Title: Progressing Home Health Rehabilitation Paradigms for Older Adults

NCT02905370

Version Date: 09.17.2021 IRB Approval Date: 09.29.2021

Study Title: Progressing Home Health Rehabilitation Paradigms for Older Adults
Principal Investigator: Jennifer Stevens-Lapsley PhD, MPT

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 research study is 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.

Other people in this study

Up to 368 people in the Denver area will be included 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 Zoom 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.

What are the possible discomforts or risks?

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

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 rarely occur 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.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about the effects of physical therapy. 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 post-hospitalization physical function. 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.

Will I be paid for being in the study?

You will be paid $25.00 dollars for the first assessment visit and $75 for the second assessment visit, for a total of $100.00 dollars for participating in both 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 participating in both 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 visit you have completed. It is important to know that payments for participation in a study are taxable income.

Will I have to pay for anything?

It will not cost you anything to be in the study.

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 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 that same kind of medical care outside of the study. Ask your study doctor.

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. 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?

If you have an injury while you are in this study, you should call Dr. Jennifer Stevens-Lapsley immediately. Her phone number is 303-724-9170.

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who is paying for this study?

This research is being paid for by a National Institute of Health grant awarded to Dr. Jennifer Stevens-Lapsley

Who do I call if I have questions?

The researcher carrying out this study is Dr. Jennifer Stevens-Lapsley. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Jennifer Stevens-Lapsley at 303-724-9170. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Jennifer Stevens-Lapsley with questions. You can also call the Colorado Multiple Institutional Review Board (COMIRB). You can call them at 303-724-1055.

A description of this clinical trial will be available on http://www.Clinical Trials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

How will my privacy be protected?

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research,
- If required by Federal, State, or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.
The institutions involved in this study include:

- University of Colorado Denver
- University of Colorado Hospital
- Berkley Home Health Agency
- Colorado Visiting Nurses Association

We cannot do this study without your permission to see, use, and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use, and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Jennifer Stevens-Lapsley, MPT, PhD
UCD Physical Therapy Program
Mail Stop C244
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and her team of researchers.
- 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
- Arcadia University

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.

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 investigator (or staff acting on behalf of the investigator) may also make *some* of the following health information about you available to your physician.

Information about you that will be seen, collected, used, and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, radiology evaluation, procedure results. We will collect these for only the duration of your involvement in the study.
- Research Visit and Research Test records

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use, and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Subject's Signature: _____ Date_____

Print name: _____

Witness Signature_____ Date_____

Print Name: _____

Witness of Signature ☐

Witness of consent process ☐

Consent form explained by: _____ Date: _____

Print name: _____