Fred Hutchinson Cancer Research Center

Consent to take part in a research study:

Cook & Move For Your Life

Testing a scalable nutrition and physical activity program for breast cancer survivors: A dose-finding study

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Important things to know about this study. You are invited to participate in a research study. The purpose of this research is to understand the best way to teach breast cancer survivors how to eat a healthy diet and be physically active. People who agree to join the study will be asked to attend 1 to 12 study sessions over a period of 8 months, as described in this consent form.

We are doing this research study to answer these questions:

1. Can online group sessions and electronic health (eHealth) communications (including text messages, newsletters and a website) be used to promote healthy eating and physical activity among breast cancer survivors?
2. Do online group sessions and eHealth communication intervention lead to changes in diet quality and changes in minutes per week of moderate-to-vigorous physical activity?
3. Do changes in diet quality and minutes per week of moderate-to-vigorous physical activity help improve blood biomarkers associated with inflammation?
4. Is there a difference in the changes in diet quality and minutes per week of moderate-to-vigorous physical activity when comparing results from participants who participate in one versus twelve online group sessions while receiving 6 months of eHealth communication?

We would like you to join this research study. We are doing this study to understand how to create an effective education program for breast cancer survivors. We want to know how to address the needs of breast cancer survivors. Since you have self-identified as a breast cancer survivor with no evidence of metastatic or recurrent disease, and older

than 18 years of age, we would like to ask you to join this research study. We will enroll up to 90 people.

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits if you say no. Whatever you decide, your regular medical care will not change.

Below is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you an electronic signed copy of this form to keep for future reference.

What research tests and procedures are part of this study? / What will happen in this study? If you decide to join this study, we will do these tests and procedures:

Baseline Data Collection

Before any data collection, study staff will explain to you the study activities, rights and responsibilities. After signing the informed consent form online, you will receive:

1. A link to an online medical records release form for permission to access and collect information from your medical records related to your cancer diagnosis and treatment.
2. A link to an online questionnaire to collect information on demographics, medical history, height, weight, current health status, and quality of life. If preferred, we can ask you the questions over the phone.

Data Collection At Home: We will mail you a study data collection package with materials and devices, along with written instructions (some will include links to video instructions) on how complete the data collection procedures. We will also be available by phone to answer any of your questions:

1. Actigraph accelerometer device, also known as an accelerometer, to collect data on your physical activity during an average week.
2. Stool (poop) sample collection user-friendly kit.
3. Self-collection blood device, called "Tasso on Demand", along with all supplies for blood sample collection at home. The devices collect blood via a device that adheres to the skin, forms a vacuum, uses a lancet to prick the skin, and draws the blood using the vacuum pressure. The whole process is completed in about 5 minutes following simple step-by-step instructions. Written instruction will be provided along with a "how to" video.
4. WIFI-enabled scale to measure your weight.
5. Materials to return study materials to us by mail
6. A link to a second online questionnaire to collect information on your technology use and health behaviors. If preferred, we can ask you the questions over the phone.

You will be asked to use pre-stamped and addressed return mailers to send us the stool samples, blood sample, and accelerometer by mail.

Telephone-based Data Collection: We will contact you by phone to complete three interviews about the foods you ate and beverages you drank during the past 24 hours. Each phone call will take 20-30 minutes to complete. During this time, we will remind you to complete all of the data collection procedures and to return the materials to us in the pre-stamped and addressed return mailers provided to you.

Randomization: After completing the data collection mentioned above, you will participate in one of two study groups:

1. **One online group session of the Cook & Move For Your Life Program:** If you are randomized to participate in the one-time online session, you will be asked to participate in the class on a Saturday morning. The class will last approximately 2 hours and will be streamed via Zoom. The class will include cooking and physical activity education, hands-on cooking, and exercise training. If you are unable to attend the class, you will be able to access a recorded copy on the study website.
2. **Twelve online group sessions of the Cook & Move For Your Life Program:** If you are randomized to participate in twelve online sessions, you will be asked to participate in 12 twice-monthly sessions on Saturday mornings for a period of 6 months. The classes will last approximately 90 minutes and will be streamed via Zoom. Classes will include cooking and physical activity education, hands-on cooking, and exercise training. If you are unable to attend any of the classes, you will be able to access recorded copies on the study website.

Start-Up Package: Study staff will contact you over the phone to inform you of your group assignment. Following this, we will mail you a study package that will include a schedule of study activities, a study participant binder with all written materials needed to participate in the online sessions, and a Fitbit device to monitor your daily physical activity throughout the study with detailed instructions on how to use the Fitbit.

Fitbit Data Collection: The Fitbit device counts your steps and measures the distance you've traveled, calories burned, and your sleep quality. You will be asked to download the free Fitbit app on your phone or computer and sync your device at least once a week. Your Fitbit data will be linked to your anonymous Fitbit user account so that you can access your Fitbit data. The study staff will also access your Fitbit data. You will be asked to wear the Fitbit for the entire 6 months of the study. If you lose your Fitbit during the course of the study, it will be replaced at the discretion of the Principal Investigator.

Weight Data Collection: The wifi-enabled scale will be used to measure your weight at the beginning and end of the study. The scale will sync with the Fitbit app on your phone. Your scale data will be linked to your anonymous Fitbit user account so that you can access your weight data. The study staff will also have access to your weight data. You can decide if you want to use the scale between the baseline and 6-month study data collection timepoints.

Electronic (e) eHealth Communication: After you attend your first online class, you will start receiving the eHealth communication intervention for a period of 6 months.

During this period, you will receive supportive text messages twice a week, links to newsletters via text, and access to a nutrition website. You will receive the text messages on your cell phone or tablet, and you will have the option to respond to the text messages. Text messages will be sent using a computer program called REDCap. Your cell phone number will be stored on the secure Fred Hutch computer servers. The website will have a public-facing section that is readily available to the public, and a participant-facing section where you will be able to login and view study-specific information and resources. The public-facing section of the website is "live" and will be continuously updated throughout the course of the study. Study staff will measure your use of the website using website analytics software.

Monthly Phone Calls: Each month, study staff will call you to ask about your use of the Fitbit and help you fix any technical issues you may have with the device. We will also ask you some questions about COVID-19.

Reminders: You will receive reminders about completing data collection and participating in the online session(s) via text messages, email and phone calls, depending on your preference.

Follow-up Data Collection (6 months): At the 6-month follow-up, baseline data collection will be repeated. We will send you a link to an online questionnaire to collect information about your current health status, weight, health behaviors, quality of life, and your thoughts on participating in the study. If you prefer, we can ask you the questions over the phone.

We will mail you a data collection package similar to one you received at baseline, including (1) an accelerometer device for you to wear for a continuous 7 days, (2) a user-friendly stool sample kit, and (3) a Tasso OnDemand device for self-blood collection. You will be asked to return the stool samples, blood sample, and accelerometer by mail using the provided pre-stamped and addressed individual return mailers.

Telephone-based Data Collection (6 months): We will contact you by phone to complete three interviews about the foods you ate and beverages you drank during the past 24 hours. Each phone call will take 20-30 minutes to complete. Finally, we will ask you about your experience in the study during a brief phone interview.

How long will I be in this study? It is likely that will be in this study for 6-8 months.

The study principal investigator or your doctor may take you out of this study at any time. This would happen if:

- They think it is in your best interest to stop participating in the study.
- You are unable or unwilling to follow study procedures.
- The whole study is stopped.

If you are thinking about not continuing with this study, please tell us. We will talk to you about any other follow-up or testing that would help you. If you leave the study, your test results and information cannot be removed from the study records.

Risks of being in this study. There are some potential risks with participating in this study. These potential risks are listed below. There may be some unknown risks linked with being in this study that are not listed.

Survey Questions: You may feel uncomfortable, embarrassed, or self-conscious about answering the study questions. The study staff's questions are to better assist breast cancer survivors in the future. You do not have to answer any part of the questionnaires or other assessments; you may ask to skip questions that may make you feel uncomfortable. Study staff will also discuss how information will be kept confidential.

Loss of confidentiality: A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. We will try to protect your information, but we cannot guarantee privacy. The plans for keeping your information private are described in the 'confidentiality' section of this consent form.

Physical injury: Research related injuries are unlikely due to the low risk nature of this study; however, there is a risk of unintentional injuries that may occur while cooking or participating in the exercise activities. You will be asked to increase your physical activity during the 6 months of the study. This increased physical activity may cause unintentional soreness, joint pain, or exercise related injuries.

Gas and bloating: Recommended dietary changes may cause gas and bloating due to increased fiber consumption.

Inconvenience: The timing and frequency of the phone calls, online sessions, text messages, and emails may be inconvenient to your schedule.

Stool sample collection at home: Stool sample collection may be embarrassing to some individuals.

Blood self-collection at home: The risks of having blood drawn include soreness and bruising at the puncture site, and sometimes there may be discomfort during the procedure. You may experience some pain or bruising or bleeding at the site of the punctures during application of the Tasso OnDemand study device. There is a rare risk of infection and bleeding may occur even after the Tasso OnDemand study device is removed. The bruising and sensitivity may last for several days.

Allergic Reaction: You may experience an allergic reaction to the Tasso OnDemand study device.

Other risks: There may be other risks of taking part in this research study that we don't know about. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

What are the benefits? We do not know if this study will benefit participants. We hope the information we learn will help cancer survivors in the future. Although the study may not benefit participants directly, we hope the information we learn will improve our knowledge about the best way to teach cancer survivors about maintaining a healthy diet and engaging in regular moderate-to-vigorous physical activity.

You have other choices besides this study. You do not have to join this study. You are free to say yes or no. Your regular medical care will not change. Enrollment in this study may exclude you from other research studies.

If you do not join this study, you have other choices. Each of these choices has risks and benefits. You should talk to your doctor or healthcare provider about them. Your other choices may include:

- Following your physician's or treatment team's directions for diet, exercise, and other health maintenance and improvement activities.
- Other research studies.
- Standard exercise programs.
- Exercising on your own.
- No exercise programs.
- Seeing a dietitian on your own.
- Taking healthy eating and cooking classes on your own.

Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information. Some people or organizations may need to look at your research records for quality assurance or data analysis. They include:

- Researchers involved with this study.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Research Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- Fred Hutchinson Cancer Research Center, University of Washington, Seattle Children's, and Seattle Cancer Care Alliance.
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, Food and Drug Administration, and other agencies as required.
- Office of Human Research Protections (OHRP).

We will do our best to keep the personal information in your medical record confidential. But we cannot guarantee total confidentiality. Your personal information may be given out if required by law. For example, workplace safety rules may require health workers to contact you about lab tests. Or a court may order study information to be disclosed. Such cases are rare.

We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

A description of this clinical trial will be available on *http://www.ClinicalTrials.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.

This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information. We could not use the Certificate to withhold research information if you give written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- To the federal Food and Drug Administration (FDA), if required by the FDA.
- To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

Will you pay me to be in this study? If you complete this study, we will give you a $25 gift card at your 6-month follow-up study visit. You will also get to keep your Fitbit device, which is approximately of a $100 value, and the WIFI-enabled scale, which is approximately of a $50 value. If you drop out of the study, or if we take you out of this study, you will not receive the gift card at the 6-month follow-up, but you will be able to keep the Fitbit. At the start of the study, you will receive cookware and exercise gear to assist you in reaching the diet and physical activity goals of the intervention.

How much will this study cost me? There may be some extra costs for being in the study. These costs may include expenses for childcare and/or transportation to FedEx to drop off packages.

What if you get sick or hurt after you join this study? For a life-threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact the Project Coordinator, Sofia Cobos at 206-321-4818 (mobile) or 206-667-2543 (office). She and/or the study investigators will refer you for appropriate evaluation and treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

You would not lose any legal right to seek payment for treatment if you sign this form.

What will my information be used for? Your information will be used for the purposes of this study. Your information, including medical records relating to your cancer diagnosis and treatment, and surveys you participate in for this study, will be used to understand how well the study activities work at helping people change their diet and physical activity behaviors.

In addition, be aware that by agreeing to participate in this study, your information could be used for future research studies or sent to other investigators for future research studies without additional consent from you. These future research studies will be reviewed by an oversight group known as an institutional review board (IRB) if required by law. The information that identifies you will first be removed from your information.

What will my blood and stool samples be used for? We would like to use your blood to measure biomarkers associated with inflammation to help researchers understand how changes in diet and physical activity can cause changes in the body that may help prevent cancer or prevent cancer growth. We would use your stool sample for future research. The remaining blood and stool sample collected will be used to create a repository. The samples in this repository will be used in future studies to help researchers understand how changes in diet and physical activity can cause changes in the body that may help prevent cancer or prevent cancer growth.

You do not have to donate your samples for future research. You are free to say yes or no. Your regular medical care will not change. If we want to use your samples for other research or share it with other scientists for research, an ethics review committee (IRB) will review the request. The IRB will decide if we need to ask for your consent to do the research.

Your donated blood and stool samples will be stored in a secure location. It will be used for research only. Researchers will not report their results to you or your doctor. The research results will not appear in your health record. They will not affect your care.
If you donate your blood and stool samples for research, you can change your mind anytime. Just call the Project Coordinator, Sofia Cobos at 206-321-4818 (mobile) or 206-667-2543 (office) and tell us you do not want us to use your samples. There is no penalty for changing your mind. Your regular medical care will not change. However, if you do change your mind, we cannot return donated blood and stool samples. We may be able to destroy samples we know is yours. But if it is stored or shared anonymously (without any label saying who it belongs to), we cannot destroy it. In this case it would still be used for research, but no one would know it was yours. Read each question and think about your choice. When you decide on each question, please circle **YES** or **NO**.

Do you agree to donate your blood and stool samples to study how changes in diet and physical activity can change biomarkers in the body? (circle one)

YES	**NO**	Initials:	Date:

Do you agree to donate your blood and stool samples to study other health problems, such as diabetes, Alzheimer's disease, or heart disease? (circle one)

YES	**NO**	Initials:	Date:

Is it OK for researchers to contact you in the future to ask you to participate in future research studies? (circle one)

YES	**NO**	Initials:	Date:

Your rights

- You do not have to join this study. You are free to say yes or no. Your regular medical care will not change.
- If you join this study, you do not have to stay in it. You may stop at any time (even before you start). There is no penalty for stopping. Your regular medical care will not change.
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we may learn new information you need to know. For example, some information may affect your health or well-being. Other information may make you change your mind about being in this study. If we learn these kinds of information, we will tell you.

For more information. If you have questions or concerns about this study, you can talk to your doctor anytime. Other people you can talk to are listed below.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	206-667-4502 (Dr. Heather Greenlee) 206-606-2053 (Dr. Rachel Yung) 206-321-4818 or 206-667-2543 (Sofia Cobos, Project Coordinator)
If you get sick or hurt in this study	206-606-2053 (Dr. Rachel Yung)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Research Center)

Signature
Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant (age 18+)

Printed Name	Signature	Date

If you served as an interpreter or impartial witness during the consent process, sign below to indicate you attest to the accuracy of the presentation and the participant's apparent understanding of and willingness to participate in the research.

Impartial Witness or Interpreter:

Printed Name	Signature	Date

Researcher's statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature:

Printed Name	Signature	Date

Protocol: IR#10335
Current consent version date: 09/23/2020
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Copies to: