Informed Consent

OA Clinic-Community CARE Model (OA CARE)

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

Consent Form Version Date: 6/28/22
IRB Study #: 22-0865
Title of Study: Osteoarthritis Clinic-Community CARE Model (*OA CARE*)

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CONCISE SUMMARY

The purpose of this study is to test a program to help people who have knee or hip osteoarthritis (OA). We are calling this program the "Osteoarthritis Clinic-Community CARE Model" or *OA CARE*. You will be randomly assigned to one of two study groups. One group will participate in the *OA CARE* intervention. Participants in this group will receive a 12-month Medical Membership to a local YMCA and participate in a 12-week weight loss program. Participants will also work with an *OA CARE* Navigator, who, in partnership with their primary care provider, will identify any additional programs or resources that may help them manage their OA symptoms. The other group will be the "usual care" control group; this group will receive no additional treatment for about 12 months. However, this group will be offered a 12-month Medical Membership to a local YMCA after completing the final assessment. Both groups will complete a baseline assessment and follow-up assessments (at 6 months by phone and 12 months in-person) . 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.

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 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.

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 study is to test a program to help people who have knee or hip osteoarthritis (OA). We are calling this program the "Osteoarthritis Clinic-Community CARE Model" or *OA CARE.*

You are being asked to be in the study because you have knee and/or hip OA.

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

- You had no documented diagnosis of knee or hip OA
- You have had major surgery in another hip, knee or ankle in the past 6 months
- You have significant cognitive impairment
- You have had a hospitalization for a cardiovascular condition in the last 6 months
- You have a diagnosis of psychosis or current, uncontrolled substance abuse disorder
- You have any other health care conditions that may make it unsafe for you to participate in a home exercise program
- You have chest pain at rest or with activity
- You have severe hearing or visual impairment (that would make study activities infeasible)
- You have a serious/terminal illness as indicated by referral to hospice or palliative care
- You have a history of ventricular tachycardia
- You have unstable chronic obstructive pulmonary disease (2 hospitalizations within the previous 6 months and/or on oxygen)
- You have had 3 or more falls in the past 6 months
- You have had a stroke with moderate to severe aphasia
- You are planning total joint replacement in next 6 months
- You are currently participating in another study related to knee or hip osteoarthritis, weight loss or physical activity
- You are unable to speak English

- You are pregnant or plan to become pregnant

How many people will take part in this study?

About 60 people will take part in this study. Participants in this study will be patients from UNC Health Care.

How long will your part in this study last?

Participants will be actively involved for about 12 months. We expect today's visit will take about 1 to 2 hours. The 6-month phone assessment will take about 30 minutes, and the 12-month in-person assessment will last approximately 1 to 1 ½ hours.

If you are assigned to the *OA CARE* group, the Weight Loss Program sessions will take about 1 hour per session, and the sessions are held weekly for 12 weeks. Additionally, a YMCA Health Coach will contact you periodically to talk about your health goals and YMCA programs that may help you achieve these goals. These contacts will be up to 30 minutes each time. At about 6 months from when you are assigned to the *OA CARE* group, the *OA CARE* Navigator will contact you by phone to complete questionnaires and discuss your interests in referrals to services and resources. This call will take about 30-45 minutes. The Navigator may will also contact you one month later to follow-up; this call will take about 15-30 minutes.

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 getting up and down from a chair. We will also complete a survey about your OA symptoms, your health, and other basic information about you. If you choose not to complete any of the functional tests or survey questions, you may still participate in the study.

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 6-month and 12-month research assessments, we will also ask you to wear the accelerometer for one week, using the same process.

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 CARE* intervention, and the other will be assigned to usual care. Both of these are described below.

Both groups will continue with any other usual care related to their knee or hip OA from their usual health care providers. 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 Care Group: Participants assigned to the usual care group will receive no additional treatment from the study for about 12 months. However, this group will be offered a 12-month Medical Membership to a local YMCA after completing the final assessment.

***OA CARE* Group:** If you are assigned to the *OA CARE* group, you will be contacted by the *OA CARE* Navigator about 1 week later to coordinate steps for initiating a YMCA Medical Membership. Then, YMCA personnel may contact you to explain the YMCA Weight Loss Program and schedule you for the first Weight Loss Program group session. The YMCA Weight Loss Program will be delivered in groups with other *OA CARE* participants. Meetings will

be weekly for 12 weeks. In the beginning of the study, the Weight Loss Program will be delivered virtually (e.g. video conferencing platform). However, the Program may be offered in-person in the future. Classes include goal-setting, food and activity tracking, introduction to physical activity offerings, and weigh-ins. Following completion of the initial 12-week Weight Loss Program, you may choose to repeat the program as many times as you wish during your study participation. You will also have access to all exercise facilities and programs at the YMCA throughout your participation in the study.
Also, you will be assigned a health coach by the YMCA. The health coach will describe their role discuss your health goals, and specific exercise or other programs that may be of interest to you. After this initial contact, the health coach will contact you periodically. These contacts can occur via phone or in person when you are visiting the YMCA.

About 6 months after you have initiated the YMCA Medical Membership, the *OA CARE* Navigator will call you to ask you some questions and discuss your interests in referrals to other services related to OA management. This may include mental health providers who specialize in pain management, physical therapy, weight management and nutrition services and sleep services. The OA CARE Navigator will provide your primary care provider with a summary of this discussion and help you connect to any programs or resources that do not require provider referrals. Additionally, about one month later the *OA CARE* Navigator may call you to follow-up on whether you have been referred to services of interest and whether additional connections or referrals are needed.

The YMCA will also provide the UNC study team with information on the programs you participated in at the end of the study. This information will be shared with the UNC study team through a UNC IRB approved platform for sharing PHI.

Your primary care provider will also be provided with a summary of your progress and activities as part of *OA CARE*.

Follow-up Assessments: No matter which study group you are assigned to, we will ask you to complete 2 follow-up assessments that involve questions similar to those you completed at the beginning of this study. These will be at approximately 6 months and 12 months. The 6-month assessment will be done by phone. We expect the 6-month assessment to take about 30 minutes. The 12-month assessment will be done in-person. We expect the 12-month assessment to take 1 to 1 ½ hours. Also, 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.

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 OA, from participating in either of the study groups. You may not receive any direct benefit from being in the research study.

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

Risks of Exercise: If you are assigned to the *OA CARE* group, you will participate in exercise programming at the YMCA. This will be tailored so it is appropriate for people with OA. 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.

Risks of weight loss interventions: If you are assigned to the *OA CARE* group, you will participate in a weight management program at the YMCA. Side effects associated with weight loss in general may be hair loss, fatigue, weakness, gall bladder disease, and electrolyte abnormalities. Also, low blood sugar or low blood pressure (lightheaded or fainting) may occur during weight loss if you are taking medications for diabetes or high blood pressure. These risks are not specific to this research but also apply to usual care.

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 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.

Some of your personal health information (name and contact information) will be shared with YMCA personnel. Any information shared between approved UNC study team members and YMCA personnel will be done verbally by phone, through encrypted email or a UNC IRB approved platform for sharing PHI.

If you are assigned to the *OA CARE* group, your primary care provider (PCP) will receive a summary of your progress and activities as part of *OA CARE*. This summary may include your name, date of birth or medical record number. This information will be shared by the *OA CARE* Navigator with your PCP through encrypted email or a UNC IRB approved platform for sharing PHI.

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. Additionally, if you are in the OA CARE group you will have contact information for the study team (e.g. OA CARE Navigator) and a YMCA health coach to discuss any concerns related to your participation in the weight loss program at the YMCA.

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.

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, 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. We will also share a limited amount of data from this study with collaborators from the YMCA. This will include your name and contact information.

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.

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 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

Will you receive anything for being in this study?
You will receive up to $160 for taking part in this study. This will include $45 for completing the baseline assessment, $25 for completing the 6-month phone assessment and $45 for completing the 12-month follow-up assessment. This will also include $15 for returning the accelerometer at the beginning of the study and then after the 6 month and 12-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 $45 "loaded" on to it. Within about 3 days after completing the 6-month assessment, your card will have $25 "loaded" on to it. Within about 3 days after completing the 12-month assessment, your card will have $45 "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.

If you are assigned to the *OA CARE* group you will receive a YMCA Medical Membership to a local YMCA . If you are assigned to the Usual Care group you will be offered a YMCA Medical Membership to a local YMCA after you have completed the 12-month assessment and your study participation ends.

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