Cherokee Health for Elderly Residents with Osteoarthritis of the Knee in the Eastern Band: The CHEROKEE Study

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Informed Consent Form to Participate in Research

Richard Bunio, Principal Investigator

Introduction

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You may or may not receive any benefit from being part of the study. There may also be risks associated with being part of research studies. You are being asked to take part in this study because you have Knee Osteoarthritis. Your participation is voluntary. Please take your time to make your decision, and ask the study staff or the study doctor to explain any words or information that you do not understand. You may also discuss the study with your friends and family.

Why Is This Study Being Done?

Osteoarthritis (OA) is the most common form of arthritis. It is very common to get arthritis in your knee. While there are no cures for OA, treatment usually combines therapies, for example, exercise combined with a medication. The purpose of this research study is to examine the effects of an exercise and diet intervention on knee pain and physical function. Our research group has previously conducted a similar trial in older adults with knee OA in both rural and urban communities across North Carolina.

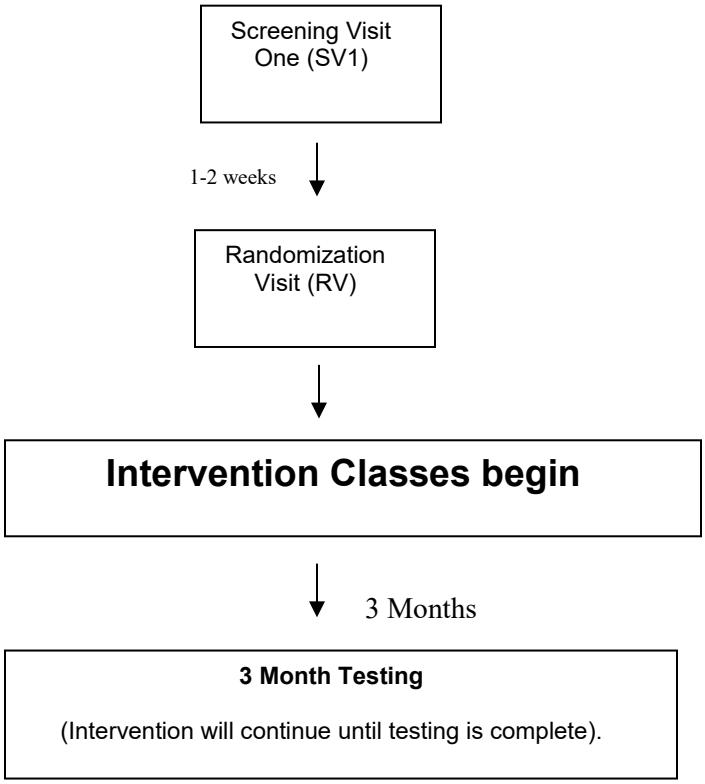
How Many People Will Take Part in the Study?

A total of 30 people will take part in this study. In order to identify the 30 subjects needed, we may need to screen as many as 100 because some people will not qualify to be included in the study. Only those who complete and pass the screening visit as listed below will be randomized into the study.

What Is Involved in the Study?

If you qualify to participate, you will undergo screening and baseline testing. The following scheduled visits and procedures will be performed.

Time line (A detailed description of the visits can be found following this figure).



Screening Visit 1 (SV1):

- *Cherokee Indian Hospital:* The study will be described in detail and you will be asked to sign this consent form and give the research staff member your medication use and medical history forms that were previously mailed to you. The staff member will review the forms with you to make sure everything is correct. Your height, weight, and hip and waist circumference measurements will be taken and you will undergo a knee exam. You will also have your blood pressure measured.
- You will perform a 6-minute walk test (where we measure the distance you walk in 6 minutes). A balance, walking speed, stair climb, and chair rise test will also be performed. You will complete questionnaires, including general background, knee pain, physical disability, physical function, physical activity history, confidence, eating habits, mental state and health status.
- This visit will take approximately 3 - 4 hours to complete.

Randomization Visit (RV):

Cherokee Indian Hospital: You will be randomized to one of the study group assignments described below: diet + exercise or nutrition and health. You will remain in this group for the entire study. Randomization means that you are put into a group by chance by a special

computer program, similar to flipping a coin. This is done so that a fair evaluation of results can be made. You will have a one in two chance of being placed in any one group.

- Below is a description of the 2 different study groups (you will be randomized into <u>one</u> of these groups):

DIET & EXERCISE GROUP

- ***Diet Intervention***
    - If you are randomly assigned to the diet and exercise group, you will be asked to carefully monitor how much you eat and to follow a low-calorie diet designed for you, with the goal of losing weight. The diet will include up to 2 meal replacements per day for 3 months, similar to Slim Fast liquid supplements (the meal replacements will be provided by the study). For the second/third meals, you will follow a weekly menu plan and recipes composed of traditional foods. The nutritionist will help you to develop a food plan for the second and/or third meal that is modified to your individual preferences.
    - You will attend regular classes once a week for about an hour over 3 months to help you with your diet program. The classes will consist of alternating weekly individual and group sessions (2 individual sessions and 2 group sessions per month). The individual sessions will alternate between face-to-face meetings with the nutrition interventionist and a method preferred by you (phone, email, text, etc.)
    - Class topics for the group sessions include: changing eating habits to lower caloric intake, information regarding what food changes to make, how to make them, and why they are important. Each group session will also include problem solving, review of a specific food topic, and tasting of several well-balanced, low-fat, foods. During the individual sessions, the nutrition interventionist will review individual progress, solve problems, answer questions, and help you to set your program goals. The minimal weight loss goal is 5% of your body weight (approximately 10 pounds for a 200 pound person). Some people will lose more weight than that, and others will lose less.
    - Your in-person, face-to-face nutrition classes will be held before or after your exercise classes to make participation easier for you.

- ***Exercise Intervention***
    - You will begin coming to exercise classes 3 days per week for an hour each day. The class will consist of 15 minutes of an aerobic activity (walking, stationary bikes, elliptical trainer, etc), followed by 20 minutes of strength training involving leg weights, bands, and/or machines, followed by another 15 minutes of aerobic activity, and 10 minutes of cool-down exercises. The goal of the exercise program is to improve your fitness. Your exercise instructor will monitor your progress and will help you reach your fitness goals. These regular exercise classes will go on for 3 months.
    - The diet and exercise classes will be held at Cherokee Indian Hospital.

NUTRITION AND HEALTH GROUP

- You will attend 2 group session classes over the 3-month period. The face-to-face group meetings will occur at months 1 and 3. During the other month (months 2) you will receive a combination of phone calls, newsletters, emails, and text messages.
- You will be provided with information on healthy eating and health behaviors. The information will cover various health topics on nutrition, health & wellness, and chronic diseases. Experts will give wide-ranging lectures.
- The face-to-face group meetings will be held at Cherokee Indian Hospital.

3 Month Follow-up Visit (FU3): You will return for a follow up visit after 3 months.

(Cherokee Indian Hospital): You will have your blood pressure, weight, hip, and waist measured. You will perform the 6-minute walk and the stair climb, balance, walking speed, and chair rise tests that were performed at baseline. Your mental status will be measured. Your medical history and medications (previously mailed) will be reviewed. You will be given the questionnaires that were given at baseline to complete at the end of this visit. This visit should last approximately 2.5 – 3.5 hours.

How Long Will I Be in the Study?

You will be in the study for about 5 months including testing visits.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. There are no serious health or safety consequences that will occur if you choose to stop participating.

What Are the Risks of the Study?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

- There may be muscle or joint soreness following the physical performance test (six minute walk/stair climb) or exercise. These symptoms usually go away quickly and are usually not serious.
- It is possible to have a more serious injury, such as a torn ligament or sprain from these tests, but this is extremely rare. Your tests will be monitored very closely to provide a high degree of safety for you.
- There is a small chance that exercise could lead to symptoms of heart disease or minor injury. Some examples of these symptoms include shortness of breath, irregular heart beat, skipped beats, a "flip-flop" feeling in your chest, weakness or dizziness, upset stomach, or a painful, heaviness, or discomfort feeling in your chest. There is a slight risk of falling during the walking portion of testing and training. Rarely, 1-2%, of older people with arthritis who exercise will suffer more serious injury such as a broken bone from a fall. Exercise participants will have continuous safety monitoring during all training and testing, which will help make sure participants will exercise safely. Pain associated with exercise usually goes away after a few days.
- There is a chance that you may experience some discomforts as a result of dieting such as

hunger or a feeling of less energy. The meal plan will be developed by the nutrition staff to meet your individual needs and will consist of a balanced diet to minimize these discomforts. In addition, the meal plan will include snacks in between your meals to minimize the feeling of hunger.

- There is a small risk that participants may lose too much weight. Your weight will be monitored regularly to reduce the chances of this occurring. In addition, some persons who diet may have dietary deficiencies; your food diaries will be reviewed weekly to make sure that you are getting all the nutrients you need.
- There also may be other side effects that we cannot predict. You should tell the research staff about any medicine, vitamins, or supplements you take and any medical problems you have. This may help avoid side effects and other risks.
- Taking part in this research study may involve providing information that you consider confidential or private. Dr. Stephen Messier and his research staff will protect your records so that all your identifying information (name, address, phone number, information in your health record) is kept private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe. In addition an internal safety committee will be reviewing the data from this research throughout the study.

  A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study.

Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be any direct benefit to you. We hope the information learned from this study will benefit other people in the future. You may benefit by having reduced pain, improved physical function, and/or weight loss.

Based on experience with diet and exercise in other studies with persons with knee osteoarthritis, researchers believe that diet and exercise are important in preventing disease and disability. Previous studies have shown that weight loss helps to decrease pain and improve function in persons with knee osteoarthritis. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case. Information received in the nutrition and health classes will provide valuable health information. In addition, each participant will contribute to our knowledge about osteoarthritis and may aid in our attempt to reduce or eliminate some disabilities associated with the disease.

What Other Choices Are There?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. The tests and medications provided are available in the community; these usually involve a charge to participants. Instead of being in this study, you have the option of being treated with conventional medical therapy.

What about My Health Information?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** health history, your family health history, how you respond to study activities or procedures, and information from study visits, phone calls, surveys, and physical examinations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office and on a password protected website and computer. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Cherokee Indian Hospital who oversee research

2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

3) Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Richard Bunio that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Richard Bunio
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form, you give us permission to use your Protected Health Information for this study.

What Are the Costs?

There are no costs to you for taking part in this study. All the study costs, including any study tests, classes, and meal replacements related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

Will I receive Transportation or Free Parking?

The study will not provide transportation or reimbursement for parking.

Will You Be Paid for Participating?

You will not be paid for participating in this study.

Who is Sponsoring this Study?

This study is being sponsored by *Wake Forest University and Cherokee Indian Hospital*. The sponsor is providing money or other support to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because but not limited to, not following the study schedule; a change in your medical condition; or new information that necessitates study closure.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

The Chairman of the Eastern Band of Cherokee Indians Institutional Review Board should be contacted at [redacted] for answers to questions about research subjects' rights.

Whom Do I Call if I Have Questions or Problems?

For questions about the study contact the site investigator, Richard Bunio, at [redacted].

You will be given a signed copy of this consent form.

Signatures

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.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm