INFORMED CONSENT FORM

Project Title:

Manual Therapy and Strengthening for the Hip in Older Adults With Chronic Low Back Pain

NCT#: NCT04009837

Last Approved: March 22, 2022

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Title of Project: Evaluating the Effects of Two Different Physical Therapy Interventions for Low Back Pain in Older Adults: A Multi-Site Clinical Trial

Principal Investigator(s): Gregory Hicks, PT, PhD

You are being invited to participate in a research study. This consent form tells you about the study including its purpose, what you will be asked to do if you decide to take part, and the risks and benefits of being in the study. Please read the information below and ask us any questions you may have before you decide whether or not you want to participate.

KEY INFORMATION

Important aspects of the study you should know about first:

- **Purpose:** The purpose of the study is to investigate the effectiveness of two different physical therapy interventions for older adults with low back pain.
- **Procedures**: If you choose to participate, you will be asked to participate in a series of standard clinical tests and questionnaires and an intervention aimed at improving your low back pain and physical function.
- **Duration:** This will take about 2 hours for each of the three evaluations, and about 1 hour for each treatment session, which occurs 2x/week for 8 weeks.
- **Risks**: The main risk or discomfort from this research is some muscle soreness, and your low back or hip pain might worsen, but that is unlikely. There is a slight risk that you could experience a fall or a related injury during testing.
- **Benefits:** The main benefit to you from this research is that you'll receive 8 weeks of free physical therapy treatment for your low back pain, and you'll be helping develop new knowledge to help care for people like you in the future.
- **Alternatives:** There are no known alternatives available to you other than not taking part in this study.
- **Costs and Compensation:** If you decide to participate there will be no additional cost to you and you could be compensated up to $125.
- **Participation:** Taking part or not in this research study is your decision. You can decide to participate and then change your mind at any point

Please carefully read the entire document. You can ask any questions you may have before deciding If you want to participate.

Participant's Initials _____

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to investigate the effectiveness of two different physical therapy interventions for older adults with low back pain. You will be one of approximately 210 participants, across 3 different locations, in this study. Participation in this study is voluntary and you may withdraw at any time.

WHY ARE YOU BEING ASKED TO PARTICIPATE?

You are being asked to participate because you…

- Are 60-85 years-old.
- Have moderately intense, chronic (≥ 3 months) low back pain that impacts your daily life.
- Also have pain and weakness in your hip.
- Are able to walk independently with or without a cane.

You will not be able to participate if you…

- Are not able to read and speak English.
- Do not pass our mental screening test.
- Have had any back trauma or surgeries in the last 6 months or have certain conditions of your back that may affect your safe participation in the study.
- Have symptoms in your legs greater than your low back pain.
- Have had a previous hip fracture with repair (or hip fracture without repair in past 15 years).
- Have had a total hip replacement.
- Received manual therapy or exercise therapy (e.g. physical therapy, chiropractic care) for your low back or hip within the past 3 months.
- Have difficulty hearing or vision loss that severely restricts your everyday activities.
- Have an acute illnesses or have had a recent hospitalization.
- Know that you will be unable to participate in the study for the full 6 months.

WHAT WILL YOU BE ASKED TO DO?

As part of this study you will be asked to participate in a series of standard clinical tests and questionnaires and an intervention aimed at improving your low back pain and physical function. The study will take place at the following site: [University of Delaware's STAR campus] and will include an evaluation, 16 physical therapy treatment sessions (2x/week for 8 weeks), and 2 follow-up evaluations (immediately after treatment and at 6 months after enrolling in the study). The first onsite evaluation will be about 2 hours, each follow-up onsite evaluation will be about 1.5 hours, and each of the 16 treatment sessions will be about 65 minutes. We will ask you to fill out a questionnaire packet prior to each evaluation, which will take 5-15 minutes. We will also telephone you months 3, 4, and 5 of the study to check on your status (<20 minutes/phone call). Therefore, the approximate total time commitment for participation in this study is about 24 hours over a 6 month period (not including your home exercise program, which will be discussed below).

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Questionnaires
Prior to your onsite evaluation, we will send you the informed consent to review and a packet of questionnaires about your medical history and medications to complete. We will review these questionnaires during your onsite evaluation. We will ask you to recomplete the medication sheet at the 2 follow-up evaluations (i.e. months 2 and 6).

Clinical Testing
During the first onsite evaluation session, we will make a final determination of your eligibility for the study based on your response to questions and some evaluation items. It is possible that you may not be eligible to continue participating in the study, but you will be informed within the first 30 minutes of the onsite evaluation. You will complete 9 electronic questionnaires evaluating your low back and hip pain, function, confidence, and mood.

The onsite evaluations will include assessment of your cognition, blood pressure, height, and weight. We will ask some clinical questionnaires about your back and hip and activity level. We will take measurements of your legs, including assessing the strength and flexibility of your hips. We will ask you to perform 5 tests assessing your walking, balance, and endurance. Specifically we will ask you to walk along a linear path, walk for 6 consecutive minutes, and reach forward as far as possible without moving your feet. We will also ask you to perform as many stands from a chair as possible in 30 seconds and time you while you stand from a chair, walk 3 meters, and return to sitting in the chair.

There will be clinical testing pre-treatment, post-treatment (at 8 weeks), and 6 months after you have enrolled in the study.

Intervention

You are being asked to participate in 8 weeks of a physical therapy treatment. Sessions will be scheduled 2 times per week. You will be randomly assigned to 1 of 2 treatment groups. “Randomly assigned” means that you are put into a group by chance, like flipping a coin. You will have an equal chance of being placed in either group. Both groups will receive an intervention consisting of heat to the low back and a trunk training program that includes exercises for the abdominal and low back muscles. One group will additionally receive manual therapy to the low back, as well as lumbar stretching exercises and stationary cycling, while the other group will receive manual therapy for the hip, as well as hip strengthening exercises. Physical therapy sessions for both groups will last about 65 minutes. In both groups you will be asked to complete your home exercises (<30 minutes/home session) at least two times on your own and complete a home exercise log.

Participant’s Initials _____

Multi-Site Low Back Pain Clinical Trial Overview
Total Time Commitment: 6 months

	Review consent form and complete packet that will be mailed to you prior to coming to your first visit (5-15 minutes)
Visit 1	• Initial Visit (2 hours) located in the clinical site (e.g. University of Delaware) ○ Informed Consent ○ Evaluation for Study Eligibility ○ Review Medication Sheet & Medical History (completed at home) ○ Electronic Questionnaires ○ Testing (interview, hip strength/flexibility, functional testing) ○ Set up Physical Therapy Appointments
Visit 2-16	• Random assignment to 1 of 2 physical therapy treatment groups. Begin physical therapy at the clinical site. ○ 2x/week for 8 weeks ○ Each visit (~65 minutes) ○ Home program (at least 2X/week) with exercise logs
Visit 17	• 8 Weeks Visit (~1.5 hours) at the clinical site ○ Review Medication Sheet (completed at home) ○ Electronic Questionnaires ○ Testing (interview, hip strength/flexibility, functional testing) • Compensation: $75 check (3-4 weeks after completion of this evaluation)
Visit 18	• 16 Weeks after the 8 Week Visit (~1.5 hours) at the clinical site ○ Review Questionnaires (completed at home) ○ Electronic Questionnaires ○ Testing (interview, hip strength/flexibility, functional testing) • Compensation: $50 check (3-4 weeks after completion of this evaluation)

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

You may experience some muscle soreness a day or two following testing or treatment. This soreness is similar to the muscle soreness that you may feel if you lift weights or vigorously exercise after a long layoff and is often a sign that you are increasing your muscle strength. Although the force levels to be used in this study pose little risk for injury, it is possible that a muscle strain could occur. Further, as with any physical activity, there is the possibility that your back or hip pain might worsen or that you may develop new pain, but this is unlikely. If there is an increase in your pain, the physical therapist treating you will modify your treatment appropriately. There is a small risk that you could fall and potentially sustain a falls-related injury

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during the walking, balance, and endurance testing. However, the researchers are trained to assist you if necessary. For higher level functional training, you will be appropriately supervised by a licensed physical therapist. Overall, the supervision of a licensed physical therapist should minimize any potential risk, especially since the testing and treatment offered within the context of this study is used on a daily basis by physical therapists in the clinical setting.

WHAT IF YOU ARE INJURED DURING YOUR PARTICIPATION IN THE STUDY?

If you are injured during research procedures, you will be offered first aid at no cost to you. If you need additional medical treatment, the cost of this treatment will be your responsibility or that of your third-party payer (for example, your health insurance). By signing this document, you are not waiving any rights that you may have if injury was the result of negligence of the university or its investigators.

WHAT ARE THE POTENTIAL BENEFITS?

The benefits of this study include free evaluations by a licensed physical therapist that will provide you with detailed information concerning your low back and hip pain. You will also receive 8 weeks (i.e. 16 sessions) of free physical therapy treatment. The information that we obtain with our testing will be used to guide future rehabilitation treatments for others and will assist in identifying factors that are related to patient outcomes following physical therapy treatment for low back pain. If you choose to participate in the study, you will not be responsible for any costs related to the physical therapy evaluations or services received. So regardless of the effects of the specific interventions, you are likely to obtain some benefit from participation, though there is no guarantee.

NEW INFORMATION THAT COULD AFFECT YOUR PARTICIPATION:

During the course of this study, we may learn new information that could be important to you. This may include information that could cause you to change your mind about participating in the study. We will notify you as soon as possible if any new information becomes available.

HOW WILL CONFIDENTIALITY BE MAINTAINED? WHO MAY KNOW THAT YOU PARTICIPATED IN THIS RESEARCH?

Your participation in this study requires us to collect some personal information from you. Any information you provide that could identify who you are (e.g., your name, your date of birth, etc.) will be stored in a locked file cabinet, on password-protected computers, or in a password-protected secure and encrypted multi-site database system. Other information we collect will be de-identified, meaning that we will replace your personal information with a number code. The key linking code numbers with individual names will be maintained in a password-protected file. Data with identifying information will be saved until the data are published. Raw de-identified data will be stored indefinitely and may be used in future related studies. Only the research team will have access to the server and database files.

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No identifying information will be used in any presentations or publications that result from this study. The confidentiality of your records will be protected to the extent permitted by law. Your research records may be viewed by the University of Delaware Institutional Review Board, which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans and by the National Institutes of Health, the government agency that is sponsoring this research.

Records relating to this research will be kept for at least three years after the research study has been completed. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

Video recording and having your picture taken is not a requirement of this study. However, at the end of this written consent you will be given the option to volunteer for having your likeness featured in pictures or video while you are a participant in this study. The pictures and video will be used for future educational purposes such as manuscripts and/or presentations. Only individuals who volunteer and give permission will be considered for use of their likeness.

WILL THERE BE ANY COSTS TO YOU FOR PARTICIPATING IN THIS RESEARCH?

There are no costs for evaluations or treatments associated with participation in this study, participants are responsible for transportation to the clinical site for each visit. In some unusual situations, if you cannot arrange transportation alone, supplementary funds may be available to assist with transportation.

WILL YOU RECEIVE ANY COMPENSATION FOR PARTICIPATION?

You will be paid $75 by check after completing the 8-week follow-up evaluation and $50 by check after completing the 6 month follow-up evaluation. Thus, if all testing sessions are completed, you will receive $125 in total. If you are found ineligible at the initial on-site evaluation, you will receive a $20 check.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is entirely voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled. Your decision to stop participation, or not to participate, will not influence current or future relationships with the clinical site.

Your participation in the study could be terminated by the investigators if we deem it inappropriate for you to continue, if your status changes such that we think you fail to meet all inclusion/exclusion criteria, or if your participation may place you at risk medically or physically.

If at any time, you decide to end your participation in this research study, please inform our research team by telling the investigators.

Participant's Initials _____

WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

If you have any questions about this study, please contact the Principal Investigator, Gregory Hicks at (302) 831-2690. If you have any questions or concerns about your rights as a research participant, you may contact the University of Delaware Institutional Review Board at hsrb-research@udel.edu or (302) 831-2137.

Your signature on this form means that: 1) you are at least 60 years old; 2) you have read and understand the information given in this form; 3) you have asked any questions you have about the research and those questions have been answered to your satisfaction; 4) you accept the terms in the form and volunteer to participate in the study. You will be given a copy of this form to keep.

_____	_____	_____
Printed Name of Participant	Signature of Participant	Date
_____	_____	_____
Person Obtaining Consent (PRINTED NAME)	Person Obtaining Consent (SIGNATURE)	Date

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OPTIONAL USE OF DATA COLLECTED FROM YOU IN FUTURE RESEARCH:

The research data we will be collecting from you during your participation in this study may be useful in other research studies in the future. Your choice about future use of your data will have no impact on your participation in this research study. Do we have your permission to use in future studies data collected from you? Please write your initials next to your preferred choice.

_____ **YES** _____ **NO**

Participant's Initials _____

OPTIONAL CONSENT FOR ADDITIONAL USES OF VIDEO RECORDINGS/PHOTOGRAPHS

I voluntarily give my permission for the researchers in this study to use videos and photographs of me collected as part of this research study to be used in publications, presentations, and/or for educational purposes. I understand that no identifying information beyond that contained in the video recording and/or photographs will be provided to educational/scientific audiences; however my facial features may be seen.

_____ _____

(Signature of Participant) (Date)

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(Printed Name of Participant)

OPTIONAL CONSENT TO BE CONTACTED FOR FUTURE STUDIES:

Do we have your permission to contact you regarding participation in future studies? Please write your initials next to your preferred choice.

_____ YES _____ NO

Participant's Initials _____