.

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

Health Information Portability and Accountability Act (HIPAA)

Who will see my research information?

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may 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 VA 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, Veterans Administration (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
- UCDenver and its Clinical Trials Management System
- Colorado Clinical and Translational Science Institute (CCTSI) REDCap (Research Electronic Data Capture) database
- CenterPoint
- Virtual Care Manager
- Transcription Outsourcing, LLC

- Fitbit

I understand that by signing this consent form, a copy of limited data about me, restricted to all research data that is collected as part of this specific VA research study will be stored in the REDCap database (or Data Storage System) at the University of Colorado Denver's (UCD's) Colorado Clinical and Translational Sciences Institute (CCTSI). This data will be used solely for the purposes defined in this consent form and for this specific study. Data collected about me for this study placed on the CCTSI REDCap Database will not be accessed or used for any other study or purposes and will only be accessed by VA-credentialed personnel. The CCTSI REDCap Database is a highly secure, nationally-utilized data management system, and it is housed within the highly-secure environment at the University of Colorado Denver.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Christiansen and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

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. 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 given the chance to ask questions and obtain answers.

By signing this form below, I voluntarily consent to participate in this study and authorize the use and disclosure of my health information for this study. I will receive a copy of this consent after I sign it. 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:_____

Print name: _____

Witness of Signature ☐

Witness of consent process ☐