IRB00033618.I-CAN
NCT03832296
Title: Independent Weight Loss Maintenance for Communities With Arthritis in North Carolina: the I-CAN Clinical Trial
Date: 3/23/2020

Wake Forest®
School of Medicine

Department of Health and Exercise Science

Weight loss and **E**xercise for **C**ommunities with **A**rthritis in **N**orth Carolina (WE-CAN) Maintenance
I-CAN

Informed Consent Form to Participate in Research

Stephen P. Messier, PhD, 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 are being asked to take part in this study because you completed the WE-CAN Study and achieved 5% weight loss in the diet and exercise group. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to examine the effect of an exercise and diet maintenance intervention on weight, knee pain and physical function.

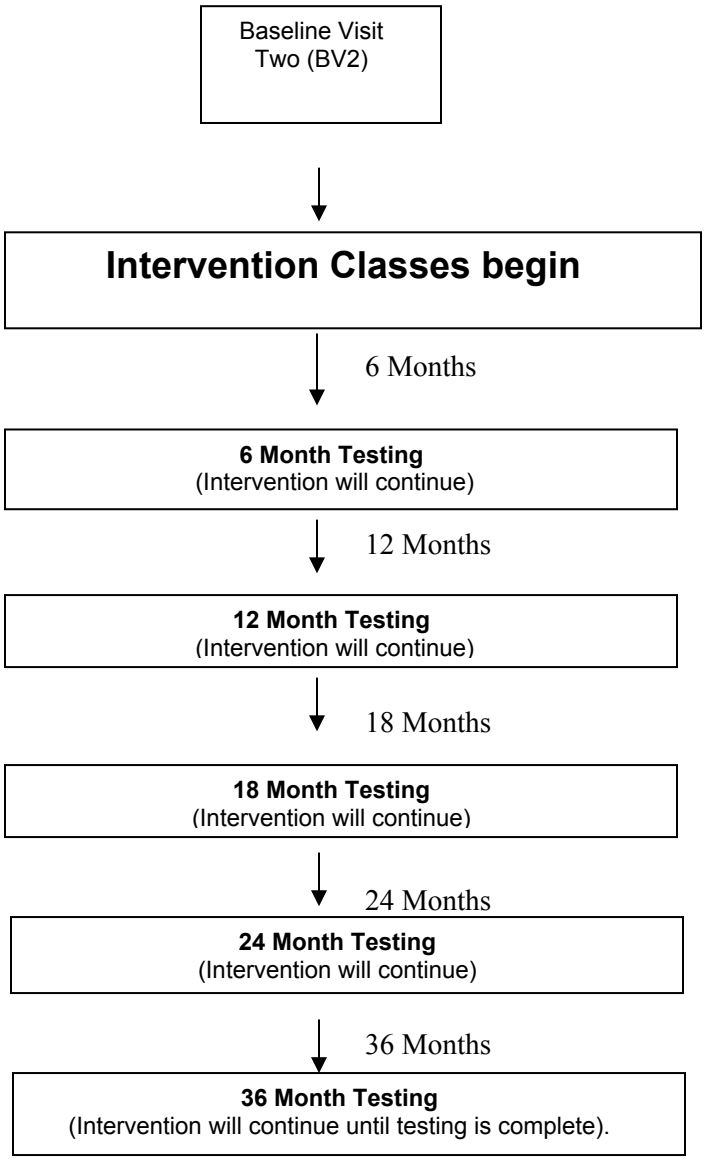
HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

The WE-CAN study has an enrollment of 840 people across all of North Carolina (Forsyth County, Johnston County, Haywood County), including approximately 420 people at this research site. Half of these in the study are assigned to the diet and exercise group (210 in Forsyth County). Only persons who were assigned to the diet and exercise group and achieved a 5% weight loss are eligible to participate in this study. We expect to enroll up to 210 persons at this site. 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).



Baseline Visit 2 (BV2):

- *Worrell Professional Center at Wake Forest University:* The study will be described in detail and you will be asked to sign this consent form. You will complete a questionnaire that asks how you handle stress in different situations and handle barriers.
- You will then be randomized to one of the study group assignments described below: weight loss maintenance or health education. 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 one

of these groups):

WEIGHT LOSS MAINTENANCE GROUP

- ***Behavioral Intervention***
    - During the first 5 months you will have 1 individual session each month (in-person consultation or phone consultation). You will have 2 individual sessions during month 6. The interventionist will visit your facility of choice during months 4-5. You will have a group session during months 1-3 and month 6.
        - In month 1 the interventionist will discuss the successes you had with WE-CAN and will meet with you to discuss which strategy you would like to continue (food logs, meal replacements, etc.). You will be weighed once per week.
        - In month 2 the interventionist will work with you on setting new goals (further weight loss or weight maintenance). They will help you develop internal incentives and identify obstacles faced in month 1. They will also help you to develop a plan to overcome these obstacles and to build social support. You will be weighed once per week during this month.
        - In month 3 the interventionist will work with you on balance and stability training and how to use a fitness tracker. You will be weighed once per week during this month.
        - In month 4 the interventionist will work on problem solving and goal re-evaluation. The interventionist will also perform a site visit to your gym of choice. During month 5 you will continue to work on problem solving. During months 4 and 5 you will be weighed once every other week.
        - In month 6 the interventionist will review your progress during months 1-5 and help to develop strategies to lose the weight that was gained back. They will help you to develop a plan for months 7-36. You will be weighed once.

- ***Exercise Intervention***
    - Throughout the entire 36 months you will be asked to exercise per ACSM guidelines for the duration of the program (150 minutes per week). You will have access to the WE-CAN exercise sessions for the first 6 months of the study. For months 1-3 you will be required to come to the facility one day per week for exercise. During months 4-5 you will be required to come to the facility once every other week. During month 6 you will be required to come to the facility once. During months 1-6, you may choose to come to the facility more often (up to 3 days per week).
    - 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.
    - Classes will be held at the Clinical Research Center at Wake Forest University and Innovation Quarter YMCA.
    - An interventionist will be at each session and will be available to answer

questions and talk through a training plan and goals.
- During months 7-36 you will transition into the facility of your choice. You will not be allowed to use the intervention facility during the study intervention times. A staff member will assist you in locating a facility for you to transition to.

HEALTH EDUCATION GROUP

- You will attend 2 group session classes during months 1-6. The face-to-face group meetings will occur at months 3 and 6. During the other months (months 1-2, 4-5) you will receive a newsletter.
- 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.
- The face-to-face group meetings will be held at the Clinical Research Center at Wake Forest University and Wake Downtown (you may choose your preferred location) in Winston-Salem, NC.

Participants in both groups will have the option of receiving a monthly text message for months 7-36. Additionally you will receive a newsletter during months 9, 15, 24, & 33.

6 Month Follow-up Visit (FU6): You will return for a follow up visit after 6 months.
(Wake Forest University): You will have your blood pressure, weight, hip, and waist 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, stress, eating habits, mental state, barriers, and health status. This visit should last approximately 1.5 – 2 hours.

12 Month Follow-up Visit (FU12): You will return for a follow up visit after 12 months.
(Wake Forest University): You will have your blood pressure, weight, hip, and waist 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, stress, eating habits, mental state, barriers, and health status. This visit should last approximately 1.5 – 2 hours.

18 Month Follow-up Visit (FU18): You will return for a follow up visit after 18 months.
(Wake Forest University): You will have your blood pressure, weight, hip, and waist 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, stress, eating habits, mental state, barriers, and health status. This visit should last approximately 1.5 – 2 hours.

24 Month Follow-up Visit (FU24): You will return for a follow up visit after 24 months.
(Wake Forest University): You will have your blood pressure, weight, hip, and waist 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, stress, eating habits, mental state, barriers, and health status. This visit should last approximately 1.5 – 2 hours.

36 Month Follow-up Visit (FU36): You will return for a follow up visit after 36 months.
(Wake Forest University): You will have your blood pressure, weight, hip, and waist 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, stress, eating habits, mental state, barriers, and health status. This visit should last approximately 1.5 – 2 hours.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 38 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.
- As part of this study, you will be asked questions about your mood and mental state. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. Taking part in this research study may involve providing information that you consider confidential or 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.

There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate 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 action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). 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 you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document (collection of health data).

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be 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 interventions 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 ARE THE COSTS?

All study costs, including any study medications and procedures 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 YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid *$25* if you complete the $36 month study visit. If you withdraw for any reason from the study before completion you will not be paid.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

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

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted]

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call [redacted].

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.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

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 or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; Clinical Research.IO (clinical trial management system),, the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives of Wake Forest University; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

1) 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.

2) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

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

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, 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 Stephen Messier 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:

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 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 due 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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the site investigator, [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted].

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

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

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