Informed Consent

Official Study Title

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First, I will provide you with an overview of the key information about this study. If you are interested, then we can go over the full information.

CONCISE SUMMARY

The purpose of this study is to test a program to help people who have knee or hip osteoarthritis (OA) to increase their physical activity (PA). We are calling this program the OA Physical activity Care Pathway (OA-PCP). You will be randomly assigned to one of two study groups. One group will participate in the OA-PCP intervention and will receive an initial PA coaching call then, 5 more calls. One will be about two weeks after the initial call, then at about 3 months, 6 months, 9 months and 12 months later. The other group, called an Osteoarthritis (OA) Education group, will receive the same number of phone calls, focused on understanding OA and current information on treatment options. Also, if you agree, the study interventionist will email you 2 separate times to check-in between the 2 week call and the 3 month call, as well as monthly follow-up emails between the 3 month call and the 12 month call. Both groups will complete a baseline assessment and follow-up assessments (at 6 and 12 months after completing the first phone call with the physical activity coach or health educator) over the telephone. Participants will also be asked to wear a small monitor that measures physical activity, at each assessment point. Participants will be actively involved for about 12 months.

The benefits to you from being in this study may be improvements in pain, physical function or other symptoms related to OA. You may not receive any direct benefit from being in the research study.

There are risks of this study that are described in this document including risk from engaging in an exercise program, which may be associated with risk of injury, muscle soreness, and joint pain. Also, some of the questions we will ask you as part of this study may make you feel uncomfortable.

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

First, I will tell you 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 done 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.

The purpose of this research study is to test a program to help people who have knee or hip osteoarthritis (OA) to increase their physical activity. We are calling this program the OA Physical activity Care Pathway (OA-PCP). We will be comparing this program to another

program that provides education on a variety of topics important to understanding osteoarthritis and its care.

You are being asked to be in the study because you have knee and/or hip OA, are age 65 or older and have at least one other health condition in addition to OA (for example, diabetes or high blood pressure).

About 240 people will take part in this study. Participants in this study will be patients from UNC Health Care and affiliated clinics within the UNC Physicians Network, as well as Piedmont Health Services.

Now I will tell you what will happen if you take part in this study.

Participants will be actively involved in the study for about 12 months after this call.

After completing this consent, we will collect a verbal HIPAA authorization from you. Then, we will complete a survey about your OA symptoms, your health, and other basic information about you. You will be paid $25 in the form of a pre-paid debit card for completing this survey. If you choose not to complete any of the survey questions, you may still participate in the study.

Afterwards, we will mail 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. We may also ask some participants to wear a monitor on both the wrist and waist. We will give you instructions for wearing the accelerometer, and we will call you to review the instructions and ask whether you have any questions. You will be asked to mail the accelerometer back to the research team after one week of wearing it. We will give you a pre-paid and pre-addressed envelope for mailing the accelerometer back to us. You will be paid $15 in the form of a pre-paid debit card for returning the accelerometer.

A pre-paid debit card will be mailed to you after we receive your signed HIPAA authorization. There will be “no value” on the card. Within about 3 days after completing the survey, your card will have the $25 “loaded” on to it. Your name and address 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.

Study Group Assignment: Using a procedure like flipping a coin, you will be randomly assigned to one of two study groups. One group will participate in the OA-PCP intervention. Participants in this group will be asked to wear a Fitbit to help them track their physical activity during the intervention period. If you agree to wear the Fitbit, the study will register the Fitbit, using an email generated by the study. Also, if you approve, the coach will use an online program to view your physical activity data from the Fitbit. The Fitbit and instructions will be mailed to you and you will be asked to begin wearing it as soon as you receive it. About a week after the Fitbit is mailed, a study team member will call you to answer any questions about device wear and setup. Then, a physical activity coach will call within about one week later.

The coach will ask participants about their current physical activity level and work with them to set physical activity goals. We expect this call will last about 30-45 minutes. Then, after the first physical activity coaching call, participants in this group will receive 5 more calls. One will be about two weeks later, then at about 3 months, 6 months, 9 months and 12 months later. We expect these calls will last between 15 and 30 minutes. During these calls, the physical activity coach will ask participants’ about their progress toward physical activity goals and work with

them to address any barriers or challenges. The coach will also help participants to identify any programs or resources that may help them to achieve their physical activity goals.

The other group, called an Osteoarthritis (OA) Education group, will receive phone calls from a health educator, focused on understanding OA and current information on treatment options. Participants in this group will receive the same number of phone calls, at the same time points, as participants in the OA-PCP group.

No matter which group you are in, if you agree, the physical activity coach or health educator will email you at about monthly in between calls.

If you are a patient of Piedmont Health Services (PHS), PHS may request that the study flags your primary care provider in your medical record in order to notify them that you have enrolled in this study.

Follow-up Assessments: No matter which study group you are assigned to, we will ask you to complete 2 follow-up assessments over the phone that involve questions similar to those you completed at the beginning of this study. These will be at approximately 6 months and 12 months after completing the first phone call with the physical activity coach or health educator. We expect these will take about 30 minutes. You will be paid $25 in the form of a pre-paid debit card for completing each assessment. After 6 months and again at 12 months, we will also ask you to wear the accelerometer for one week, using the same process at the beginning of the study. You will be paid $15 for wearing and returning the accelerometer.

Do you have any questions?
If Yes: Answer questions and proceed
If No: Proceed with script

Now I will tell you about possible benefits and risks 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 OA, from participating in either of the study groups. You may not receive any direct benefit from being in the research study.

Risks of Exercise: If you are assigned to the OA-PCP group, the physical activity coach will give you information on exercise programs appropriate for people with OA. 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.

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 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 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.

Now I will tell you how information about you will 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 activity coach / health educator, statisticians and database programmers). Information on paper forms will be minimal and will be stored in a locked filing cabinet of a study team member. Your deidentified data may be used for future research without your additional consent.

You will not be identified in any report or publication about this study. 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.

Who is sponsoring this study?

This research is funded 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.

Do you have any questions?
If Yes: Answer questions and proceed
If No: Proceed with script

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 919-966-0558 or at the following address:

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

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal

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 research for this study, Kelli D. Allen, PhD at 919-966-0558.

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 you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

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.

Do you agree to be in this study?
If Yes: Answer questions and proceed
If No: Thank you for your time today.