Official Title: Incorporating Nutrition, Vests, Education, and Strength Training in Bone Health (INVEST in Bone Health)
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Wake Forest™
Baptist Health

Section on Gerontology and Geriatric Medicine

Maintaining Gravitational Loading to Prevent Weight Regain: Follow up to the INVEST in Bone Health Trial
Informed Consent Form to Participate in Research

Daniel Beavers, PhD, Principal Investigator

SUMMARY

You are invited to be in a research study because you are participating or have participated in the INVEST in Bone Health study. The purpose of this study is to evaluate whether maintaining gravitational loading during intentional weight loss results in less regain of body and fat mass following weight loss. Your participation will involve completing 2 assessment visits, where you will undergo height and weight measurements, a DXA (dual energy x-ray absorptiometry) scan to measure your bone density, a resting metabolic rate test to measure the number of calories that your body uses at rest, and you will be asked to provide blood samples for future storage. You will also be asked to wear an activity monitor on your thigh. Your participation is voluntary. Research studies are designed to gain scientific knowledge that may help other people in the future.

Participation in this study will involve minimal risk. All research studies involve some risks. Some risks of this study that you should be aware of are: 1) claustrophobia during the resting metabolic rate test; 2) radiation from the study scan; 3) skin irritation from wearing the activity monitors; and 4) bruising, bleeding, and infection from the blood draw

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 include learning more about your health, losing weight, and reducing fracture risk.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you, including not participating. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Daniel Beavers, PhD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: [redacted]. If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

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 are participating or have participated in the INVEST in Bone Health study. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Please 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 see whether maintaining gravitational loading during intentional weight loss results in less regain of body and fat mass following weight loss. We will also explore the effects of external gravitational loading during weight loss on mechanisms of weight regain, including: body composition, resting and physical activity energy expenditure, and fasting/circulating levels of hormonal regulators of appetite.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

A total of approximately 100 people will take part in this study. This study will take place at Atrium Health Wake Forest Baptist facilities and at the Wake Forest University campus.

WHAT IS INVOLVED IN THE STUDY?

If you agree to participate in this study by signing this consent form, you will be asked to complete 2 assessment visits. The details about all study visits and procedures are provided below. We will make every effort to follow the visit procedures in the order they are outlined below; however, it may be necessary at times to make changes to accommodate different schedules.

Follow-Up Visit 24A (FV24-A)

We will ask that you come to Wake Forest University. At this visit you will learn more details about the study and you will be given time to ask questions and get satisfactory answers. You will then be asked to sign this informed consent form. After signing the consent form, we will:

- Measure your body weight and height;
- Perform a series of DXA (dual energy x-ray absorptiometry) scans, which are painless scans of your body that determine the amount of bone, fat, and muscle you have (more details provided in the Risks Section of this form);
- Place an activity monitor on your thigh for you to wear for approximately one week and return at your next visit.

This visit will take approximately 1 hour.

Follow-Up Visit 24B(FV24-B)

For your next visit, you will come to Atrium Health Wake Forest Baptist in the morning for an additional study visit, having fasted for at least 10 hours prior to your appointment time. We will also ask that you refrain from exercising for 24 hours prior to coming in. At this visit, we will:

- Measure your body weight and height;

- Measure the number of calories your body uses at rest. [The number of calories you burn at rest will be measured before and after the intervention using a resting metabolic rate test (RMR, for short). For this test, you will lie comfortably on a bed for 30 minutes, and a face tent will be placed over your nose and mouth. You are able to breathe through this face tent. Based on the air you breathe in and out, your resting metabolic rate is calculated.];
- Draw blood (about 2 tablespoons) from a vein in your arm to store blood for future testing of levels of hormones related to appetite;
- Provide you with light breakfast snack

This visit will take approximately 1.5 hours.

HOW LONG WILL I BE IN THE STUDY?

Your participation in this study will last until you have completed both assessment visits. You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the study investigators or study staff first to learn more about potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study investigators or study staff. Risks and side effects related to the study diet and study procedures include:

1 Resting metabolic rate (RMR) test

Some participants begin to feel claustrophobic when the face tent is placed over the nose and mouth. Should this occur we will remove the face tent and stop the test.

2. Body measurements and radiation

A dual energy X-ray absorptiometry machine (DXA) scan will measure the amount of your muscle, bone and fat. This machine uses photons (energy) which scan across your body while you are lying quietly on a padded table. You will lay flat on a padded table with a machine moving around you for about 45-60 minutes for the DXA scan. You will be lying down the whole time and will not be able to get up until the scan is complete.

This research study involves exposure to radiation from the DXA scan. The amount of radiation that you will receive from this procedure is equivalent to a uniform whole body dose of 45 millirem. This is equal to 0.15 times the average yearly radiation exposure from background radiation (300 mRem).

The risk of this procedure is small. Please be aware that this radiation exposure is necessary for this research study only and is not essential for your medical care. Atrium Health Wake Forest Baptist's Radiation Safety Committee, a group of experts on radiation matters, has reviewed the use of radiation in this research study and has approved this use as being necessary to obtain the research information desired. The potential long-term risk from these radiation doses is uncertain.

The scans are being conducted only for the purpose of research. It is a different test than what is

used in the clinical setting to detect or discover medical conditions. It is not a substitute for a clinical scan. Research personnel will analyze the scan only for the specified research findings. If we should happen to see an abnormal finding that may be harmful to your health, we will notify you. Unexpected findings on the limited research scan will occasionally allow early discovery of a medical condition for which you may need treatment. They may also cause undue worry or result in additional testing, sometimes costly, which may or may not benefit your health.

If you participate in this study, you will be exposed to amounts of radiation above what you would normally receive in daily life. To be sure that you do not receive an unhealthy amount of radiation from your participation in this study, you should let your study doctor know if you have had, or are going to have, any other scans or x-rays as part of your medical or dental care. It is very important that you let your study doctor know if you already are participating in, or plan to participate in, any other research study that involves radiation exposure.

3. Wearing the activity monitors

Risks are minimal, but may include minor skin irritations if the monitor is worn directly on your skin. Monitors will be worn on your thigh and vest wearers will also wear in their vest on occasion. You will be instructed to note these on your log and if it becomes bothersome to remove the device and call staff for further instructions.

4. Blood sampling

Blood samples (about 2 tablespoons total) will be drawn from a vein in your arm at 1 visit after an overnight fast. You may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally, some people become dizzy, lightheaded or feel faint. Infection may occur on rare occasions.

If you agree to participate in this study, your blood will be stored to use for future research. These samples will be kept frozen and may be used in future research to learn more about other diseases. Blood samples will be stored in the Biogerontology Laboratory in the Nutrition Research building at Wake Forest School of Medicine (WFSM) under the supervision of Dr. Barbara Nicklas, and it will be used only by researchers approved by Dr. Beavers. An Institutional Review Board (IRB) must also approve any future research study using your blood and urine samples. Blood samples will be stored at Wake Forest University Medical Center for up to twenty years after the end of the trial at which time the samples will be destroyed. In order to participate in this study, you must be willing to provide this sample for future research.

Your blood samples will be stored with a unique identifier and will not include any identifiable information about you, such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule regulations. The unique identifier will be a randomly assigned number and only Dr. Beavers will have access to the code that links the unique identifier to you. Your name, address, social security number, etc. will never be disclosed to future researchers and neither will the code that links your identifiers to the sample.

The research that may be done with your blood samples is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of this study. It might help people who have diseases at some point in the future, but it is not known if this will happen. The

results of the research done with your blood sample will not be given to you or your doctor. These results will not be put in your medical records. The research using your blood samples will not affect your care. Your blood samples will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of this research.

In the future, people who do research may need to know more about your health. While the study investigator may give reports about your health, she will NOT be given your name, address, phone number, or any other identifying information about who you are.

There also may be other side effects and/or risks 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.

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.

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 include receiving information about your body fat amount and location and bone density.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

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 the National Institutes of Health 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.

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, how you respond to study activities or procedures, laboratory and other test results, 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 may 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.

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.

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. 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 Wake Forest University Health Sciences and Wake Forest University who oversee research

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

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

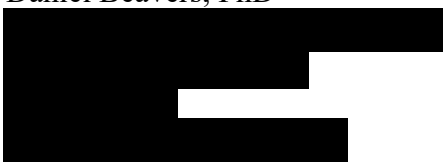
publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your original medical record for verification of clinical trial procedures or data, without violating your confidentiality 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 law.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least 6 years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. Study identifiers will be kept indefinitely. 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 Dr. Daniel Beavers 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:

Daniel Beavers, PhD


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.

If you choose to participate in this study, your medical record at Atrium Health Wake Forest Baptist will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://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 Web site at any time.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE THE COSTS?

All study costs, including 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. You will receive a parking voucher that will cover the cost of parking for each of your visits.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid $50.00 for completing study visit FV24-A and $50.00 for completing study visit FV24-B ($100.00 total for both visits). If you complete one visit, you will only be paid for that visit. If you withdraw from the study before completion of either study visit, you will not receive any payment. Payments will be made by gift card.

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Translational Science Center at Wake Forest University. The sponsor is providing money or other support to Atrium Health Wake Forest Baptist and Wake Forest University 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 1 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 Daniel Beavers, PhD, at [redacted] during normal business hours or [redacted] after hours and identify yourself as an INVEST study participant.

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:

- your study doctor feels it is in your best interest;
- you may not be following the instructions properly;
  you do not later consent to any future changes that may be made in the study plan;
- or for any other reason.

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 study investigator, Daniel Beavers, PhD, at [redacted] during normal business hours or [redacted] after hours and identify yourself as an INVEST study participant.

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

WFU School of Medicine
Institutional Review Board
IRB Number: IRB00058279
Meeting Date Approved 3/5/2024
Version Valid Until: 1/2/2025

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