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Study Title: A Proof-of-Concept Study Evaluating an Intermittent Energy Restriction Weight Loss Intervention in Adults with Breast Cancer and Overweight or Obesity

Key Information

Please read all the information below and ask questions about anything you don't understand before deciding if you want to take part.

You are being asked to be in a research study. Participation in research is voluntary.

Purpose of the Study: This is a 6-month trial to examine the impact of intermittent energy restriction (IER) in adults who are overweight or obese and have stage 1-3 breast cancer. Weight loss and increasing physical activity (PA) can reduce breast cancer risk and improve prognosis.

Procedures: If you agree to participate, the following will happen:
Participants will receive a 3-month integrated behavioral weight loss intervention with a dietary focus on intermittent fasting. Participants will be instructed to perform a modified fast on 3 days/week with no calorie restriction on the other 4 days/week. Group-based classes will be held with an experienced registered dietitian. Participants will also attend *BfitBwell* exercise sessions in person and virtually to receive individualized support.

Risks: Participation in research involves risks, including the following:

- Risk of DXA Scan: Participants will be exposed to radiation during the DXA scans.
- Risks of Phlebotomy: The collection of blood samples may result in temporary discomfort, bruising, bleeding, and on rare occasions infection.
- Risks of Lifestyle Wight Loss Program: side effects include, insomnia, irritability, headache, nausea, diarrhea, gastrointestinal reflux, or abdominal discomfort. Weight loss may lead to bone loss or increased fracture risk, especially among those with osteoporosis. Rarely gallstone formation, dehydration, kidney stones, hypoglycemia, arrhythmia, or seizures.

Benefits: There is no guarantee that your health will improve if you join this study. This study may lead to information that could help patients and health care providers in the future.

Detailed Consent

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about the effects of an intermittent fasting lifestyle weight loss program on pre-specified clinical milestones, including weight loss, diet adherence, and change in physical activity. This study will also collect feedback to refine the weight loss program for a larger future research study.

You are being asked to be in this research study because you are an adult between the ages of 18-65 years with a BMI 25-45 kg/m^2 with breast cancer who has completed any recommended standard of care surgery, chemotherapy, and/or radiation.

Other people in this study

Up to 75 people will be consented to participate in the study.

What happens if I join this study?

If you join the study, you will undergo screening evaluations to see if you are eligible to be in the study. If you are eligible to be in the study, you will participate in weekly weight loss group meetings that focus on changing your eating and activity behaviors. Group meetings are taught by a registered dietitian and will occur weekly during months 0-3 and twice monthly during months 4-6. You will also be asked to gradually increase your level of physical activity by participating in the *BfitBWell* Oncology Exercise program for 6 months.

We will ask you to use an intermittent modified fasting (IMF) approach to reduce your calorie intake. This means that on 3 days per week, you will be asked to eat about 20% of your energy needs (approximately 500 calories per day for women and 600 calories per day for men). On the other 4 days per week, you will be asked to eat healthy food and portions, but will not restrict calories on those days.

Your participation in the study will last approximately 9 months to complete all study measures including screening, baseline testing, the intermittent fasting behavioral weight loss program, outcome measures at month 3 and month 6, and 1-2 focus groups. During outcome measures you will undergo assessments of your body weight, body composition, blood pressure, eating and physical activity behaviors, waist circumference, and laboratory results. These are described in more detail below.

During the 9 months you are enrolled in the study, you will be asked not to participate in any other weight loss, nutrition, or exercise programs. You will also be asked not to participate in any other research studies involving weight loss or exercise. You will be asked not to take any prescription or over-the-counter weight loss medications or supplements. If you are female and can become pregnant, you will be asked not to become pregnant and to use a reliable method of birth control during the study.

If you join the study, you will be asked to undergo the following steps:

1. Screening Procedures

You will be asked to have the following screening procedures done to see if you are eligible to be in this study. These screening procedures will take a total of about 2.5-3 hours and will be divided over 2-3 visits. The procedures will be performed at the Anschutz Medical Campus and the University of Colorado Hosptial.

- Review of the Consent Form: This consent form will be reviewed with you in detail and you will sign the last page if you agree to be in the study. No other procedures will occur until you sign the consent form.

- Vital Signs and Body Measurements: Your blood pressure, height, weight, and BMI will be measured.

- Health History and Physical Exam: A standard medical history will be taken and a physical exam will be performed by a study physician or advanced practice provider.

- 12 Lead ECG: We will measure your heart rate and rhythm with an electrocardiogram (ECG).

- Screening Questionnaires: You will be asked to fill out questionnaires that give us information on your demographic information, weight history, medical history, social history, mood, and eating attitudes.

- Blood Test: You will be asked to have your blood drawn for routine blood tests to further evaluate if you are eligible to be in this study. Approximately 5 teaspoons of blood will be removed by putting a needle into your vein. You will be asked to fast overnight for this test.

- Pregnancy Test: If you are a female of reproductive age, you will be given a urine pregnancy test. You cannot be in this study if you are pregnant.

- Test Fast: You will be asked to fast for 36 hours starting at midnight prior to the test fast day through approximately 8 AM of the morning following the fast day, except for a light dinner on the fast day (we will provide you with a sample meal menu and a calorie goal). The test fast is designed to be similar to a fast day in the intermittent fasting intervention. You will be asked to record all food intake during this fast. You will also provide information about your experience with study staff over the telephone or via an online survey.

- Physician Clearance Note: You will be asked to obtain a signed physician clearance form from your Primary Care Provider or Oncologist in order to participate in the study.

2. Study Interventions

You will be asked to complete the following interventions for research purposes:

- Weight Loss Group Meetings: You will be asked to attend weight loss group meetings virtually and/or at the AHWC with about 15-20 other people in the study. The group will meet on a regular schedule (weekly during months 0-3 and then 2 times monthly during months 4-6). Meetings will last about 60-90 minutes. Group meetings will be taught by a registered dietitian and will focus on making changes in your eating and exercise behaviors to help you lose weight. There will be a mix of lecture presentations, individual worksheets, and discussion during the group meetings. You will also be given acceptance and commitment based materials during months 4-6 to help with adherence to the exercise portion of the intervention. Participants will also have up to 3 individual phone calls or virtual meetings with the registered dietitian. You will be asked to keep a food log on fast days to help you monitor your food intake. You will be asked to measure and report your weight on the day of each group meeting. Group meeting

attendance and completion of food logs will be tracked to monitor your progress in the weight loss program.

- Dietary Intervention: You will be asked to perform a modified fast (eat only 20% of your energy needs) three days a week. You will be provided a calorie goal and sample menus to help you meet this modified fast day calorie goal. For women, the calorie goal will be 500 calories a day and for men the calorie goal will be 600 calories a day on the modified fast days. On non-fast days, you will be asked to eat a sensible, healthy diet but you will not have to restrict your calorie intake.

- Physical Activity Intervention: You will be enrolled in the AHWC *BfitBwell* oncology exercise program and asked to gradually increase your physical activity level to 150-300 minutes per week of moderate intensity aerobic exercise. You will also complete two, 50-minute sessions each week of resistance and flexibility training. You will receive supervised *BfitBwell* exercise sessions (either in-person at the Anschutz Health and Wellness Center Fitness Center or using Zoom videoconferencing) once per week and unsupervised exercise sessions (using TrueCoach, a personal training application) 3-7 times per week. The aerobic exercise targets and the resistance and flexibility exercises will be individualized to your level of fitness and your current level of exercise. You will also have access to the AHWC Fitness Center for the duration of the intervention.

3. Study Assessments

You will be asked to perform the assessments outlined below at the Anschutz Health and Wellness Center or the CTRC.

- Body Measurements: Your weight will be measured at baseline and months 3 and 6 in the morning after you change into a hospital gown. You may also be issued a digital “smart” scale for the duration of the study weight loss intervention and follow up period and asked to weigh yourself at home on a regular basis. These weights will be transmitted via wireless cellular network to a secure website. Your waist circumference will be measured at baseline and months 3 and 6. Your blood pressure will be measured at baseline and months 3 and 6.

- Blood Tests: You will be asked to fast overnight (12 hours) and your blood will be drawn in the morning. Up to 1-2 tablespoons of blood will be removed by putting a needle into your vein. Your blood will be drawn at weeks baseline and months 3 and 6.

- Body Composition: You will be asked to measure your level of body fat using a special x-ray. During this procedure, you will lie on a hospital bed and a small amount of x-ray will be passed through your body. This scan takes approximately 6 minutes. There is no pain associated with this test. A pregnancy test will be given prior to the scan in all women of childbearing age who have not had their uterus removed. The DXA scan will be performed at baseline and months 3 and 6.

- Dietary Record: You will be asked to complete a record in which you will record all of your food and beverage intake for 7 days. These records will be performed at baseline and months 3 and 6.

- Focus Groups: You will be asked to participate in one 90-min focus group interview with 6-10 other participants. You will be asked about your experiences and perceptions of the intervention including suggestions for improving the program and barriers or facilitators to adhering to the intervention. These focus groups will be digitally recorded. These focus groups

will be performed after you complete the first 3 months of the intervention.

- Program Feedback Questionnaires: You will be asked to complete questionnaires that give us information on your satisfaction and feedback with the dietary intervention, the *BfitBwell* exercise program, and the group and one-on-one meeting frequency and structure. These questionnaires will be completed at study months 3 and 6. These can be completed during study visits or we can send you a secure link to complete the questionnaire from your home computer. All of your answers will be kept confidential and you do not have to answer any questions that you do not want to answer. A separate questionnaire will also address the likelihood of continuing the dietary and physical activity prescriptions. This questionnaire takes about 5 minutes to complete. This questionnaire will be sent weekly during the first 3 months of the intervention, and then after each bimonthly class during months 4-6 of the intervention.

- Activity Measurements: You will be asked to wear the ActivPAL physical activity monitor for a 7-day period. The ActivPAL is a small monitor that senses movement and body position that you wear on your thigh. This device is small and will not restrict your movement. You will wear this device all the time for seven days in a row. This week you wear the monitor should be a typical week, for example you should not be going on vacation or performing activities that are unusual for you. You will be asked to log all exercise you perform during the week you wear the activity monitor. You will be asked to return the activity monitor to the investigators promptly after the 7 day period. These activity measurements will be performed at baseline and at months 3 and 6.

- Veggie Meter® Scan: Pigments in your skin will be measured using a light on your finger as a proxy for fruit and vegetable intake. This measure will be done 3 times back-to-back and will take under 2 minutes. This will be done at the first group class and the last weekly group class.

- *BfitBwell* Exercise Program Assessments: You will be asked to perform tests of physical fitness and function, measuring how fast you walk, how many times you can rise from a chair in 30 seconds, how well you balance, and how high your heart rate rises while stepping on and off a step for three minutes. These measurements will be performed at the first session and final session of the 3-month *BfitBwell* exercise program.

- Outcome Questionnaires: You will be asked to answer a series of short questionnaires related to your eating, exercise, sleep, mood, chronotype, and health beliefs. You will be asked to answer these questionnaires either on a paper form or on a computer or ipad. All of your answers will be confidential. These questionnaires will take up to approximately 2 hours to complete. These can be completed during study visits or we can send you a secure link to complete these questionnaires from your home computer. You will be asked to answer these questionnaires at baseline and study months 3 and 6.

- Weekly Dietary Adherence Questionnaires: You will be asked to answer 3 questions about your adherence to the IMF dietary program over the past week. This questionnaire will be emailed out weekly during the first 14 weeks of the study and will take 1-2 minutes to complete.

- Medication Review: You will be asked to report any changes in your prescription and over the counter medications to study staff at baseline and at months 3 and 6.

Note: Lab and DXA results obtained in this study are for research purposes only and should not be relied on to make decisions about clinical health or care. While we will share results of some of the DXA data and labs obtained in this study that have clinical relevance with you, there are

often substantial delays in processing research labs and it may be several months before results are available. Labs that will be shared in this study are as follows: total cholesterol, triglycerides, LDL, HDL, fasting glucose, and hemoglobin A1c.

In the event of a public health emergency, natural disaster, severe weather, or for other compelling reasons at the discretion of the study PI, study group meetings and physical activity support sessions may held by Zoom videoconference or phone call and may not follow the exact timeline outlined in the protocol. Consent and screening procedures, including the medical history and physical exam with a study physician (with the exception of screening labs and vital signs) may be performed virtually (rather than in person) if needed for participant safety. Under these circumstances, study outcome measure visits may be delayed, postponed or cancelled as necessary for participant/staff safety and thus may not follow the exact timeline outlined in the consent. Under these extreme circumstances, study visits normally held at the AHWC and the outpatient CTRC may also be held at alternative locations at the University of Colorado Anschutz Medical Campus.

Study Measure	Pre-screening (Pre-consent)	Screening	Baseline	Month 3	Month 6
REDCap Screening Review Eligibility	X				
Informed Consent		X			
Demographics		X			
Health History Questionnaire		X			
H+P with MD or APP		X			
Height		X			
Weight		X	X	X	X
Blood pressure		X	X	X	X
12 Lead ECG		X			
Resting Heart Rate		X			
36hr Test Fast		X			
Screening Labs		X			
Screening Questionnaires		X			
Urine pregnancy test (females only)		X	X	X	X
Waist Circumference			X	X	X
Dietary Adherence, Dietary energy intake and macronutrient content (food records)			X	X	X
MVPA (ActivPAL)			X	X	X
Body Composition (DXA)			X	X	X
Blood Draw/Outcome Labs			X	X	X
Outcome Questionnaires			X	X	X
Program Acceptability Questionnaires				X	X
Focus Groups for Qualitative Program Acceptability				X	

*Participant satisfaction and adherence questionnaires will be emailed weekly during the first 3 months of the study and then 1-2 times monthly during months 4-6 of the study.

Generally, this will translate into the following number of visits:

- **Screening:** 2-3 visits (1-2 x 1 hour visit(s), 1-2 x 30 minute visit(s))
- **Baseline:** 2-3 visits (30 min - 1 hour)
- **Month 3:** 2-3 visits (30 min - 1 hour)
- **Month 6:** 2 visits (one 30-minute visit to complete measures followed by one 5-minute visit to return study materials)
- **Focus Group:** 1 90-minute visit

Data and Specimen Banking for Future Research

Dr. Catenacci would like to keep some of the data and blood samples that are taken during the study but are not used for other tests. If you agree, the data and samples will be kept and may be used in future research to learn more about the treatment of obesity. The research that is done with your data and samples is not designed to specifically help you. It might help people who have obesity and other diseases in the future. Reports about research done with your data and samples will not be given to you or your doctor. These reports will not be put in your health records. The research using your data and samples will not affect your care.

The choice to let Dr. Catenacci keep the data and samples for future research is up to you. No matter what you decide to do, it will not affect the care that you will receive as part of the study. If you decide now that your data and samples can be kept for research, you can change your mind at any time and contact your study doctor to let her know that you do not want Dr. Catenacci to use your data and samples any longer, and they will no longer be used for research. Otherwise, they may be kept until they are used up, or until Dr. Catenacci decides to destroy them.

When your data and samples are given to other researchers in the future, Dr. Catenacci will not give them your name, address, phone number or other information that will let the researchers know who you are.

Sometimes data and samples are used for genetic research (about diseases that are passed on in families). Even if your data and samples are used for this kind of research, the results will not be told to you and will not be put in your health records. Your data and samples will only be used for research and will not be sold. The research done with your data and samples may help to develop new products in the future, but there is no plan for you to be paid.

We may share data from our research with other researchers or data banks. One such data bank is called dbGAP, which collects genetic and other data and is sponsored by the National Institutes of Health. By broadly sharing data in data banks like this, we can make our discoveries more accessible to other researchers. Information which directly identifies you will not be sent to these data banks.

Because your genetic information is unique to you, there is a small risk that someone could connect the information back to you. Also, genetic research and broadly sharing data may involve risks to you or people like yourself that are unknown at this time.

The possible benefits of research from your data and samples include learning more about what causes obesity and other diseases, how to prevent them and how to treat them. The greatest

risk to you is the release of your private information. Dr. Catenacci will protect your records so that your name, date of birth, address and phone number will be kept private. The chance that this information will be given to someone else is very small. There will be no cost to you for any data or sample collection and storage by Dr. Catenacci.

Dr. Catenacci will store your contact information in a recruitment list in a secure data base so that she (or someone she chooses) can contact you in the future to ask you to take part in other research studies.

You can cancel your permission to use your data and samples or to contact your for future research studies at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use your data and/or blood samples, they will be disposed of and no longer used for research. If you withdraw consent to contact you for future studies, we will delete your from our recruitment list.

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What are the possible discomforts or risks?

Risks of the Test Fast and Weight Loss Program: You will be asked to decrease your calorie intake through intermittent modified fasting (IMF) to help you lose weight and maintain your weight loss. On three days a week, you will eat 500-700 calories per day.

Common: The most common side effects associated with dietary weight loss interventions (including intermittent fasting) are likely to be hunger, fatigue, trouble sleeping, irritability, anxiety, headaches, impaired concentration, and cold intolerance. It is possible you may miss school or work, have to take medications, or have to see a doctor if you experience one of these diet-related conditions.

Uncommon: Occasionally people can experience constipation, nausea, abdominal discomfort, or diarrhea when changing their usual diet. It is possible you could develop weakness, dizziness, lightheadedness, tremor, psychological stress, or changes in your ability to think or process information when limiting your calorie intake. These conditions usually improve within a few weeks. Weight loss may lead to bone loss or increased fracture risk, especially among those with osteoporosis. Very rarely participation in a weight loss program can worsen an underlying eating disorder like anorexia, bulimia, or binge eating disorder or even cause someone to develop an eating disorder. Very rarely, participation in a weight loss program can cause ongoing stress in relationships with friends, family and co-workers. Very rarely, participation in a weight loss program can impact performance or impair ability to function at home, school, or at work.

Rare and Serious: The most serious but rare side effect of reducing your calorie intake is gallstone formation, which usually only occurs with extremely low-fat diets. Very rarely dehydration, kidney stones, hypoglycemia (low blood sugar), electrolyte abnormalities, confusion, changes in mood or behavior, changes in ECG, arrhythmias (irregular heart rhythms), syncope (passing out), or seizures can occur with fasting or significantly limiting energy intake.

Risks of Exercise: You will be asked to increase your level of aerobic exercise to help you lose weight and maintain your weight loss. You will also participate in resistance and balance training sessions.

Common: Exercise may cause sweating, fatigue, or feeling out of breath. These effects are normal, but the duration and difficulty of exercise will gradually be increased to minimize these effects. It is also possible that you could develop soreness or injuries (most commonly in your feet, knees, legs, hips, or back) from exercising. If this occurs, you may need to see an outside medical doctor. If necessary, you will reduce the amount of exercise temporarily. It is possible you may miss school or work, have to take medications, or have to see a doctor if you experience one of these exercise related injuries or conditions.

Uncommon: Occasionally, exercise can cause headache, dizziness, shortness of breath, nausea, vomiting, high or low blood pressure, wheezing or lower extremity claudication. Occasionally, people can trip or fall during aerobic exercise. Occasionally exercise can cause or worsen lymphedema.

Rare and Serious: Exercise can rarely cause abnormal heartbeats (almost always reversible), chest pain, passing out, heart attack, stroke, or death. These are extremely rare events.

Risks of Screening Medical History and Physical Exam: In this study, you will be asked to complete a medical history interview and physical exam with the study physician, who will also review the results of the 12 lead ECG and screening blood tests. It is possible that during these procedures we could find a medical condition or disease that you otherwise might not have known about. If this occurs, we will contact you and you may be referred to your primary care provider for follow up or to the emergency room if there is a serious abnormality.

Risks of 12 lead ECG: We will measure your heart rate and rhythm with an electrocardiogram (ECG) during the screening visit. There are no direct risks of performing an ECG. It is possible that the ECG might find an existing abnormal heart rhythm or condition that you otherwise might not have known about. If this occurs, we will contact you and you may be referred to your primary care provider for follow-up or to the emergency room if there is a serious abnormality.

Risks of Screening and Outcome Questionnaires: You may find completing the screening questionnaires and feedback questionnaires uncomfortable. You don't have to answer any questions you do not want to answer. However, we need complete information about your baseline medical and social history, moods and eating attitudes to determine whether it is safe for you to be in the study. Therefore, if you do not complete the **screening** questionnaires you will not be able to participate in the study. If screening questionnaires reveal you may be depressed, we will refer you to your primary care doctor for follow-up or to the emergency room if you are severely depressed. If screening questionnaires reveal you may have an eating disorder or a serious problem with alcohol or drug use, you will be withdrawn from the study and we will refer you to your primary care doctor for follow-up.

Risks of Fasting for Blood Draws: Fasting overnight prior to blood draws may cause you to feel hungry, lightheaded, dizzy, nauseated and/or weak or very rarely to faint.

Risks of Having Blood Taken: In this study we will need to get about 1-2 tablespoons of blood from you at each blood draw. Blood will be drawn once at screening, baseline, month 3, and month 6. We will get blood by putting a needle into one of your veins and letting the blood flow

into a glass tube. You may feel some pain when the needle goes into your vein. A day or two later, you may have a bruise where the needle went under the skin. Very rarely people may experience bleeding, infection, or numbness in the arm as a result of having blood drawn.

Risks of the DXA: As part of this study we will perform three whole body DXA scans to measure your body composition. DXA is a way of looking inside the body by using X-rays. X-rays are a type of radiation. Your natural environment has some radiation in it. One whole body DXA scan will give you about half of the amount of radiation you are exposed to during a cross-country flight from New York to L.A.

Risks of the Activity Monitor: Rarely, skin irritation, redness, or rash can occur due to the activity monitor or the adhesives used to attach the activity monitor to your skin.

Economic Risk: It is possible that you may need to pay for medical care as a result of participating in this study. For example, if the screening tests reveal an abnormality you may need to be further evaluated by an outside medical provider before you can participate in the study. If you experience an injury or illness during the study, you may need to be further evaluated by an outside medical provider.

Risk of Loss of Confidentiality and Privacy: The use of questionnaires, digitally recording group sessions, participating in focus groups, transcription of the recording of interviews, and collection of personal medical information poses a risk to confidentiality and privacy and may cause embarrassment. There are no alternatives that would allow the collection of the information required. These risks will be minimized by not including personal identifying information on the forms, when possible, and by conducting interviews and collection of personal information in a private setting. We will assign an identification number to you. Any audio recordings from the group sessions, focus groups, and transcription of focus group recording will be coded and identified using this number, rather than your name. If you wish to share something during the group sessions, and/or focus group that you do not want recorded, you can type your response to the facilitator using the chat function. In addition, you can leave the meeting at any time. The recording and transcript will be saved on a password-protected, secure drive. These files will be kept for at least 3 years, then erased. We will do all we can to protect your information, but it cannot be guaranteed. In addition, you will be asked to fill out several questionnaires which will take some time and effort. Some of the questions may include sensitive information. If you wish to not answer a question, you may skip that question. There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

Risk if you Become Pregnant: If you become pregnant during the study, the particular treatment or procedures involved in the study may involve risks to the embryo or fetus which are currently unclear.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about the effect of an integrated intermittent fasting, nutrition and exercise intervention on weight, eating patterns, and physical activity patterns in adults with overweight or obesity and breast cancer. The study is also designed to collect information to help the researchers refine the intervention for delivery in a future, larger research study.

This study is not designed to treat any illness or to improve your health. You may experience benefits from the lifestyle intervention, but there is no guarantee that your health will improve if you join this study. This study may lead to information that could help patients and health care providers in the future.

Are there alternative treatments?

There are other ways of treating overweight or obesity through changes in your lifestyle. These other ways include alternative lifestyle intervention programs, meeting with a registered dietitian and/or personal trainer, weight loss medication, and/or bariatric surgery. You could also choose to get no treatment at all.

You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?

This research is being sponsored by The National Institutes of Health (NIH).

Will I be paid for being in the study?

You will be paid $100 for completion of 3-month outcome measures and $100 for completion of the 6-month follow-up measures. You will be paid $50 for participating in the focus group. This will add up to a total of $250 if you complete all of the measures. If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

Occasionally, an assessment may need to be repeated to obtain an adequate measurement. For example, if the physical activity monitor did not work properly during the data collection period, we will ask you to repeat the outcome measure that was not adequate. However, you will only be compensated for one outcome measure.

You will also be provided a membership to the Anschutz Health and Wellness Center (AHWC) exercise facility for the *BfitBwell* Oncology Exercise Program. You will be provided with a parking code with your AHWC exercise facility membership that you can use to park for free in the visitor lots for up to 3 hours. The AHWC Fitness Center membership is not transferrable to another individual. The AHWC Fitness Center membership cannot be converted to cash compensation nor can it be refunded or credited to you if you do not use the facility.

If you withdraw from the study, we will ask you to come to the clinic to get a final weight and return all study materials that you have in your possession. You will not be paid for outcome measures you have completed if you have not returned study materials. If needed, study staff will mail you a pre-paid envelope to return study materials in your possession. Once you return all study materials, you will be compensated for any outcome measures you have completed as well as $25 for your final weight measurement.

It is important to know that payments for participation in a study is taxable income.

Will I have to pay for anything?

You will not be charged for the integrated lifestyle intervention program or any of the study procedures or clinic visits for the study.

You may need to pay for parking during study visits. Parking in the visitor lots near the AHWC is $1 per hour on weekdays, and a flat rate of $1 on weekends and after 4 PM on weekdays.

You may need to purchase appropriate exercise footwear (properly fitting and supportive sneakers) to wear during your exercise. Exercise specialists recommend having 2 pairs of sneakers and alternating these in order to allow the cushioning to fully recover between exercise sessions. Appropriate footwear is important in preventing exercise-related injuries such as ankle sprains, plantar fasciitis, and shin splints.

You may need to pay for medical care to follow up abnormalities that may be found during screening procedures or outcome measures. You may need to pay for medical care for any injuries or illness that occurs during or as a result of your participation in the study.

If you need more information about these costs, please discuss this with the study team.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. You will be removed from the study if you become pregnant or develop a medical condition that makes you ineligible for the study. You will be removed from the study if you choose to participate in another weight loss, nutrition, or exercise program or research study. You will be removed from the study if you choose to see a medical provider, nutritionist, or exercise specialist for weight loss, nutrition, or exercise treatment. You will be removed from the study if you choose to take a weight loss medication or supplement. You will be removed from the study if you choose to undergo bariatric surgery or other weight loss procedure. You may be removed from the study if you need to undergo surgery, radiation, or chemotherapy for your breast cancer. You can be taken out of the study even if you do not want to leave the study. Also, the sponsor may stop the study at any time.

Certificate of Confidentiality

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research,
- If required by Federal, State or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. Victoria A. Catenacci immediately. Her phone number is (303) 724-9052. We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

In the event of an illness or injury resulting from your participation in this study, you should seek appropriate medical care. However, you and/or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Victoria A. Catenacci, MD. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Catenacci at (303)724-9052 or email her at vicki.catenacci@cuanschutz.edu. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Catenacci with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What will happen to my recorded information?

In this study we will be recording the virtual group dietary support classes via Zoom. We will use the Zoom recording feature to do this. We will keep this information secure and private and will only share it with other active participants who were unable to attend the group class. We will store it for the duration of the study. At the end of that time, we will destroy it. Digital recordings

of the focus groups will also be performed and will be securely stored for at least 3 years and then erased.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- University of Colorado Health
- Anschutz Health & Wellness Center

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information, but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Victoria A. Catenacci, MD
University of Colorado Denver
Campus Box C263
12348 E. Montview Boulevard
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board that is responsible for overseeing this research
- The study doctor and the rest of the study team.
- The National Institutes of Health (NIH), who is the company paying for this research study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed.

Information about you that will be seen, collected, used, and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, surgical reports, procedure results, and medical treatments you have received.
- Research Visit and Research Test records
- Psychological and mental health tests
- Alcoholism, Alcohol or Drug abuse
- Blood samples and the data with the samples.

What happens to Data and Blood that are collected in this study?

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data and blood collected from you during this study are important to this study and to future research. If you join this study:

- The data and blood given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data and blood collected from you.
- Your data and blood may be distributed to other researchers for future study without additional consent if information that identifies you is removed from the data.
- If data and blood are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name:_____