STUDY INFORMED CONSENT

Improving Physical Activity and Gait Symmetry After Total Knee Arthroplasty

NCT number NCT04090125
Document Date 10/06/2022

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 10/6/22
IRB Study #: 19-0568
Title of Study: Improving Physical Activity and Gait Symmetry after Total Knee Arthroplasty

Principal Investigator: Kelli Allen
Principal Investigator Department: School of Medicine
Principal Investigator Phone number: 919-966-0558
Principal Investigator Email Address: kdallen@email.unc.edu
Co-Investigators: Robin M. Queen, PhD, Carla Hill,PT, Todd Schwartz, DrPH, Christopher Olcott, MD, Derek Hales, PhD

Funding Source and/or Sponsor: National Institutes of Health (NIH)

Study Contact: Kimberlea Grimm
Study Contact Telephone Number: 919-843-9256
Study Contact Email: kimberlea_grimm@med.unc.edu

CONCISE SUMMARY

The purpose of this research study is to compare how well two types of physical therapy (PT) programs work for people who have recently had total knee replacement (TKR). One program is typical postoperative PT. The other program is typical postoperative PT with additional balance training and physical activity coaching. Both groups will complete typical postoperative PT followed by two additional visits with a study physical therapist (one phone call and one in-person). Participants will also complete three in-person assessments. Participants in this study will be actively involved for about 6 months.

The benefits to you from being in this study may be improvements in pain, physical function or other symptoms related to knee OA, from participating in either program. The greatest risks of this study include the possibility of injury or soreness from physical therapy activities, feeling uncomfortable when answering study questions, and loss of confidentiality.

If you are interested in learning more about this study, please continue reading below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.
You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is complete will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to compare how well two types of physical therapy (PT) programs work for people who have recently had total knee replacement (TKR). One program is typical postoperative PT. The other program is typical postoperative PT with additional balance training and physical activity coaching. By doing this study, we hope to provide people who have TKR in the future, as well as their health care providers, with information that will help people following TKR to increase their physical activity and improve their walking mechanics after TKR.

You are being asked to be in the study because you recently had TKR and are participating in postoperative PT.

Are there any reasons you should not be in this study?

You should not be in this study if:

- You have a significant memory problem
- You have a diagnosis of rheumatic disease
- You have a neurological disorder affecting gait
- You have had a hospitalization for a cardiovascular condition in the last 6 months
- You have psychosis or substance use disorder
- You have had major surgery in another hip, knee or ankle in the past year
- You plan to have total joint replacement in the next 6 months
- You have any other health care condition that may make it unsafe for you to participate in a home exercise program

How many people will take part in this study?

A total of approximately 60 people will take part in this study. Participants in this study will be patients from the University of North Carolina (UNC) Health Care System or outside UNC physical therapy clinics.

How long will your part in this study last?

Participants in this study will be actively involved for about 6 months after you complete post-knee replacement physical therapy visits. We expect today's visit will take about 1 ½ to 2 hours. About 1 month after your final "routine" physical therapy session, you will have a follow-up phone call with a study physical therapist; this will take approximately 15-25 minutes. You will have then have an in-person visit with a study physical therapist about 1 month later; this will take approximately 20-40 minutes. About 1 month after that in-person session with the physical therapist (or about 3 months after your complete "routine" in-person physical therapy), you will have an in-person visit with the research team to complete the study assessments again. You will have a final in-person visit with the research team about 6 months after you complete "routine" physical therapy to complete the study assessments a last time; this visit will take about 1-1 ½ hours.

What will happen if you take part in the study?

Baseline Visit: During today's visit, we will ask you to complete some simple functional tests, such as a short walk, getting up and down from a chair, and some balance tests. If you choose not to complete any of the survey questions or functional tests for any reasons, you may still participate in the study.

We will also complete some surveys about your joint symptoms, your health, your physical activity level and other basic information about you. We may complete these surveys at today's visit or we may set up a time to call you to complete the surveys.

At the end of today's visit, we will give you a device called an accelerometer, which measures your physical activity level. We will ask you to wear the accelerometer, on your waist (using an elastic belt or clip), for one week. You will be asked to mail the accelerometer back to the research team after one week of wearing it. We are providing a pre-paid and pre-addressed envelope for mailing the accelerometer back to us. At the 3-month and 6-month research assessments, we will also ask you to wear the accelerometer for one week, using the same process. You will be paid $15 in the form of a pre-paid debit card for returning the accelerometer at each time point.

Study Group Assignment: Using a procedure like flipping a coin, you will be randomly assigned to one of two study groups. One group will receive typical PT for postoperative TKR. The other group will receive typical PT for postoperative TKR with additional balance training and physical activity coaching. This group will also be asked to track performance of specific exercises and overall physical activity in a web-based program or on a paper exercise log if preferred. Both groups will participate in 2 additional visits with a study physical therapist beyond usual postoperative TKR PT treatment (one phone call and one in-person).

Both groups will continue with any other usual care they receive following TKR from their usual health care providers. Within about a few days after we receive your accelerometer back in the mail, a study team member will call to tell you which study group you have been assigned to.

Usual Physical Therapy (PT) Group

If you are assigned to the Usual PT group, you will complete your usual in-person postoperative TKR PT care, which will be followed by two additional visits with a study physical therapist (one phone call and one in-person visit). These two additional visits will be at no cost to you.

Physical Activity and Symmetry (PAS) Group
If you are assigned to this group, you will receive balance training and physical activity coaching during two of the last usual postoperative TKR PT treatment sessions and in two additional sessions with a study physical therapist (one phone call and one in-person visit). These two additional visits will be at no cost to you.

This group will also be asked to track performance of specific exercises and overall physical activity in a website or mobile app called Physiotec. You will be provided with a user name and password in order to log in to Physiotec or you may set up your own user name and password. A physical therapist will have access to your online physical activity log to help you keep track of your physical activity minutes and specific exercises. For participants who do not have regular internet access but want to record their information electronically, the study will provide an iPad and data plan for the intervention period or you will be asked to keep a paper log recording your physical activity and specific exercises.

Follow-Up Visits
No matter which study group you are assigned to, we will ask you to return two times to complete functional tests similar to those you will complete today. These will be approximately 3 months and 6 months after your final PT session and will take about 1- 1 ½ hours.

After each follow-up visit, we will set up a time to call you to complete some surveys about your joint symptoms, your health, your physical activity level and other basic information about you.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be improvements in pain, physical function or other symptoms related to knee OA, from participating in either the PT or PAS program.

What are the possible risks or discomforts involved from being in this study?

Risks of Exercise: If you are in the PT or PAS group, your risks will be the same as in usual care physical therapy following TKR. If you are in the PAS group, your physical therapist will give you information on specific balance exercises and increasing physical activity. This information follows guidelines recommended by physicians and researchers. However, exercise programs may be associated with risk of injury, muscle soreness, and joint pain. The risk of sudden death during physical activity is about 1 death per 656,000 hours of physical activity. In general, the risk of these events with moderate physical activity is very low.

Breach of confidentiality: we will be collecting some elements of personal health information necessary for the study. To minimize breaches of confidentiality, all data will be stored on a secure UNC server or a UNC IRB approved platform for sharing PHI, and any paper information will be stored in locked filing cabinets in the office of a study team member. Only approved study personnel will have access to those data.

Other Possible Risks: Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time. You may stop your participation in this study at any time.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
The information you provide for this study will be stored on a secure UNC computer server. The database with your information (including your name, contact information, and responses you provide to survey questions for this study) will be accessible only to approved study personnel (research assistants, project coordinator, investigators, study physical therapists, statisticians and database programmers). Information on paper forms will be minimal (e.g., a copy of this consent form) and will be stored in a locked filing cabinet of a study team member. We will also share a limited amount of data from this study with collaborators from the Virginia Polytechnic Institute and State University (Virginia Tech). This will include data from some of the functional tests, along with IDs for each participant. No other data about you (e.g., your name or contact information) will be included.

Participants will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any

federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you develop a health condition that would make your participation unsafe or that would interfere with obtaining accurate study assessments. If you choose to withdraw from the study at any time, you are instructed to contact Dr. Kelli Allen at the following address or telephone number:

Thurston Arthritis Research Center
The University of North Carolina at Chapel Hill
3300 Thurston Bldg., CB# 7280
Chapel Hill, NC 27599-7280

919-966-0558

Will you receive anything for being in this study?

You will receive up to $145 for taking part in this study. This will include $50 for completing the baseline assessment and $25 for completing 3 month, and 6-month follow-up assessments. This will also include $15 for returning the accelerometer at the beginning of the study and then after the 3 month and 6 month assessments.

A pre-paid debit card will be given to you at your initial visit with a study team member. There will be "no value" on the card. Within about 3 days after completing the baseline assessment, your card will have $50 "loaded" on to it. Within about 3 days after completing the 3 month and 6-month assessments, your card will have $25 "loaded" on to it. We will load $15 for returning the accelerometer at each time point within 3 days of receiving the accelerometer back. Your name, address and phone number will be shared with the University of North Carolina and their debit card contractor so they can process your payments. If the debit card is lost, damaged or stolen, the study team can replace it. You will hold onto the card for as long as you are in the study.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?
This research is funded by the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on 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.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent