Title: Progressing Home Health Rehabilitation Paradigms for Older Adults

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Subject Name: _____ **Date:** _____

Title of Study: Progressing Home Health Rehabilitation Paradigms for Older Adults

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

VA Investigator: Jennifer Stevens-Lapsley PT, PhD **COMIRB# 15-2125**

SOC Group Consent

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 or rehabilitation facility. The purpose of this research study is to compare the results of usual home care physical therapy with a more structured form of physical therapy and a nutrition supplement.

You are being asked to be in this research study because you have had a stay in a hospital or rehabilitation facility, and you have been prescribed physical therapy.

Other people in this study

Up to 368 people from your area will participate in the study.

Up to 368 people around the country will be in the study.

What happens if I join this study?

If you join the study, we will call you 30 days after you leave the hospital or rehabilitation facility to ask about any hospitalizations, emergency room visits, illnesses, injuries, falls, and your general health since you returned home. We will ask your physical therapist to share your home exercise prescription and associated physical therapy notes with us. You will also complete 2 tests over 60 days after you leave the hospital or rehabilitation facility. The test visits will last approximately 45-60 minutes and will be performed in your home. Some tests may be performed via phone, online, or video call.

You will be tested two times, once before your physical therapy begins and once 60 days after you return home. For testing, we will measure your balance in 3 different positions, measure your ability

to walk approximately 12 feet at your normal speed and with any walking aid you need, and measure your ability to get up from a chair We will also watch you perform 7 other tasks, such as lifting a book, putting on a jacket, picking up a pen from the floor, rising from a chair 5 times, turning in a circle, walking, and standing balance. You will be timed during each of these tests. You will also be asked to complete 6 short questionnaires asking about your overall health and energy, your ability to do tasks in the home, your neighborhood, your social support for exercising, and your confidence in your balance. The tests will take approximately 45 minutes to complete, but with rest periods you may spend up to 1 hour. At the end of some testing sessions, we will provide you with a device that will measure how much you walk in the next week. You will wear this device on your thigh for up to 10 days that measures your physical activity. We will collect it from you after that.

You may be asked to participate in one semi-structured interview. If you are invited to participate in the semi-structured interview, it will take place approximately one week after your 60-day follow-up visit. Interviews will take place either in person, via phone, or via VA Video Connect (VVC) and will last approximately 45 minutes to 1 hour. The researcher will ask a series of open-ended questions about your perceptions of the rehabilitation process and your physical activity after getting home from the hospital or skilled nursing facility. You have the choice to disclose as much or as little as you desire during this interview. The interview will be digitally recorded for analysis.

After you have completed your participation in the research study you will be offered the option to receive a home exercise program and patient education. You are free to accept or decline this home exercise program. It is not part of the research study.

This research study is expected to take approximately 6 years. Your individual participation in the project will take 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 unexpected risks also may occur.

The physical tests we will be doing to look at your function include activities most people do on a daily basis. The risks of the physical testing are, therefore, not expected to be more than you would encounter in daily life.

Risks that <u>rarely occur</u> include:

- A very small risk of rash on the area of skin in which the TegaDerm patch is applied to hold the activity monitor in place.
- Distress caused by physical activity questions is also a small risk. If you experience distress, please discuss this with a member of the research team. Study team members are trained in methods to promote patient comfort and empathy.

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 the effects of physical therapy (PT) following a stay in the hospital or rehabilitation facility.

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.

Are there alternative treatments?

There may be other ways of treating your physical function after a hospital stay. You could also choose to get no treatment at all. You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?

This research is being sponsored for by a National Institute of Health grant.

Will I be paid for being in the study?

You will be paid $25.00 first assessment visit and $75 for the second assessment visit. The total amount possible to be paid to you is $100.00 if you complete both of the assessment visits. If invited to participate in the interview, you will be paid $25.00 for completing the interview, for a total of $125.00 for completing both assessment visits plus the interview. 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 from participation in a study are taxable income. The University of Colorado Denver will be disbursing the payments.

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 further information.

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. Jennifer Stevens-Lapsley at 303.724.9170.

If you have an injury while you are in this study, you should call Dr. Stevens-Lapsley immediately. Her phone number is 303.949.9304. 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. Jennifer Stevens-Lapsley. You may ask any questions you have now. If you have any questions, concerns, or complaints later you may call Dr. 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 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 in a locked filing cabinet in a locked office and on password protected computers accessible only to authorized study personnel.

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.

Certificate of Confidentiality

We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. The Certificate of Confidentiality will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others. The Certificate does not prevent you or a member of your family from releasing data about yourself or your involvement in this study. Your study participation will be included as a part of 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. 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 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, the National Institutes of Health (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
- Arcadia University
- Berkely Home Health
- Colorado Visiting Nurses Association

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. Jennifer Stevens-Lapsley and her 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: _____

Print name: _____

Witness of Signature ☐

Witness of consent process ☐