Title: Improving Function in Older Veterans With Hospital-Associated Deconditioning

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Subject Name: _____ **Date:** _____

Title of Study: Improving function in older Veterans with hospital-associated deconditioning

Veteran Consent Form

Principal Investigator: Jennifer Stevens-Lapsley, PT, PhD **VAMC**: 554

VA Investigator: Jennifer Stevens-Lapsley, PT, PhD **COMIRB# 15-1571**

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 the effects of physical therapy (PT) following a stay in the hospital. The purpose of this research study is to compare the results of usual homecare physical therapy with a different program of more intensive physical therapy. You are being asked to be in this research study because you are a Veteran who was referred to home physical therapy after being hospitalized or you are a Veteran who has experienced a decline in physical function due to physical activity restrictions due to COVID 19 and have been referred to home physical therapy.

Up to 250 Veterans like you will participate in this study.

What happens if I join this study?

If you join the study, we will review the study with you and get your consent before we ask you to complete any study related procedures. After you have consented, we may ask you to complete a walking speed test while you are still in the hospital so that we can determine if you are eligible to stay in the study. If you are eligible to stay in the study, you will receive either usual care physical therapy or a more intensive physical therapy program from the Visiting Nurses Association. In both cases, licensed physical therapists will provide all physical therapy treatments. None of the treatments are considered experimental or unsafe. Neither treatment approach has been conclusively demonstrated to be superior to the other in the treatment of older adults after a hospital stay. We are trying to determine which therapy helps people like you recover your strength and walking ability better.

Testing:
If you join the study, there will be 5 tests over 180 days following your hospital stay. These will take place before physical therapy begins, after 30 days, after 60 days, after 90 days, and after 180 days.

The test visits will last approximately 45-60 minutes and will be performed in your home, separately from your physical therapy session. The tests will look at your ability to walk in your home, your leg strength, and your balance. These tests are often done by physical therapists in the home setting. We will also ask you to fill out surveys to determine your ability to do activities at home like bathing and dressing, and also to see how often you are able to leave home to do activities in the community. We will also look at your quality of life. We will also ask you questions about major illnesses or injuries, emergency room visits, hospitalizations, your exercise program, and your health. We will ask these questions at each of the 5 testing sessions and we also will call you on day 120 and 150 after your hospital stay to ask these questions. We will also ask you to wear a device called an activity monitor that measures how physically active you are. You will wear this device for 5 days. Both physical therapy groups will be tested five times in addition to the 10 assigned therapy visits. All tests we are using are commonly used to assess patients participating in physical therapy. You are free to skip any questions or surveys or any testing procedure that you would prefer not to do.

Interventions:
If you are randomly chosen (like the flip of a coin) to receive the usual care or structured physical therapy, the therapy will be delivered by a physical therapist who will visit you between 10 and 12 times over 4 weeks depending on your therapy needs (3-4 visits/week for weeks 1-2 and 2 visits/week during weeks 3-4). Each session lasts 45-60 minutes.

Usual care physical therapy will consist of training you when getting on and off chairs, toilets, and your bed; improving your walking ability and distance; teaching you to get up and down stairs or curbs; and giving exercises to help make your muscles stronger. These are typical activities performed by physical therapists with patients like you.

The intensive physical therapy intervention uses a combination of strength training, walking training, function task training, and education. For the strength training, you will work your leg muscles. You will push against a small machine that provides resistance to the hip, thigh, and ankle muscles. You will perform 3 sets of 8 repetitions with weights. The walking training will involve taking single steps in a several positions and at different speeds as well as walking in specific patterns like ovals and spirals. You will be taught to get on and off the commode, chair, bed, and floor; climb steps and curbs, and get in and out of a car. You will perform all these activities with the guidance of a physical therapist. If you are assigned to this group, you will also receive additional nutritional education from the home health professionals to help improve your recovery.

This research study is expected to take approximately 4 years to complete. Your individual time commitment would be over a period of 180 days (26 weeks) following hospitalization.

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 muscle soreness after the first few sessions, especially if you are randomly assigned to the structured physical therapy group, but in the usual care group as well. The soreness typically does not last more than 2-3 days and does not damage the muscle. The physical therapist will instruct you in the proper use of heat or ice if muscle soreness occurs. There is a risk that you may fall during one of the physical therapy sessions in either the usual care or structured exercise group. However, this risk is minimal and is no different than the risk that is normally present during walking or moving around in the home. The physical therapist will be beside you during all activities that will greatly diminish any risk of falling. You agree to assume responsibility for the risks of this project. Less common risks may include chest pain, fainting, low blood pressure, or a muscle injury. These risks are associated with any exercise intervention.

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 a very small risk of rash on the area of skin where the TegaDerm patch is applied.

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?

Physical therapy is known to help improve function in older adults after a hospital stay. We do not know if there is additional benefit to the structured program, but we are testing this idea. There is a larger benefit to society by examining different ways to help people recover better after hospitalization.

Are there alternative treatments?

Usual care physical therapy is part of the study, and is delivered by the Visiting Nurses Association. All participants receive therapy which meets the usual care requirements. However, you do not have to participate in the study to receive usual care physical therapy from the Visiting Nurses Association or any other home health agency.

Who is paying for this study?

This research is being paid for by a Veterans Administration grant awarded to Dr. Jennifer Stevens-Lapsley

Will I be paid for being in the study?

You will be paid $25.00 for each assessment visit in this study. This will add up to a total of $125.00 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. This includes all additional physical therapy assessment visits required under 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 do not take part or leave this study, you will still receive your normal care. The only care that you will lose is the care you are getting as part of this study. You might be able to get the same kind of care outside of the study. Ask your study doctor or physical therapist.

The investigator may continue to review the data already collected for the study but cannot collect further information, except from public records, such as survival 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 withdrawn from the study?

The study doctor or physical therapist 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. We may also withdraw you if you develop a new medical issue that makes it unsafe to participate. This decision can be made by the study investigators, the medical safety officer in the study, or a doctor who treats you. 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 and non-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. Jennifer Stevens-Lapsley 24 hours a day/7 days a week at 303-724-9170. Dr. Stevens-Lapsley is a research investigator at the Veterans Administration.

Who do I call if I have questions?

The researcher carrying out this study at the VA is Dr. Jennifer Stevens- Lapsley. You may ask any questions you have now. If you have any questions later you may **call Dr. Jennifer Stevens-Lapsley at 303-724-9170**. 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 at720.858.5094. If applicable Information can also be found at http://www.clinicaltrials.gov.

Who will see my research information?

Taking part in this study will involve collecting private information about you, including your medical records. 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 a locked filing cabinet in a VA facility, or on a computer that is only accessible by VA employees. We will collect your social security number in order to process your payments as part of the study. You can still participate in the study if you do not provide your social security number; however, we may not be able to compensate you without it.

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
- University of Colorado-Denver

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.

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.

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].

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.

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. Jennifer Stevens-Lapsley at 303-724-9170 during the day and at 303-949-9304 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. If I am not a veteran, a health record will be created for me in the VA computerized patient record system (CPRS) to include my research records.

Subject's Signature: _____ Date:_____

Print name: _____

Consent form explained by: _____ Date: _____

Print name: _____

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

Witness Signature_____ Date_____

Print Name: _____

Witness of Signature

Witness of consent process

Investigator: _____ Date: _____

Print name: _____