Improving Rehabilitation Outcomes After Total Hip Arthroplasty

NCT02920866

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Department of Veterans Affairs	Informed Consent Form	
Version Date: **11.11.2019**	**R&D Stamp:**	**COMIRB Approval Stamp/Date:**

Subject Name: _____ **Date:** _____

Title of Study: Improving rehabilitation outcomes after total hip arthroplasty

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

VA Investigator: Jennifer Stevens-Lapsley, MPT, PhD **COMIRB# 16-0956**

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 total hip arthroplasty (THA). The purpose of this research study is to compare the results of standard-of-care (i.e. usual) physical therapy with a different program of structured physical therapy. You are being asked to be in this research study because you are undergoing a THA.

Other people in this study

Up to 150 people like you will participate in this study.

What happens if I join this study?

If you join the study, you will receive either usual care physical therapy or a structured physical therapy program. In both cases, licensed physical therapists will provide all physical therapy treatments. Some of the physical therapy treatments may occur at your home. 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 adults after a THA. We are trying to determine which therapy helps people like you recover your strength and walking ability better.

If you join the study, there will be 4 testing sessions; 1 before surgery, and three after your total hip arthroplasty (4 weeks, 8 weeks, and 26 weeks after the start of physical therapy). The test visits will last approximately 120 minutes and will be performed at the Geriatric Research, Education, and Clinical Center (GRECC) Human Movement Analysis Laboratory, or remotely via Zoom or video call, or at your home, separate from your physical therapy session. The tests will look at your movement patterns, your leg strength, and your balance. We will also ask you to fill out surveys to determine your quality of life, activity level, and the impact of osteoarthritis on pain, stiffness, and disability. 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.

This research study is expected to take approximately 4 years. Your individual participation in the project will take 7 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.

Discomforts you may experience while in this study include muscle soreness, strains, or tears, although the force levels that will be used in this study are well within safety limits and comparable to those required for activities of daily living. The stresses placed on you with this testing and treatment are similar to those used in some current physical therapy programs following a THA, which have been shown to pose no greater risk for injury. 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.

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.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about physical therapy following total hip arthroplasty. 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 total hip arthroplasty. By knowing this information, we may be able to help people get back to previous levels of activity faster. There may be risks, as discussed in the section describing the discomforts or risks.

Are there alternative treatments?

Usual care physical therapy is part of the study and is delivered by physical therapists. 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 physical therapy clinics.

Who is paying for this study?

This research is being paid for by a VA merit award to Dr. Jennifer Stevens-Lapsley.

Will I be paid for being in the study?

You will be paid $50.00 for each assessment visit in this study. The total amount possible to be paid to you is $200.00 if you complete all of the assessment 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.

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 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 removed from this study?

The study doctor or physical therapist 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. 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 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 and non-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 24 hours a day, 7 days a week, at 303.724.9101.

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 303.724.9107. 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. Social security numbers are collected for reimbursement purposes only. Records about you will be kept in Clinical Building South (CBS), 3rd floor, in a locked filing cabinet in locked Room A3-235. 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. Only copies of the information are entered into CCTSI REDCap; the original copies of all data will be stored on a VA server behind a firewall.

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.

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.

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, Veterans Administration, 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 and its Clinical Trials Management System

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.

Title of Study:	COMIRB Approval Stamp/Date:

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. 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: _____.

Witness Signature: _____ Date: _____

Print name: _____

Witness of Signature ☐

Witness of consent process ☐