Title: Progressing Home Health Rehabilitation Paradigms for Older Adults

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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, you will receive either usual care physical therapy or a more structured physical therapy program. In both cases, licensed physical therapists will provide the treatments.

There will be 5 tests over 6 months 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 also receive physical therapy in your home by a physical therapist who will visit you approximately 12 times. Each session lasts 45-60 minutes, and you will have 2 sessions per week for a month, and then 1 session per week for another month after you return home. If you need additional physical therapy beyond the 12 study visits, the home health agency will work with your insurance provider to get these services for you. If you need additional services such as nursing or occupation therapy, the home health agency will work with your insurance provider to get these services.

If you are randomly chosen (like the flip of a coin) to receive usual care physical therapy, you will receive an individually designed program by the physical therapist that will include training you to become safe in getting on and off chairs, commodes (toilets) and your bed; improving your walking ability and distance, teaching you to get up and down stairs or curbs, and giving you exercises to help make your muscles stronger.

The structured physical therapy intervention uses a combination of strength training, walking training, functional 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. 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 also receive a daily supplement of protein in the form of a liquid protein. We will provide this to you. This will help your muscles respond to exercise better.

Both groups will be tested five times, before physical therapy begins, 30 days after you return home, 60 days after you return home, 90 days after you return home, and 180 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.

What are the possible discomforts or risks?

Risks and side effects that may occur 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.

Risks and side effects that are less likely to occur include:

- 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. This will greatly diminish any risk of falling.

- It is possible that during the intervention you may experience chest pain, fainting, dizziness, shortness of breath, or muscle strain; these risks are the same for each treatment. To prevent these problems during the intervention, the physical therapist will take your heart rate and blood pressure during the session. They will also teach you when it is safe for you to begin the activities and when you should stop the activity because of physical problems. In the event that there is an injury during an interventional session, the physical therapist will provide immediate assistance and help you get additional care as needed. The interventions have been designed specifically to minimize this risk and are conducted by a licensed physical therapist.

Risks that rarely occur include:

- With any type of exercise, there is always a small risk that something abnormal could occur with your heart. The risk is minimal. For safety, blood pressure will be taken at the beginning and end of the training session and more frequently if the physical therapist finds it necessary.

- A very small risk of rash on the area of skin in which the TegaDerm patch is applied.

- While there are no reports of persons fracturing bones during these types of interventions, a very small risk still exists. Again, the interventions have been designed specifically to minimize this risk and are conducted by a licensed physical therapist.

- 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?

Physical therapy is known to help improve function after a hospital stay in older adults. 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. Also, there may be risks, as discussed in the section about discomforts and risks.

Are there alternative treatments?

Usual care physical therapy is part of the study and is delivered by the Berkley Home Health Agency or the Colorado 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 Berkley Home Health Agency, the Colorado Visiting Nurses Association, or any other home health agency.

Will I be paid for being in the study?

You will be paid $25.00 dollars per outcome assessment visit (which are in addition to standard physical therapy), for a total of $125.00 dollars for participating in all outcome visits. If invited to participate in the interview, you will be paid $25.00 for completing the interview, for a total of $150.00 for participating in all outcomes visits plus the interview. You will not be charged for receiving physical therapy services. 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 is 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 primary care physician.

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?

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.ClinicalTrials.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: _____