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UNIVERSITY OF WASHINGTON
CONSENT FORM
"ACTIVATE" Study

Researchers: Kerryn Reding, PhD, MPH, RN
University of Washington School of Nursing
206-221-1571; kreding@uw.edu

Study Contact: Lora Prosser
University of Washington School of Nursing
206-482-5808; redinglab@uw.edu

We are asking you to be in a research study. This form gives you information to help you decide whether to be in the study. Joining the study is voluntary. Please read this form carefully. Feel free to take your time and ask any questions you may have about the study. If you would like, you can have this form read aloud to you. Then you can decide whether you want to be in the study.

KEY INFORMATION ABOUT THIS STUDY

This study is designed to look at how practical and beneficial a particular exercise program is for women who have finished breast cancer treatment. Learning this information would help determine if this exercise program shows promise for being looked at in a larger study.

This research project lasts about 6 months. Our team is studying a 24-week (6 month) exercise program. The exercise program will involve 2-3 sessions per week of either aerobic exercise ("cardio"), resistance exercise ("weights"), or a mixture of the two. One or two sessions per week will be led by a trained instructor over videoconferencing. We will provide participants in the exercise program with a Fitbit to wear during the 24-week program that will collect information about movement patterns. We will also provide any materials, like weights or a mat, needed to complete the exercise sessions at home.

Not everyone who joins the study will do the exercise program as part of the study. About one third of participants (1 out of every 3) will be in the "waitlist control" group. This group will attend study visits but will not be asked to complete the exercise program during the study. At the end of the study, people in the waitlist control will be given a detailed 24-week plan of how to do the exercise program and a copy of recorded exercise sessions. The waitlist control group will be selected by chance, like rolling dice.

If you join the study, we will ask you to attend 3 in-person study visits. These will take place at the University of Washington Medical Center (UWMC) and at the Fred Hutch Prevention Center. Two of these visits – at the start ("Baseline") and the end of the study ("6-Month") – will

last about 4-5 hours. The Baseline and 6-Month visits may require two separate trips to UWMC in order to complete. One visit in the middle of the study ("3-Month") will be much shorter – about 30 minutes to an hour. At each visit, you will be asked to complete measurements of basic vitals and a standard test of strength ("1 Rep Max"). At the two longer visits, we will ask you to do an "MRI" scan and a 45-minute exercise test called a "CPET", along with other procedures. See below for more detail. At the shorter visit we will ask you to complete a walking exercise test.

After the Baseline Visit and before the 3-Month and 6-Month Visits, we will ask you to wear a wrist-worn activity monitor (FitBit) and a waist-worn monitor for 7 days to measure your physical activity levels. We will also ask you to complete online questionnaires about your current health.

Many studies show that exercising consistently improves cancer survivors' physical fitness. Therefore, if you complete the exercise program during the study expect you to experience similar fitness benefits. However, each person is different, and we cannot guarantee that you will benefit. Participating in this study may involve some mild discomforts. Completing the 1 Rep Max activity may result in mild muscle soreness. The MRI scan can cause some feelings of claustrophobia and anxiety. During the CPET you may be asked to exercise intensely for a short period, which can cause discomforts such as higher body temperature, sweating, and heavy breathing. These possible discomforts are usually mild, but they are not uncommon.

All tests will be administered by trained staff and are considered safe for most people, including breast cancer survivors. We encourage you to share any feelings of discomfort as you are able to in the moment, and we will do our best to accommodate you.

If you are assigned to receive the exercise program, you may experience other mild discomforts. Exercise sessions will be somewhat challenging, so temporary side effects like fatigue and muscle soreness may happen both during and after exercise sessions. There is a risk of injury such as a muscle strain or joint sprain. We do not believe the risks in this program will be any greater than the risks of exercising in everyday life, and we will check in with you often to make sure you feel comfortable with the exercise sessions.

We are asking you to participate in a 6-month research project. Taking part in this study is completely voluntary. You are free to stop at any point, even after you have signed this form. If you join the study, it will not affect your outside medical treatment. If you decide not to participate in this study but are interested in increasing your physical activity, we recommend you talk to your doctor or healthcare provider about starting and maintaining an exercise routine.

PURPOSE OF THE STUDY

The purpose of this research study is to evaluate how feasible and acceptable a 24-week exercise treatment program is for female breast cancer survivors who have decreased physical fitness after breast cancer treatment. We want to learn this information to determine if this at-home exercise program shows potential to be studied with a larger group of breast cancer survivors.

STUDY PROCEDURES

Participating in this study lasts for a total of 24 weeks (about 6 months). Two-thirds of participants who join the study (2 out of 3) will be asked to take part in the exercise treatment program. One-third of participants who join (1 out of 3) will be given recorded exercise sessions to follow and detailed guide of how to complete the exercise program when the study is over.

Assessment Visits
If you decide to participate, we will ask you to attend 3 assessment visits at the University of Washington Medical Center and Fred Hutch Prevention Center (FHPC) over the course of 24 weeks. These visits will happen at "Baseline" (the first week of the study), 3 months (FHPC only), and 6 months.

Some of these visits will be longer than others. The Baseline and 6-month visits will last about 4 hours, and may require two separate appointments at UWMC in order to complete. The 3-month visit is expected to last about 1 hour. Below is a description of the types of things you will be asked to do at these visits.

Questionnaires: All visits. You will be asked to fill out surveys about your general wellbeing, current and past health, exercise habits, physical activity levels, and your experience in the intervention. You will also be asked about any negative side effects you may have experienced due to the exercise program.

6-Minute Walk Test: All visits. You will be asked to walk as far as possible in six minutes. This test will be supervised by trained study staff.

One Repetition Maximum (1 Rep Max): All visits. You will be asked to use standard weight machines to lift the maximum amount of weight you are able to lift in one attempt. The exercises included will be chest press and leg press. This test will be supervised by trained study staff.

Vitals: All visits. We will ask to collect several standard medical vital signs including height, weight, heart rate, and blood pressure, among others.

Magnetic Resonance Imaging (MRI): Baseline, 6-month visits. At these two clinic visits, you will be asked to complete a 30-minute "MRI" scan. MRIs are a safe and widely used tool in clinical and research practice. The MRI machine uses powerful magnets to create detailed images of the inside of our bodies. In this study, we will collect images of your abdominal area and your thigh.

Before you participate in the MRI, you will go through a screening process with a trained technician to make sure you will be safe in the scanner machine. The most common conditions that cause issues with MRI scans are claustrophobia, implanted medical devices, and certain kinds of breast implants or tissue expanders.

Cardiopulmonary Exercise Testing (CPET): Baseline, 6-month visits. At these two clinic visits, you will be asked to complete a "CPET." During the CPET, you will be asked to exercise on a stationary bike while wearing a mask over your mouth and nose. This mask will allow you to breathe normally. It will also be connected to a machine to measure your breathing as you exercise with greater and greater intensity. In addition to wearing the mask, you will have some recording electrodes placed on your skin with light adhesive, in order to measure your heartbeat. This test lasts about 45 minutes to 1 hour and will be performed by a trained technician supervised by a medical doctor.

Randomization

At the end of your Baseline visit, you will learn whether you have been assigned to start the exercise program in Week 1 of the study, or if you have been assigned to the "Waitlist Control." Participants in the Waitlist Control will receive a detailed guide of how to complete the exercise program when they finish their final study visit. Which group you end up in is determined randomly, like flipping a coin or rolling dice.

Exercise Program

If you are assigned to the exercise program, you will receive further instructions and materials during the Baseline ("Week 0") visit. The exercise program is designed to be completed at home. The length and intensity of exercise sessions will depend on your individual fitness level and your progression over the course of the program.

The program will begin with 40-minute sessions, 2-3 times a week. All sessions will include 5 minutes at the beginning and end for warm-up and cool-down. The sessions will get longer and more challenging as you progress. At the most, you will be asked to complete 70-minute sessions, 3 times a week. During the program, the study team will remain in close contact to ensure you are able to complete the exercises being asked of you.

All exercise sessions will involve either aerobic exercise ("cardio"), resistance exercise ("weights"), or a combination or the two. The sessions will be designed to take place at home, using minimal equipment – though any exercise equipment required for the exercise program (excluding clothing and footwear) will be provided by the study. The intent of the sessions will be to produce moderate to vigorous effort as you complete the exercises (for example, some heavy breathing and sweating).

Each week, at least one session will be a "group" exercise session led by an experienced fitness instructor. You will be asked to virtually attend these scheduled sessions via videoconferencing, along with other members of the study. The instructor will provide some feedback and coaching. In addition, this instructor will set weekly goals for your other sessions that week. All sessions other than the supervised group sessions will be completed at your convenience.

Physical Activity Tracking

This study includes physical activity tracking with a device known as an "actigraph." These devices monitor and record body movement. One device you'll be asked to wear is a "FitBit," which is worn on the wrist and monitors activity and heart rate. We will ask you to wear a FitBit in two ways: 1) during all exercise sessions completed for the study; and 2) for the 7 days after the Baseline Visit and for the 7 days before the 3-Month and 6-Month Visits – 24 hours a day, even while sleeping. We'll also ask you to wear a more precise actigraph around your waist for those seven days – but only while awake.

Waitlist

If you join the study, you will have a 1/3 chance of being randomly assigned to the Waitlist Control group. If you are assigned to this group, you will receive instructions for going through the exercise program when you complete your 6-month (Week 24) visit. You will also be provided with recorded videos created by a certified fitness instructor that can be used as a guide. You will not be provided with other materials (like weights or a gym mat).

COVID Protocols & Testing

Study staff affiliated with the University of Washington may be vaccinated against the SARS-CoV-2 virus (COVID-19). All study staff members will continue to wear a mask and follow physical distancing guidelines while interacting with you until local, state, and national guidance advise this practice is unnecessary. If required, you will be asked to follow these guidelines during your study visits as well, even if you have been vaccinated.

You may be asked to obtain a negative COVID test prior to your in-person visits, dependent on UWMC and FHPC policies. If a negative COVID test is required to complete study visits, you will be given directions on how to obtain one for free. If you obtain a COVID test elsewhere, study staff may be unable to reimburse you.

Voluntary Participation
It is important to say that we are asking you to voluntarily participate in this study. You do not have to agree, and if you do agree now you can always change your mind at a later time. Also, you may refuse to answer any question or item on any test, questionnaire, or interview. Signing this consent form does not obligate you to complete all or part of the study procedures.

RISKS, STRESS, OR DISCOMFORT

Participating in this study may involve some mild discomforts. Questionnaires will ask about potentially sensitive topics such as personal well-being, mental health, and current health habits. The 1 Rep Max test may result in mild muscle soreness. Completing the MRI scan can cause some feelings of claustrophobia and anxiety. During the CPET you may be asked to exercise at near max intensity for a short period of time, which can cause discomforts such as elevated body temperature, sweating, and heavy breathing. These potential discomforts are usually mild, but they are not uncommon. We encourage you to share any feelings of discomfort as you are able in the moment, and we will do our best to accommodate you. You are always free to skip any question or test that makes you feel uncomfortable.

Participating in the exercise program may also create some discomfort. Sessions will be designed to provide some challenge, and so some temporary side effects like fatigue and muscle soreness are expected, both during and after exercise sessions. There is a slight risk of mild to moderate injury, such as a muscle strain or joint sprain. While you are in the exercise program, we will be checking in often to ensure you feel comfortable with the exercises we are asking you to do. We do not expect the risks associated with this program to be any greater than the risks associated with everyday exercise.

There is a slight risk that your personal information could be exposed by participating in this study. We will protect your information by assigning you an identification number at the beginning of the study and storing all information you provide us with that ID number instead of your name. The database that links your ID to your name will be encrypted, password protected, and stored on a HIPAA-compliant secured network.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you decide not to participate in this study but are interested in increasing your physical activity, we recommend you talk to your doctor or healthcare provider about initiating and maintaining an exercise routine.

BENEFITS OF THE STUDY

We expect a mild physical health benefit for participants who complete the exercise program. Though breast cancer survivors benefit on average from participating in this type of regular exercise, that does not guarantee that you will personally receive the same benefit by participating.

In addition to a potential personal benefit, the information we learn from this study will help us better design exercise treatment programs for breast cancer survivors into the future.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from the National Cancer Institute, part of the National Institutes of Health.

CONFIDENTIALITY OF RESEARCH INFORMATION

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
    - Authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIH funding for this study ends. Currently this is 12/31/2022. Any data collected after expiration is <u>not</u> protected as described above. Data collected prior to expiration will continue to be protected.

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.

Your participation in this study will be noted in your UW medical record.

USE OF INFORMATION AND SPECIMENS

Commercial Profit
The information we collect from you as part of this study will not be used for commercial profit.

Returning Results to You
We will inform you if we discover a potentially severe or life-threatening condition during the study.

In addition, after you complete the study you will have the option to receive some of your results collected during the study, including vital measurements, 6-minute walk test results, and exercise testing results. These tests are conducted for research purposes only and results should not be considered clinically valid. The exercise intervention has not been proven to cause any change in the results returned, and it can only be proven effective by combining many people's results.

Using Your Data in Future Research
The information that we obtain from you for this study might be used for future studies. We will remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you.

Re-contacting for Future Studies
____ I agree to be re-contacted about similar future studies under the purview of Dr. Kerryn Reding.

OTHER INFORMATION

If you agree to participate, you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

In appreciation for your time, you will receive gift card compensation for each assessment visit. The 2 longer appointments (Baseline, 6-Month) will pay $50 each, while the 1 shorter visit (3-Month) will pay $20. Travel costs (gas or public transportation) will be reimbursed up to $5; all parking will be reimbursed in full when applicable.

You will not be billed for any study-related activities.

RESEARCH-RELATED INJURY

If you think you have been harmed from being in this research, please contact Kerryn Reding, Principal Investigator at 206-221-1571.

The UW does not normally provide compensation for harm except through its discretionary program for medical injury. However, the law may allow you to seek other compensation if the harm is the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

Participant's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I will be offered a copy of this consent form.

Printed name of participant	Signature of participant	Date

Copies to: Researcher
Participant