

INFORMED CONSENT FORM

NCT03228719

Last Approved 09/20/2021

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Title of Project: [946165] A novel physical therapy administered physical activity intervention after TKR

Principal Investigator (s): Daniel K. White, PT, ScD, MSc

You are being asked to participate in a research study. This form tells you about:

- The purpose of the study
- What you will do if you decide to participate
- Risks and benefits of participation

Please read the information below. You can ask the research team any questions that you may have. Your participation is voluntary and you can refuse to participate or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you will be asked to sign this form and a copy will be given to you to keep for your reference.

WHAT IS THE PURPOSE OF THIS STUDY?

Total knee replacement (TKR) is a common surgery for people with severe knee degeneration, or osteoarthritis (OA). TKR often relieves pain. However, people remain generally inactive following TKR. Physical inactivity can lead to higher risk for heart disease, diabetes, and death. Little is known about how best to improve physical activity after TKR. Therefore, the purpose of this study is to investigate how to increase physical activity after TKR.

Physical activity monitors, such as the Fitbit®, are common. These monitors are worn on the body. They can accurately record the number of steps you take in a day. As the user, you can access these data on smart phones, computers and tablets. These monitors can help people increase physical activity. *We do not know if providing monitors combined with physical activity coaching by a licensed physical therapist can increase physical activity during and after outpatient rehabilitation.*

The findings of this study will help physical therapists increase physical activity in patients after TKR.

WHY ARE YOU BEING ASKED TO PARTICIPATE?

We will enroll about 130 individuals in this study.

You qualify for this study because:

- You are at least 45 years of age.
- You are seeking outpatient physical therapy after a unilateral TKR.

Note: You are included regardless of time since your unilateral TKR surgery.

You do not qualify if:

- You are not interested in increasing your physical activity.
- You have any other medical conditions that limit your physical activity.
- You have had or are planning on having another leg surgery within 6 months that is unrelated to your TKR.
- You have previously enrolled in a physical activity intervention study at this clinic.

Note: You are not excluded if you don't have a smart device and/or access to internet.

We will collect medical, demographic, insurance and function data related to your course of physical therapy from your University of Delaware Physical Therapy Clinic medical chart. If you are unable to complete the paper versions of the study forms, an electronic version will be emailed to you by the physical activity lab via Redcap.

WHAT WILL YOU BE ASKED TO DO?

As a patient at the University of Delaware, you will receive standardized rehabilitation from a licensed physical therapist. You will progress in rehabilitation based on the guidance of your physical therapist.

If you consent to participate in the study, you will be enrolled. You will be randomly chosen to be in the control group or the intervention group. Both groups will be asked to wear a small accelerometer called an Actigraph prior to randomization. This device measures your daily amount of physical activity. This includes the number and speed of steps you take in a day. You will also receive a binder that includes your home exercise program. The home exercise program will include pictures of the exercises and a log to record your exercises.

People in the intervention group will have a receive a Fitbit® monitor. The research assistant will meet with you in person to set up your Fitbit®. You will need an email account to sync your Fitbit® to your smart phone, tablet or home computer. You will receive instruction on how to use your Fitbit® to check your steps per day. You will self-report this data to your physical therapist, or allow the physical therapist and/or the research team to view this data. Your physical therapist will talk with you once a week about the average number of steps per day you take in a week. Based on your average steps per day, you will create a weekly goal with your physical therapist. In the first 3 weeks after surgery, you will not be expected to increase your steps per day. After 3 weeks, you will be encouraged to increase your steps per day. The goal is to achieve at least 6,000 steps per day by the time you discharge from physical therapy rehabilitation.

At 3rd and 9th month after discharge, you will receive a thank you letter to remind you of your upcoming 6-month and 12-month follow-ups, respectively. At the 5th month and 11th month, the research assistant will call you to remind you of your upcoming 6-month and 12-month follow-ups, respectively, and ask you about changes in medications or changes in health status.

At discharge from physical therapy rehabilitation, both groups will be asked to wear an Actigraph for one week (7 days) and fill out questionnaires. You will be given an envelope with postage to return the Actigraph along with the questionnaire to the research team after one week. Again at 6-months and 12-months, both groups will be asked to wear an Actigraph for one week and fill out questionnaires. The Actigraph and questionnaire will be mailed to you with a pre-stamped return envelope.

You may also receive a 12-month phone call from a member of the research team to complete an exit interview.

If your Fitbit® and/or Actigraph is lost or damaged, you should inform your physical therapist and/or contact the Physical Activity Lab at TKRstudy@udel.edu or 302-283-9713.

Physical Activity after TKR Study Timeline

1 st physical therapy appointment (evaluation)	2 nd physical therapy appointment (follow-up)	3 rd physical therapy appointment (follow-up) Intervention Group Only	Last physical therapy appointment (discharge)	Periodic Thank You Notes or Phone Calls	6-month	12-month
<ul style="list-style-type: none"> ●Receive Recruitment Flyer with QR code ●Use QR code to fill out Consent to Contact Form on Redcap (2 min) 	<ul style="list-style-type: none"> ●Pre-screen for study eligibility (2 min) ●Review and sign Informed Consent Form (as much time as needed) ●Actigraph given (2 min) ●Complete 3 questionnaires (PCS, TSK, SEE) 	<ul style="list-style-type: none"> ●Fitbit® monitor set up/sync (10 min) 	<ul style="list-style-type: none"> ●Actigraph given, worn for 7 days, and mailed back (2 min) ●Complete 3 questionnaires (PCS, TSK, and SEE) 	<ul style="list-style-type: none"> ●Thank You Notes at 3-months and 9-months ●Phone Calls at 5-months and 11-months 	<ul style="list-style-type: none"> ●Actigraph sent, worn for 7 days, and mailed back ●Complete questionnaire (SF-36) 	<ul style="list-style-type: none"> ●Actigraph sent, worn for 7 days, and mailed back ●Return Fitbit® if given one ●Complete questionnaire (SF-36) ●Exit Interview (15 min)

1. Actigraph

The Actigraph is a small device that monitors your physical activity. We will disinfect the Actigraph monitor in accordance with EPA guidelines before sending it to you. We ask that you wear the monitor from the time you wake up in the morning until you go to sleep. You may only remove it when it may get wet, such as bathing or swimming. You will wear the Actigraph around your waist at your right hip. You will wear the Actigraph for one week at each of the following four time points:

1. After your initial physical therapy evaluation
2. At discharge from physical therapy rehabilitation
3. At 6-months after discharge
4. At 12-months after discharge

Mailing and return shipping will be provided to send and return the device to the Physical Activity Research Team.

2. Fitbit® Zip

If you are in the intervention group, you will be given a Fitbit® monitor. If you already have a physical activity tracker, you can choose to use it instead of the provided Fitbit® monitor. You will be asked to return the Fitbit® monitor with your Actigraph via the same return postage at 12-month follow-up. The Fitbit® monitor should be worn at your wrist. The research team may suggest an alternate location if your Fitbit monitor is having difficulty

registering steps. Batteries will be provided if needed during the study. You will be asked to check your steps per day on your Fitbit® monitor daily.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Risks associated with participation are those typically found during physical therapy rehabilitation after TKR. These potential risks include risk of soreness from muscle strength testing, fluctuating knee pain and/or swelling related to recovery from TKR, and fatigue during or following the evaluation or after increasing your physical activity. To minimize these risks, a physical therapist will evaluate your physical activity goals and physical therapy rehabilitation and tailor them to your stage of recovery. There is minimal risk for participating in the physical activity intervention. This risk includes being challenged to increase your physical activity. There are no known risks associated with wearing a monitor.

There is a possibility of a breach of confidentiality if data or identifying information should accidentally be released. We will minimize this risk by keeping identifiable information in locked files and on secured servers. Only the research team will have access to this information.

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

If you are injured or have a change in health status at any time during the study, you will be offered first aid at no cost to you and you will be contacted by the research team. 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 results of this study will help us better understand physical activity after TKR. If you increase your physical activity, you may receive benefits. These benefits may include increased strength, improved cardiovascular health, and improved quality of life.

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?

We will make every effort to keep all research records that identify you confidential to the extent permitted by law. A copy of your consent form will be stored in a locked file, accessible only to the research team at the University of Delaware.

In addition to your medical charts, the results of your evaluation will be electronically, securely stored on the Department of Physical Therapy server. These results will be accessible only to research personnel. Your evaluation, insurance, medical, treatment and questionnaire data will be entered from your medical record to a computerized database (Redcap) where all patients will be identified by code numbers only. Your information

will be indefinitely stored using this coded number for future/additional research. A list linking your name to your code number will be securely stored on a secure server and will be accessible only to research personnel. In the event of any publication or presentation resulting from this research, no personally identifiable information will be shared. Your research records may be viewed by the University of Delaware Institutional Review Board, but the confidentiality of your records will be protected to the extent permitted by law.

WILL THERE BE ANY COSTS RELATED TO THE RESEARCH?

There are no costs associated with participating in this study.

WILL THERE BE ANY COMPENSATION FOR PARTICIPATION?

You will receive a \$25 Wawa or Amazon gift card for wearing the Actigraph at the time that you are discharged from physical therapy rehabilitation. We will ask for your preference at discharge, and if you do not provide us with a preference, we will give you Amazon gift card. We will continue the same gift card preference as stated by you at discharge for the 6-month and 12-month follow-ups. You will receive an additional \$25 gift card after you wear the Actigraph and complete a questionnaire at 6 months after discharge. You will also receive a \$50 gift card for wearing the Actigraph and completing a questionnaire at 12 months after discharge.

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 refusal will not influence current or future relationships with the University of Delaware. *If at any time an evaluator believes it is unsafe for you to continue participation, your participation will be stopped.*

WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

If you have any questions about this study, please contact the Principal Investigator, Daniel White at **302-831-7607** or at **dkw@udel.edu**. Or you can contact the Physical Activity Research Team at **TKRstudy@udel.edu** or **302-283-9713**. 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 **302-831-2137**.

Your signature on this form means that: 1) you are at least 18 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 the questions have been answered to your satisfaction; and 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

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 (and/or my child) 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, and my facial features will be obscured.

Printed Name of Participant

Signature of Participant

Date

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