Title: Patient-Centered, Interprofessional Approach to Improve Functional Outcomes in a Skilled Nursing Facility

NCT04300413

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Department of Veterans Affairs	Informed Consent Form	
Version Date: **01.28.2020**	**R&D Stamp:**	**COMIRB Approval Stamp/Date:**

Subject Name: _____ **Date:** _____

Title of Study: Patient-Centered, Interprofessional Approach to Improve Functional Outcomes in a Skilled Nursing Facility

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

VA Investigator: Jennifer Stevens-Lapsley MPT, PhD **COMIRB# 19-2490**

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 whether using a structured movement program in addition to your regular rehabilitation time while in a skilled nursing facility is feasible and acceptable.

You are being asked to be in this research study because you are a patient in a skilled nursing facility.

Other people in this study

Up to 100 people from your area will participate in the study.

What happens if I join this study?

If you join the study, you will have an activity monitor taped to your upper leg. The monitor is (1.4 x 2.1 x 0.3 in) You will be asked to keep this monitor on your leg for the remainder of time you are in the skilled nursing facility. The activity monitor measures the amount of time per day you are walking, standing, sitting, and lying down. For the first three days of your skilled nursing facility stay, you will also wear an activity monitor which will count your steps.

You will have a mobility coach who will guide you in a regular, structured mobility program in addition to your regular rehabilitation time. You will select activity goals for the week and will keep a diary of your activity. You will start the week with 70 points and if you meet your goals for the day, you will remain at 70 points. If you are unable to meet your goals for the day, you will lose 10 points. At the end of the week, you will choose a prize with levels depending upon how many points you have remaining.

You will also be asked to complete questionnaires about your health, activity, physical function, and satisfaction with your therapy. You will complete the questionnaires on a tablet that we provide to you. You are free to skip any questions that you prefer not to answer.

You will also be asked to complete a semi-structured interview. The researcher will ask a series of open-ended questions about your perceptions of the rehabilitation process and your physical activity at the Community Living Center at Fitzsimons. You have the choice to disclose as much or as little as you desire during this portion of the testing session. This portion of the testing session will be digitally recorded for analysis.

You will have two follow up phone calls, one 7 days after you are discharged from the skilled nursing facility and one 60 days after your discharge. These phone calls will only take a few minutes and will ask about how you've been moving since you've been home.

This research study is expected to take approximately 26 months.

Your individual participation in the project will take up to 100 days.

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 a slight risk of skin irritation from the adhesive used to hold the activity monitor to thigh.

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.

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.

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.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about using a mobility program in a skilled nursing 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 rehabilitation. These other ways include standard of care treatment only.

You can receive standard therapy without participating in the study.

You may discuss these options with your doctor.

Who is paying for this study?

This research is being sponsored by The University of Colorado Denver, Science Data to Patient Value Initiative.

Will I be paid for being in the study?

You will not be paid to be in the study; however, you may earn small prizes each week by reaching your activity goals.

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 this study, we will stop collecting information. The investigator may continue to review data already collected prior to your leaving the study.

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 at any time.

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. 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 room and on password protected computers only accessible by authorized study team members.

Identifiers might be removed from the identifiable private information 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.

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.
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.

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 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 University of Colorado Denver D2V, (group paying for the study)
- 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
- CCTSI REDCap

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. 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.

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.

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. 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 ☐