Health, Aging and Later-Life Outcomes Pilot Trial (HALLO-P): A 9-month Randomized Pilot Trial of 3 Nutritional Interventions in 120 Older Adults With an Indication for Weight Loss
NCT05424042
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Health, Aging and Later-Life Outcomes Pilot (HALLO-P) Study

Informed Consent Form to Participate in Research
Internal Medicine – Gerontology and Geriatric Medicine

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SUMMARY

You are invited to participate in a research study. The purpose of this research is to better understand whether reducing the number of calories you consume or changing when in the day you consume them affects how you age. You are invited to be in this study because you are at least 60 years old and you meet other eligibility criteria for the study. Your participation in this research will involve visits to our clinic for testing and weekly intervention visits (in-person or remote depending on your group assignment) for nine months with your total participation lasting about a year.

This study has screening and baseline testing visits to ensure you are eligible and that it is safe for you to participate. Once that is determined, you will be assigned to one of two groups which meet for about 9 months. During the intervention period you will have one follow-up clinic visit after 6 months and two clinic visits after about 9 months. You will be assigned by chance to one of the following study groups:

- Remote/virtual counseling to reduce calorie intake combined with increasing physical activity across the day.
- In-person counseling to reduce the time that you eat each day to an 8-hour window combined with increasing physical activity across the day.

All research studies involve some risks. A few risks involved in this study that you should be aware of are muscle soreness from physical testing, bruising from blood draws, and radiation from the body composition and bone density scans. These risks are low. You may or may not benefit from participation in this study.

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. Some other choices may include talking with your doctor about drugs you might be prescribed to promote weight loss, surgery, or an eating program that may fit your dietary needs and goals. You will not lose any services, benefits, or rights you would normally have if you decide not to participate in this study.

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 Stephen Kritchevsky, PhD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, contact him at [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 called HALLO-P. 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 at least 60 years old and you meet other eligibility criteria for the study.

Your participation is voluntary. Please take your time as you review this form and make your final decision about participating in this study. Ask the study staff to explain any words or information you do not understand. You may also discuss the study and this consent form with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research is to better understand the effects of caloric restriction and time restricted eating (TRE). Caloric restriction (CR) means eating fewer calories than you usually do. TRE means limiting when in the day you eat your calories. In this study, participants in the TRE group will reduce the time that they eat each day to an 8-hour window. The data collected from the study will provide us with preliminary information needed to test whether CR or TRE might slow aging.

Information from this study will be used to plan for a future study where participants may be asked to participate for four to five years. Being in this study does not mean that you have to participate in the future study. The information learned from this study will help us know if a long-term study is feasible.

WHO IS SPONSORING THIS STUDY?

The National Institute on Aging (NIA) and the National Cancer Institute (NCI) are funding this study. Other than support to conduct the study from the NIA and NCI, the researchers do not benefit financially from your participation.

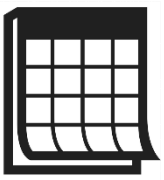
NIH National Institute on Aging

NIH NATIONAL CANCER INSTITUTE

HOW MANY PEOPLE WILL BE IN THIS STUDY?

Approximately 100 people will take part in this study. In order to identify these people, we may need to screen around 500 people.

HOW LONG WILL I BE IN THIS STUDY?



If you are eligible, you will be in this study for approximately one year. This includes two screening visits to find out if you are eligible for the study, two baseline visits that take place before you are assigned to a study group, one follow-up visit at about 6 months after you start intervention, and two follow-up visits at around 9 months after you start intervention. Your

participation also includes being in one of two groups for 9 months with weekly then monthly visits (either in-person or by e-mail or the internet depending on your group assignment). You can stop participating at any time.

WHAT IS INVOLVED IN THIS STUDY?

If you agree to participate in this study by signing this consent form, your involvement will last around 12 months. We will first ask that you come to Atrium Health Wake Forest Baptist to complete two screening visits to make sure you qualify for the study. If you qualify, you will be asked to complete two baseline testing visits before beginning one of the 9-month interventions. You will also be asked to complete one testing visit after about the first 6 months of the intervention, and two visits towards the end of the intervention. The details about all study visits and tests are provided below. We will try to conduct these visits in the order they are outlined below; however, it may be necessary to make changes to accommodate scheduling. There may be down time during some of your visits so we recommend bringing a book or something to keep you occupied as needed.

Screening Visit 1 (SV1)

Before this visit, we will ask you to fast for at least 10 hours prior to your appointment, having nothing to eat or drink except water. At this visit, we will ask you to come to the Sticht Center where 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 height, weight, blood pressure, pulse, and waist circumference.
- Draw blood (about 1 tablespoon) from a vein in your arm to test your blood cell counts, lipids and sugar levels, thyroid (TSH), and liver and kidney function as well as a tube to help with quality control for the machines we use to analyze your blood
- Provide you with a light snack.
- Ask you to answer questions about your medical history, medications, feelings, and memory
- Ask you to answer questions about your eating habits now and whether you are ready to change them.
- Measure your body composition and the bone density of your hip and spine using a Dual X-ray Absorptiometry (DXA) scanner.

This visit will take approximately 2-3 hours. If you continue to qualify for the study, you will be scheduled for a second screening visit. If something comes back from your blood tests or DXA scans that would disqualify you, we will call you and your second screening appointment will be cancelled. The results of the tests will be shared with you.

Screening Visit 2 (SV2) / Run-in Evaluation

No matter which group you are assigned to, you will be asked to use several electronic devices to monitor your progress throughout the study. Therefore, it is important for us

to know that you are willing to use these tools. You *do not need to be experienced in the use of technology to participate in the program*; *we will teach you what you need to know.* N*o prior experience is required*. We will ask you to come to Piedmont Plaza where a study staff member will provide instructions on what to do for the next week. You will use a paper diary to track everything you eat and drink for the following 7 days. If you cannot or do not comply with the run-in instructions to record your food and weigh yourself for the next week, you may not be eligible for the study.

The staff member will also provide you with a body weight scale that automatically sends your weight measurement to study staff using a cellular chip. You will be asked to weigh yourself once per day for the next month or so. The staff member will guide you through an orientation to each of these devices so that you are comfortable in their use. You will be given a handout with key information and you will receive a call within a few days to see if you have questions and to check that you are able to use them easily.

You will also be given a single pill of labeled creatine with instructions on when to take it. Creatine is a substance that your body uses to make muscle. Labeled creatine is just like the natural compound creatine. The only exception is that the regular hydrogen atoms have been replaced by deuterium, which is a stable isotope of hydrogen. Deuterium in not radioactive. It is found in nature, even in the water we drink. By replacing the hydrogen with deuterium, the labeled creatine molecule can be traced in experiments. We will ask you to take the creatine 3 to 6 days before your next visit and will collect a urine sample during that visit. By measuring the amount of labeled creatine in your urine 3 to 6 days after you take it, we can determine the total amount of skeletal muscle in your body. A member of the research team will remind you to take the labeled creatine pill so we can collect the urine sample at your next visit.

This second screening visit will last less than one hour.

Baseline Visit 1 (BV1)

Before this visit, we will ask you to fast for at least 10 hours prior to your appointment, having had nothing to eat or drink except water. We will also ask you to refrain from exercising, consuming caffeine, and drinking alcohol 10 hours prior to this visit. At this visit, we will ask you to come to the Sticht Center where we will:

- Ask you to provide a urine sample for storage, creatine measurement, and for use during the doubly labeled water measurement described below.
- Measure how many calories your body burns. This will be done in two ways:
    - One way to do this is the "doubly labeled water technique." It is often used in research to measure total calorie usage over a period of 10-15 days. You will be asked to drink approximately 4 oz. of water that contains naturally occurring heavy oxygen and hydrogen atoms, which are also found naturally in our bodies and in the food and water we consume. These atoms are NOT radioactive and are completely safe as this has been used safely in studies of premature infants, newborns, pregnant and lactating women (more details provided in the Risks Section of this form). Four to six hours after drinking the water, we will ask you for two additional urine

samples at least 30 minutes apart. We will ask you to drink some water throughout your visit but you will not be able to have any other beverages.
    - Another way is to measure your calorie needs while you are resting (your resting metabolic rate). This is done by having you recline and placing a mask-like device over your nose and mouth. You will breathe normally as a machine measures your oxygen use (more details provided in the Risks Section of this form).
- Draw blood (about 5 tablespoons) from a vein in your arm to measure substances in your blood that are associated with how we age and to store some blood that will be analyzed at a later date (more information in the Storage of Biological Tissue section).
- Give you a light snack.
- Give you an activity monitor to be worn on your thigh for 10-15 days (until your next visit) to record your activity level.
- Give you a written log to track your sleep.
- Ask you to recall what you ate and drank over the last 24 hours. We will teach you how to record this information on the iPad that the study will provide to you. We will also show you how to do this two more times at home during the next several weeks. You will be prompted when we want you to enter this information for these two days.
- Ask you questions about food cravings, your weight, your quality of life, stress, fatigue, sleep, and other items affecting your day-to-day life.
- Ask about any health events or new medications you may be taking since your last visit.
- Remind you to keep using the home scale to weigh yourself daily.
- Offer you lunch in the cafeteria if you would like to eat before leaving.

This visit will take approximately 6 hours.

Baseline Visit 2 (BV2)

Ten to 15 days following your first baseline visit, you will be asked to come in for a brief visit to provide two urine samples and to return the activity monitor you have been wearing. The 2 urine samples will be collected at least 30 minutes apart to complete the doubly labeled water testing from the last visit. We will also ask you to do a series of physical performance tests to measure your balance, chair rise time, walking speed, and grip strength. We will also ask you to walk 400 meters (which is about 3-4 blocks) as fast as you can.

You will need to continue to weigh yourself daily for the week following this visit.

This visit will take about an hour. This visit completes your baseline testing and someone from the study team will call you a few weeks before the intervention start date to tell you what study group you have been assigned to and give you more information about that group. Depending on your assigned intervention group, we may collect your scale; otherwise, you will keep the devices throughout intervention.

Randomization
You will be randomly assigned (like flipping a coin) to one of the study groups listed below.You will have an equal chance of being placed in any of the 2 groups. You must agree to be in either group and you may not pick or change the group that you are placed in. You will participate in your assigned group for a total of 9 months before the final testing visits are conducted.

The groups include one of the following:

- Remote counseling to reduce calorie intake combined with increasing physical activity across the day.
- In-person counseling to reduce the time that you eat each day to an 8-hour window combined with increasing physical activity across the day.

General Introduction to the Interventions
The specific requirements of the two different interventions are summarized in the table below. All interventions have a similar schedule of individual and group session contacts across the 9 months. They all involve the use of technology with goals focused on both *eating* and *physical activity* behavior. The main difference is one involves a reduction in calorie intake and use of an electronic scale for daily weigh-ins and the other involves restricting when you eat to the same 8-hour time interval each day. You get to choose when this occurs out of the following options: 7am-3pm, 8am-4pm, 9am-5pm, 10am-6pm or 11am-7pm. Regardless of which group you're in, you will wear a watch that records the steps you take each day. Everyone will receive a Fitbit watch to help track their steps.

Key Features of the Different Groups		
Feature	**The Two Intervention Groups**	
	Remote Intervention Focused on Reducing Calorie Intake	**Restricting the Time that you Eat Each Day to an 8-hour Period**
2 Individual Orientation Sessions: Technology & Nutrition—about 40 min each	1. A technology session on the use of study devices. 2. A nutrition session to explain the dietary goals of the study and what it means for you.	1. A technology session on the use of study devices. 2. A nutrition session to explain and select an 8-hour eating window.
Dietary Goal	20% reduction in calories	8h Time Restricted Eating (TRE); no reduction in calories
Physical Activity Goal	Increasing steps taken throughout the day from what you do now on most days of the week.	Increasing steps taken throughout the day from what you do now on most days of the week.
Individual Sessions (~30 min)	1 videoconference call monthly (iPhone or video conferencing as needed)	1 in-person each month (in person, phone, or video conferencing as needed)
Group Sessions (30-45 min each)	3 videoconference calls monthly for first 6 months; 1 monthly thereafter	3 in-person monthly for first 6 months; 1 monthly thereafter
Use of an iPad	A study-provided iPad, paired with an activity monitor, is used daily to enter data and receive feedback on your eating and activity goals.	A study-provided iPad, paired with an activity monitor, is used daily to enter data and receive feedback on your eating and activity goals.

If you are assigned to the TRE group, we will ask you to wear a continuous glucose monitor (CGM) for around 7-10 days after being in the intervention for about 2 months. A CGM is a small device that is placed on the lower stomach. The device monitors glucose levels through a small sensor inserted just underneath the skin (see risk section for more information). We will place this on you during one of your intervention sessions and will remove it the following week at your next session. If you happen to miss the next session, please remove the device as instructed, after approximately 7-10 days and place in a sealed bag and bring it back to the next intervention visit along with the form that says when you removed it. You will do this again after being in the intervention for at around 7 months.

6-month follow-up visit (FV1)

After participating in your group for about 6 months, we will ask you to come to the clinic for your first follow-up visit. Before this visit, we will ask you to fast for at least 10 hours prior to your appointment, having had nothing to eat or drink except water. At this visit, we will ask you to come to the Sticht Center where we will:

- Measure your height, weight, blood pressure, pulse, and waist circumference.
- Draw blood (about 2 tablespoons) from a vein in your arm for measuring substances in your blood that are associated with how we age.
- Collect a urine sample for storage.
- Give you a light snack.
- Ask you to complete an online cancer risk assessment and ask you questions about any history of cancer and any cancer screenings you may have had. We may ask you to do this at a later visit or over the phone if you have already completed this visit.

This visit will last about an hour.

First 9-month follow-up visit (FV2)

Before this visit, we will ask you to fast for at least 10 hours prior to your appointment, having had nothing to eat or drink except water. We will also ask you to refrain from exercise, consuming caffeine, and drinking alcohol 10 hours prior to this visit. You will also be mailed a creatine pill and instructions on when to take prior to this visit. At this visit, we will ask you to come to the Sticht Center where we will:

- Measure your height, weight, blood pressure, pulse, and waist circumference.
- Ask you to provide a urine sample for storage, creatine measurement, and for use during the doubly labeled water measurement.
- Measure how many total calories your body burns using the doubly labeled water technique just like you did at baseline. Four to six hours after drinking the water, we will ask you for two additional urine samples.
- Measure the number of calories your body uses at rest just like at baseline. This is done by having you recline and placing a mask-like device over your nose and mouth. You will breathe normally as a machine measures your oxygen use.
- Draw blood (about 6 tablespoons) from a vein in your arm to test blood cell counts, lipids, insulin and sugar levels, thyroid (TSH), liver and kidney function, and for

substances in your blood that are associated with how we age. Some blood will be stored and analyzed at a later date.
- Provide you with a light snack.
- Provide you with an activity monitor to wear for 10-15 days (until your next visit) to record your activity level.
- Ask you to use the home scale to weigh yourself daily for the next approximately 2.5 to 3 weeks.
- Measure your body composition and the bone density of your hip and spine using a Dual X-ray Absorptiometry (DXA) scanner.
- Ask you to recall what you ate and drank over the last 24 hours and record this information on the iPad that the study provided you. We will remind you how to do this two more times at home during the next week. You will be prompted when we want you to enter this information again for these two days.
- Ask you questions about your mood, memory, food cravings, your weight, your quality of life, stress, fatigue, sleep, and other items affecting your day-to-day life.
- Offer you lunch in the cafeteria if you would like to eat before leaving.

This visit will take approximately 6 hours.

Second 9-month follow up-visit (FV3)

Ten to 15 days following your FV2, you will be asked to come in for a brief visit to return the activity monitor that you have been wearing and to also collect 2 urine samples at least 30 minutes apart.

We will also ask you to do a series of physical performance tests to measure your balance, chair rise time, walking speed, and grip strength. We will also ask you to walk 400 meters (which is about 3-4 blocks) as fast as you can. We will also ask about your experience in the study and give you a chance to offer any feedback.

You will need to continue to weigh yourself daily for the week following this visit. This visit completes your study participation and someone from the study team will arrange to collect the body weight scale and iPad after completion. You will be able to keep the Fitbit watch as a thank you for participating.

This visit will last about 1-2 hours.

We may call you around a year later to see how you are doing and ask about your weight. You don’t have to take this call or answer any questions and if we wanted to do anything else, we would ask you to sign another consent form, which would be optional.

STORAGE of Biological Specimens

If you agree to participate in this study, we will draw a little less than a cup of blood (~211 ml) and about a cup of urine (~300 ml) over the course of all study visits. About half of this amount will be stored for use at a later date. These samples will be kept and may be used in future research to learn more about aging and disease. Your samples will be obtained within the Clinical Research Unit at Atrium Health, Wake Forest University Health Sciences. The samples will be stored at Atrium Health, Wake Forest

University Health Sciences and it will be given only to researchers approved by one of the study PIs. Your samples may be transferred to the Aging Research Biobank for long-term storage under the direction of the NIH. An Institutional Review Board (IRB) must also approve any future research study using your blood and urine samples. In order to participate in this study, you must be willing to provide these samples for future research.

The research that may be performed with your blood and urine samples is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research 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 performed with your blood or urine will not be given to you or your doctor. The results will not be put in your medical record. The research using your blood or urine sample will not affect your care.

Your blood and urine 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 the research.

Your blood and urine 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. The unique identifier will be a randomly assigned number and only the principal investigator 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.

AUDIO AND VIDEO RECORDING

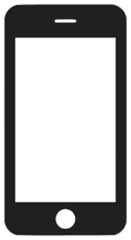
As part of this study, you may be audio- and video-recorded during the intervention sessions. This is to ensure that the sessions are being conducted in a consistent way. You should also understand that you will not be able to inspect, review, or approve the recordings before they are used in this study.

HOW WILL I BE CONTACTED?

While you are participating in the study, you will be contacted by HALLO-P study staff.

You may be contacted in the following ways:

- Text messages
- Phone calls
- Email
- Through an app on your iPad



The iPad you will be given has an app that needs internet to connect but

your home Wi-Fi or data plan is sufficient. Depending on the settings used on the iPad, messages received through the app may appear on your device as soon as they are received, even when it is locked. These messages could be seen and read by others who are near your device when the messages are received.

WHAT ARE THE BENEFITS OF BEING IN THIS STUDY?

If you join this study, there may or may not be a direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating may include learning about your own eating behaviors and making positive changes in your diet to improve your overall nutrition. In addition, people who follow a caloric restriction or a time restricted eating diet have been shown to experience weight loss and other benefits in their overall metabolic health, including reductions in inflammation, and improvements in glucose control and in specific risk factors for heart disease, diabetes and arthritis. You may also benefit from the physical activity intervention that will teach you to get up and move more frequently and you may learn things you can incorporate into your daily routine that could make you heathier. You will also receive some of the results of your tests that you can share with your doctor.

WHAT ARE THE RISKS OF BEING IN THIS STUDY?

Being in this study may involve risk to you. You should discuss the potential risk of being in this study with the study investigators or staff. A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing safety and other data from this research throughout the study. Risks and side effects related to the study programs and study procedures include:

1. Caloric Restriction

There are no known serious risks associated with using caloric restriction to lose weight. Changes in usual bowel function (diarrhea and/or constipation) may occur when beginning a caloric restriction diet due to differences between this diet and your usual diet. With weight loss, most people naturally lose some muscle mass and bone, along with body fat. In some cases, people who reduce their calories by 20% for nine months may experience extensive weight loss that causes even more loss of muscle and bone. Also, under conditions of rapid weight loss (more than 2% of weight lost on average per week), there is a very small chance of developing gallbladder disease. This will be monitored by the study dietitian and if you are losing weight too rapidly, you will be guided to slow down the rate of weight loss.

2. Time Restricted Eating (TRE)

Side effects of TRE may include hunger, irritability, difficulty concentrating and low energy levels during the time you are asked not to eat/drink any calories. These side effects will be minimized by providing guidance on consuming meals with adequate dietary protein (~25 g protein) and fat (20-30% of kcals) at the last meal of the day to promote fullness and minimize potential side effects of hunger and irritability during the overnight fast. Side effects usually go away after a few days of following the eating plan. Hypoglycemia or low blood sugar can also be a risk of TRE, particularly in those with diabetes.

3. Devices and Mobile Applications

While the devices themselves don't pose any risk, you may become frustrated with some of the technical aspects of the devices and applications you may be asked to use. You will be given time to learn with the study staff but please reach out if you ever have any questions.

4. Resting metabolic rate (RMR) test

The number of calories you burn at rest will be measured. For this test, you will recline comfortably for up to 30 minutes with a face mask placed over your mouth and nose; you will be able to breathe easily. However, some participants may feel claustrophobic when the mask is placed over the nose and mouth. Should this occur, we will stop the test.

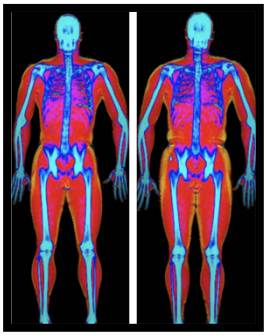
5. Physical performance tests

There is a slight risk of falls while participating in the balance test. However, you will be positioned beside wall that can be reached immediately if you feel that you are going to lose your balance. Additionally, the staff member conducting the test will stand next to you at all times. There is a small possibility that you may stumble, fall or aggravate one of your joints/muscles during the walking test. You will not be asked to conduct these tests if you have a pre-existing and serious leg injury.

6. Doubly labeled water

There are no known risks associated with the consumption of doubly labeled water. The advantage of this method is that it uses stable isotopes so there is no radiation exposure associated with the assessment. The method uses two heavy isotopes (2H2O and H218O), both of which occur naturally in our bodies and in the food and water we consume. There are no known side effects of either isotope at the dose given in this study. This is considered extremely safe as this assessment has been used in studies of premature infants, newborns, pregnant and lactating women.

7. Body composition and bone density measurements and radiation



A dual energy X-ray absorptiometry machine (DXA) will measure the amount of your muscle, bone and fat. We will conduct whole body scans and scans of the hip and spine two times. This machine uses photons (energy) which scan across your body while you are lying quietly on a padded table for the duration of each scan (5-10 min), for a total of up to 30 minutes. 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 DXA scans. The risk of these procedures is small and is similar to that received from clinical x-ray and nuclear medicine studies. The amount of radiation exposure that you will receive from these procedures is equivalent to a uniform whole-body exposure of 30 millirem. This is equal to one-tenth of the amount of natural background radiation that the average person in the United States receives each year (300 millirem).

Please be aware that this radiation exposure is necessary for this research study only but is not essential for your medical care. Atrium Health Wake Forest University Health Science's Radiation Safety Committee, a group of experts on radiation, has reviewed the use of radiation in this research study and has approved this use as necessary to obtain the research information desired. The potential long-term risk from these radiation doses is uncertain, but these doses have never been associated with any definite adverse effects. Thus, the risk to you, if any, is estimated to be slight. 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.

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 to obtain specific research results. If we see something that indicates a risk to your health, we will notify you. Unexpected findings on the limited research scan will occasionally allow early discovery of a medical condition (such as osteoporosis) 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.

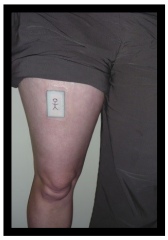
8. Blood sampling

You may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally, some people become lightheaded or feel faint. Infection may occur on rare occasions. These rare occurrences will be minimized by having a trained phlebotomist do the blood draws.

9. Continuous Glucose Monitoring (CGM)

CGM systems are considered minimally invasive, involving a sensor probe placed on the lower stomach to measure glucose levels in the interstitial fluid. They are painless to apply, and easy to wear and remove. They are water resistant, allowing for bathing, swimming, and exercise, and should not hinder or impact activities of daily life. Risks primarily include infection at the device insertion site and skin irritation or reaction from the adhesive used to secure the device. These risks will be minimized by having trained staff place and remove the CGM device to maximize correct and comfortable placement and alleviate any potential participant concerns. If it falls off before your next intervention session, please place in a sealed bag and bring it with you to your next class noting the day and time it came off.

10. Activity Monitor



You may have some redness, chafing, or other skin irritation from the tape used to apply the activity monitor. Some hair on the thigh may need to be shaved to secure the monitor.

11. D3 or Deuterated Creatine

Deuterated creatine is a natural compound found in muscle and the amount you will be given is small, 30 mgs or less than 1/100th of an ounce. People in other studies have been given 5,000 – 30,000 mgs of creatine daily for days or weeks without evidence of side effects other than mild diarrhea at the higher doses. Please notify the study research team if you experience rare side effects such as a stomach pain, diarrhea, nausea, or muscle cramping.

12. Confidentiality

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. By participating in this study, you will use several technologies that will help you stay in touch with your peers and your coaches and to better understand your patterns of moving and eating. Any time you use this type of technology there is risk that others could view the data collected on these devices. Within this study you will use:

- An Apple iPad Tablet Computer. This is a small touchscreen tablet computer that you may use to communicate with the study team on a video calling program called Zoom. It will have a Fitbit program installed on it (see next bullet), and you will use it to access a study-specific website to get feedback and to chat with your peers. We will not enter any of your personal information into the iPad. However, the iPad has a global positioning system (GPS) feature that will help us locate it if it is lost or stolen. Therefore, Apple may collect information about where in the world the iPad is located.

- A Fitbit step tracker plus iPad app. The Fitbit is a small watch that collects information on your steps throughout the day. Depending on your device, it may also collect information about your heart rate as you move during the day, though we will not use this information in this study. The watch sends this information to an app (or program) on the iPad, which then uploads this information to Fitbit (a Google company) on the internet. We use this information to give you feedback on how often you move. We might ask you to also use the Fitbit app on the iPad to enter the foods and beverages you consume during the day. To use Fitbit, you may need to have access to a Google account—the same type of account that you would use to access Gmail or Google Calendar—to use the device and participate in this study. We will work with you to create a study-specific account to provide an added layer of privacy. It is important to recognize that use of services from companies such as Google may reduce your privacy and prior to participating in this research you should be comfortable knowing that Google and other third parties may be able to view your physical activity and eating behaviors or other information you provide to Fitbit, as well as other information such as browsing behaviors or where your iPad is in the world. We advise against editing your account to include your name or other personal information or using the Fitbit app to share your information as part of a “challenge,” as these activities reduce your privacy.

- A BodyTrace wireless weight scale. At times in this study, you may be asked to use a BodyTrace wireless weight scale. This uses a cellular chip to transmit your body weight to BodyTrace Inc, and then on to the research team. Your weight information is associated only with the serial number of the scale, though BodyTrace may be able to see roughly where in the world the scale is located.

• The Companion App website. Finally, you will use the iPad to access a website throughout the study period that will allow you to connect with your group and receive feedback on your eating and moving goals each day. This website is managed by Atrium Health Wake Forest University Health Sciences and will securely store information such as how often you open up the app and the content of your group messages.

We will work closely with you to minimize the amount of personal information that is included in these tools. Still, there is always a risk when using technology that individuals outside of the study team may see the information described above. You are not required to use these technologies and you can cease using them at any point in the study period, though you would be unable to continue in the study.

13. Other

There may be other side effects that we cannot predict. You should tell the research staff about any medical conditions you have, as this may avoid side effects, interactions, and other risks.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study, you do not have to participate. You do not have to be in this study to make lifestyle changes. Some other choices available include talking your doctor about drugs you might be prescribed to promote weight loss or surgery. You can also talk to other specialists in the community, such as a health coach or dietitian, about other choices you can make to have a healthier lifestyle.

WHAT IS THE COST TO JOIN THIS STUDY?

There are some costs to you for taking part in this study. The study RD may recommend an individualized meal plan and specific changes to your diet which may include a calcium and/or vitamin D supplement. You will be responsible for the costs of any dietary changes you choose to make. All study costs 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 be responsible for maintaining adequate Wi-Fi coverage during the study intervention. If you no longer have Wi-Fi, please let the study team know and we can provide you with an iPad that has a data plan.

Depending on what group you are assigned to, you may be given an iPad, Fitbit and a body weight scale to use. We expect that you will keep up with these devices throughout the study as described under the intervention section and return them when requested. If lost or stolen, the device(s) may be replaced (if any are available).We would not expect you to pay for replacement but we ask you to keep these devices in a safe place.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study. You will be able to keep the Fitbit provided to you at the beginning of the study as a thank you.

WHAT ABOUT MY HEALTH INFORMATION?

What is Protected Health Information (PHI)?
In this research study, any new information we collect from you and information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information (PHI). The information we will collect for this research study includes**:** your name, address, phone number, date of birth, medical history, and the information we receive during the intervention and clinic visits.

Will my PHI remain confidential?
We will make every effort to keep your PHI private. We will store records of your PHI in a cabinet in a locked office or on a password protected computer. Your identity and your PHI will not be shared unless: it is required by law; it is necessary to protect the safety of yourself or others; if you give us permission to share it.

Who has access to my PHI?
Your PHI may be given to others during and after the study. This is for reasons such as carrying out the study, determining the results of the study, making sure the study is being done correctly, providing required reports, and getting approval for new products.

Some of the people, agencies and businesses that may receive and use your PHI are:

- HALLO-P Investigators and staff
- Study doctors
- National Institutes of Health and National Cancer Institute (the funding agencys)
- Representatives of the funding agencys assisting with the research
- Investigators at other sites who are assisting with the research
- Laboratories, reading centers or analysis centers
- Other companies who are assisting with the research
- The Institutional Review Board
- Department of Health and Human Services (DHHS)
- Representatives of Wake Forest University Health Sciences and Atrium Health Facilities
- Representatives from government agencies that review our study for safety.

Some of these people, agencies and businesses may further share your PHI if they need to. Once they share your information, it may no longer be covered by federal or state privacy rules.

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

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 only to the extent permitted by other applicable laws.

How long will you keep my PHI?

We will keep your PHI for at least two years after the study has ended, although by joining the study you are giving us permission to keep your information for as long as we need it. This authorization does not expire. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your PHI in the research records until all activities in the study are completely finished.

What about my medical record?

If you choose to be in this study, your medical record at Atrium Health Wake Forest University Health Sciences will show that you are in a research study. Information about our research may also be included in your medical record. Only people who normally have access to your medical record (like your doctors or nurses) will be able to see this part of your medical record.

If you are not a patient of these health care facilities, a medical record will be created for you to make sure this important information is available to doctors in case of an emergency.

Any laboratory test result and other medical reports created by this study may be entered into the computer systems of Atrium Health Wake Forest University Health Sciences. Like all your other information, we will keep this data as safe and private as possible. Only people who have been trained to keep your information safe will be able to see these results, but they may not be directly involved with this research study. For example, they might work at a blood laboratory that we partner with.

Do I have to share my PHI with you?

No. You can tell Dr. Stephen Kritchevsky that you want to take away your permission to use and share your PHI at any time by sending a letter to this address:

Stephen Kritchevsky, PhD

[redacted]

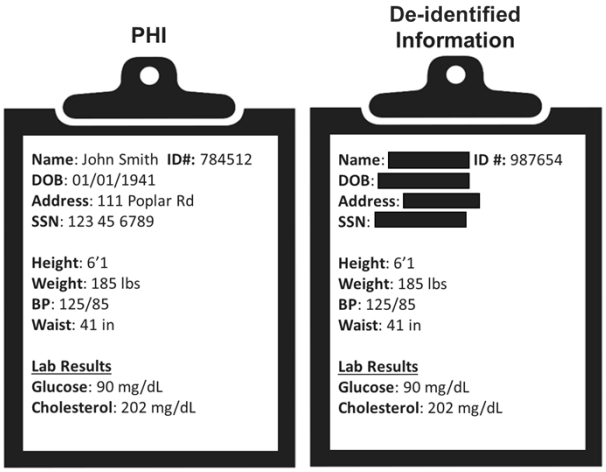
However, if you take away permission to use your PHI, you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the research study. By signing this form, you give us permission to use your PHI for this study.

What is de-identified information?
Your PHI may be used to create information that does not identify you. This de-identified information will not include anything that could identify you, such as your name, date of birth, address, or social security number. Your identity will be replaced with an ID number that cannot be linked back to you. Any publication or presentation that may result from this study will only report de-identified information. There is always some risk that even de-identified information might be re-identified.

Who has access to my de-identified information?
Your de-identified information will be shared in a few ways:

- Your de-identified information will be shared on secure websites and research databases. For example, a description of this study will be on http://www.ClinicalTrials.gov, as required by U.S. Law. This website does not include information that can identify you. At most, the website will include a summary of the study results; no individual results will be included. You can search this website at any time.
- We will share the results of this study at scientific meetings and we will publish the data in scientific journals.
- Lastly, your de-identified information will be shared with researchers in the future. Researchers want to study your data to make new discoveries and help cure diseases.

What is the difference between PHI and de-identified information?
De-identified information will not identify you in any way. Your identity will be replaced by an ID number that cannot be linked back to you. Protected Health Information (PHI) will include things like your name and address but this information will be heavily protected.



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 your safety or that of 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, in response to 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.

WHAT HAPPENS IF I GET INJURED OR SICK FROM BEING IN THIS STUDY?

Wake Forest University Baptist Medical Center maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of injuries or illnesses to some participants in certain research studies. 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. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

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 Stephen Kritchevsky, PhD, at [redacted] after hours and identify yourself as a HALLO-P study participant.

DO I HAVE TO BE IN THE STUDY?

Being in this study is voluntary. You may choose to not take part or you may leave the study at any time, but if you are thinking about stopping the study, you should talk to HALLO-P study staff first. If you do not join the study or you leave the study at any time, your normal medical care will not be affected. We will always give you any new information we find that might make you want to stop being in the study. Also, if new information becomes available, your study doctor may stop your participation without your consent. If this happens the reasons will be explained.

WHO SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions about the study or you have an injury caused by the study, please call Stephen Kritchevsky, PhD, at [redacted] after hours and identify yourself as a HALLO-P study participant. If you have concerns about your information privacy, your rights when you are in the study, or any problems you experience, you should call the Institutional Review Board (IRB). The IRB is a group of people who review the research to protect your rights. You can call the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted]. You will be given a copy of this signed consent form.

PARTICIPANT'S STATEMENT OF CONSENT

I have had the opportunity and enough time to review the study information and ask questions about this study, and my questions have been answered. I understand the study, and I have been informed of the possible risks and benefits of taking part in this study. I am willing to be assigned to any of the two groups.

Participant Name (Printed):_____

Participant Signature:_____

Date:_____Time:_____

Name of Person Obtaining Consent (Printed):_____

Signature of Person Obtaining Consent: _____

Date: _____Time:_____

Please review each question below and place your initials in the space that goes with your answer. You can still participate in this study even if you answer NO to any of the following questions.

AGREEMENT TO REPORT RESULTS TO YOUR DOCTOR

Do you agree to have medical results from your study tests or exams reported to your doctor if needed? _____ YES _____ NO

AGREEMENT TO CONTACT ME FOR FUTURE RESEARCH STUDIES

Do you agree to be contacted for future research studies? _____ YES _____ NO

AGREEMENT TO AUDIO/VIDEO RECORD ME FOR FUTURE STUDIES

Do you agree to allow audio/video recordings of you to be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB? (You will not be able to inspect, review, or approve their future use.)

_____ YES _____ NO, destroy when use in this study is finished.