UNIVERSITY OF WISCONSIN-MADISON

Subject CONSENT to Participate in Research
AND
AUTHORIZATION to Use and/or Disclose Identifiable Health Information for Research

Title of Study: Home-based resistance training in endometrial cancer survivors

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INVITATION

You are invited to participate in a research study about the effects of an at-home strength training program on overall fitness and body mass in women diagnosed with endometrial cancer. Studies show that physical activity improves health and we want to see if resistance training can improve health following treatment for endometrial cancer.

You have been asked to participate because you were diagnosed with endometrial cancer and have completed your initial treatment. This study will include 40 women who are 18-74 years of age and who have completed primary treatment (surgery, radiation, and/or chemotherapy) for type 1 endometrial cancer. Women are only enrolled if they are currently participating in less than 2 days per week of resistance training. There will be two arms of this study which will be determined randomly, meaning you have equal chances of being allocated to either group, but your group assignment will be determined by the equivalent of a coin flip. One group will receive the intervention immediately, and the other group will be the wait-list control group, meaning they should continue to live their lives as normal, and will receive the intervention after 15 weeks in the control group.

This 15-week study involves three visits, which will take place at UW – Madison. In between these visits, participants will be participating in various activities (e.g. questionnaires, lifestyle changes, follow-up phone calls) from home.

Your participation in this research study is voluntary. If you decide not to participate, the health care provided to you by the University of Wisconsin-Madison (UW-Madison) and its affiliates (the University of Wisconsin Hospital and Clinics) will not be affected in any way.

A. WHAT IS THE PURPOSE OF THE STUDY?

The purpose of the research is to help improve our understanding of adherence to home-based exercise, to understand the role of home-based exercise in survivorship care. This is important because other studies in other populations have shown that resistance training is associated with factors such as insulin resistance which may be also related to endometrial cancer survivorship.

B. WHAT WILL MY PARTICIPATION INVOLVE?

If you decide to participate in this research, you will be asked to:

1) **Attend two Study Visits, plus one additional visit if you are in the treatment group**

Visits will be conducted at the UW – Madison Marsh Center. The initial visit takes about 60 minutes. During the first visit we will discuss the study goals and research activities as well as collect baseline measures. We will then allocate you to a treatment group (exercise or wait-list control) over the telephone within a week of the initial visit. After the telephone call, approximately a week later, we will ask you to come in again (if you are assigned the treatment group) to have a 60-90 minute

instructional visit where we will provide you with materials and instructions on how to complete the exercises as a part of this study.

Finally, all subjects will be asked to return for a final visit after 15 weeks in the study where we will repeat the measurements collected at the first visit. Parking fees will be covered for all visits.

2) Complete Questionnaires

Questionnaires will be completed at 3 time points (baseline, mid-point, and at the final visit). The questionnaires will ask you about your medical history, lifestyle and health habits, use of technology and the Internet, quality of life, mental well-being such as anxiety, depression, sleep and fatigue. These questionnaires will be completed online at your convenience, and at the mid-point mark we will email the surveys to you again. Demographic questions will also be asked in order to help us describe the women in the study at the baseline visit only. Not all of these items will be covered at each time point. Questionnaires may take from 15-45 minutes to complete.

3) Complete Study Measures: Anthropometrics, FFT, blood spots, DXA scan

At two points (baseline and final visit) during the study, you will be asked to complete study measures. These include an assessment of height, weight, waist and hip circumference; an assessment of functional fitness through a battery of tests that reflect activities of daily living; a blood draw from a finger prick to collect blood for testing; and undergo a body composition test, which tells us the breakdown of fat and lean tissue.

Body composition will be assessed using dual-energy absorptiometry (DXA) scan. The scan takes approximately 5 minutes, and you will have to lay flat on a large table as the arm of the scanner moves over your body.

Functional fitness. The functional fitness test (FFT) is a battery of six tests measuring strength, flexibility, fitness, body composition, and agility. The functional fitness test battery includes the following 6 assessments:

- 1. The 30 second chair stand, which assesses the strength of the lower body. You will have 30 seconds to stand up and sit down from a chair as many times as possible within the time frame.
- 2.The 30 second arm curl assesses the strength of the upper body, where you will hold a 5 pound dumbbell in a seated position, and you will have 30 seconds to curl your arm and extend it as many times as possible within the time frame.
- 3. The 6 minute walk test measures the total distance that you can quickly walk on a flat hard surface within a period of 6 minutes.
- 4. The chair sit and reach assesses the lower body flexibility where you will sit in a chair, extend one leg in front of them and flex at the waist, reaching toward your toes, and we will measure the distance between their toes and fingers.
- 5. The 8-foot-up and go is an assessment of speed agility and balance. With this assessment, you begin in a seated position, and will be timed for the duration it takes to rise from the chair, walk as quickly as possible around a cone 8 feet away from the chair, and return to a seated position.
- 6. The back scratch test is an assessment of the flexibility of the upper body, where you will be seated and one arm will be flexed behind your head, and the other arm will be extended behind your shoulder. The assessment measures the distance between the fingertips of both hands.

Blood Sample Collection. Blood samples will be collected from all subjects at the baseline and final study visits. Samples will be collected through a finger stick and a few drops of blood will collected for testing. Results of the testing will not be reported to you.

4) Wear Motion Sensors

At three points (beginning, mid-point and end) during the study, you will be asked to wear a waist-worn motion sensor for all of your waking hours for 7 days. This sensor is used to objectively tell us about your overall physical activity, and the motions are worn on a belt and are relatively unobtrusive.

5) Participate in Video Calls

If you are assigned the intervention group, you will be asked to participate in eight scheduled video-based coaching calls over the course of the intervention. These calls will take 15-30 minutes and are intended to help you reach the study goals. Participation in these calls is an important aspect of the study. The calls can be scheduled for a time that is convenient to you.

6) Participate in your Assigned Study Group

Depending on your assigned group you will be asked to do the following:

- Participate in 2 sessions of home-based resistance training per week, each session having 8 exercises with 2-3 sets of 8-12 repetitions at an appropriate intensity. These are exercises that strengthen the muscles of the body, including exercises like a biceps curl, a squat, a chest press or a calf raise, all of which you can do at home with the exercise equipment that we will provide. You will be asked to log, track and report all exercises that you complete over the course of the study. You will be able to keep your exercise equipment after the study is over.
- If you assigned to the wait-list control group, you will receive printed information with health tips related to healthy eating and stress. You will not be asked to make any specific changes to your lifestyle. After the 15 weeks is complete, you will receive the study materials for the first group so that you can have access to the exercises if you are so interested but you will not undergo the instructional/training session.

7) Complete End of Study Interviews (Intervention group only)

To understand how the intervention was received, you will be asked to do an informal interview with the study coordinator at the end of the study if you are assigned to the intervention group. These interviews will ask about overall satisfaction with the interviews, areas for improvement, barriers to participation, best parts of the intervention, and other items relevant to your participation. The interviews will be audio-recorded to help in analyzing the results of the study. A written copy of the recordings will be made for use in the research. Recordings will be kept for the duration of analysis and destroyed following completion of the study. Recordings will not be used for purposes outside of the study or in any papers or publications.

We will also collect the following information about you for this research study:

From you:

- Age, home address, phone number, email address (optional)
- Information about your endometrial cancer diagnosis, ability to exercise, and information about your health habits (physical activity, alcohol and tobacco use, menopausal status)
- Information from tests performed for this study (e.g., scans, blood tests)

From your medical records, health records and/or billing records kept by UW Madison:

- Details of your endometrial cancer diagnosis including: date of diagnosis, tumor stage, tumor type, and treatment(s) received.

C. USE OF EMAIL

We are requesting your email address so we can communicate with you throughout the course of the study, mainly to be a point of contact, to deliver surveys and to schedule calls. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Dr. Lisa Cadmus-Bertram. You do not have to provide your email address to participate in this study. Please initial one choice below regarding use of email:

_____Yes, you may use email to contact me for this study

_____No, I do not want to be contacted by email

D. ARE THERE ANY BENEFITS TO ME?

You are not expected to benefit directly from participating in this study. Your participation in this research study may benefit other people in the future by helping us learn more about cancer survivorship and the role of resistance training.

E. WILL I BE PAID FOR MY PARTICIPATION?

You will receive $50 after the initial visit as well as another $50 at the final visit of the intervention. You will be allowed to keep all the exercise equipment that you are given (bands, weights, towels etc.).If you are in the waitlist group we will provide you with this equipment to keep at the final study visit.

F. ARE THERE ANY SIDE EFFECTS OR RISK TO ME?

There is a risk that your information could become known to someone not involved in this study. If this happens, it could result in damage to your reputation, which could also affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job.

Depending on the group to which you are randomly assigned, you may be asked to increase your exercise level. You may experience some muscle soreness, fatigue, or other mild discomfort as you adjust your overall activity levels. Potential risks of participating in this study include acute injury, musculoskeletal soreness.

The risks/discomfort associated with the functional fitness test (FFT) include acute injury, musculoskeletal soreness from some of the assessments.

The risks/discomfort associated with the DXA scan include discomfort with laying flat, or anxiety associated with scans. The DXA scans will also expose you to a small amount of radiation. The radiation exposure is equivalent to about $1/10^{th}$ of an x-ray per scan. This is less radiation than you would be exposed to when flying on an airplane.

The risks/discomfort associated with the blood sample collection from the finger prick has the minimal risk of causing a small bruise and a remote risk of resulting in infection. The sight of blood may make you dizzy or nauseous, but you will be advised to not watch the prick.

The questionnaires in this study include some items about emotional and psychological well-being. There is the risk of emotional distress as a results of completing these items. The questionnaires you will complete in this study ask about symptoms of emotional distress such as depression and anxiety. We are using the questionnaires only for research, not to diagnose mental health issues. We will not tell you the results. If you are experiencing emotional distress, you should contact your physician or other health care provider, such as a mental health professional.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

Possible Discovery of Findings Related to Medical Imaging.

Whenever a DXA scan of the body is done, there is the chance of finding something unexpected. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as problems with getting insurance or a job, or feeling worried about a finding for which no treatment is required or appropriate).

The DXA scan we are using in this research study is not the same quality as a DXA scan that you may have as part of your health care. The images from the DXA scan will not be reviewed by a physician who normally reads such images. As a result, you will not be informed of any unexpected findings. The results of your DXA will not be placed in your medical record. If you believe you are having symptoms that may require clinical imaging, you should contact your primary care physician.

G. WILL COMPENSATION BE MADE FOR INJURY RESULTING FROM THIS RESEARCH?

Being injured during this research is very unlikely. However, accidents can happen.

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, [specify what subjects should do, e.g. contact the study team for instructions, contact your regular health care provider].
- Call the Principal Investigator, Lisa Cadmus-Bertram, at (608) 265-5946 to report your sickness or injury.

H. HOW WILL THE RESEARCHS KEEP MY RESEARCH INFORMATION CONFIDENTIAL?

We have strict rules to protect your personal information. We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials and study sponsors responsible for monitoring this study. By signing this consent form, you are authorizing this access to your records.

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- The study sponsor, the American Cancer Society

Will information from this study go in my medical record?

- None of the information we collect for this study will be put in your medical record.

Authorizing the research team to use your PHI means that we can release it only to the people or groups listed above, and only for the purposes described in this form. However, once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others.

Also, if ALL information that can identify you is removed from the health information collected in this study, then it is no longer PHI and this authorization will no longer limit how the remaining information can be used. This means the information could be used or shared for reasons other than the ones described in this form, such as a research study about another kind of disease. It also means that the information could be shared with researchers working at institutions that are not listed above.

I. WHAT WILL HAPPEN TO MY DATA AFTER MY PARTICIPATION ENDS?

We would like to keep your data for an indefinite period of time, which means we have no plans to destroy your data. Keeping data or samples for future research is called “banking.” The banked data will be kept in a secure location for use by our research team in future research projects. The banked data will be labeled with a code instead of your name. You can request to have the data removed from the bank by contacting the study team at any time.

Please initial one of the lines below to indicate whether or not you agree to the optional data banking:

____ Yes, I agree to have my data banked for future research purposes.

____ No, I DO NOT agree to have my data banked for future research purposes.

J. IS MY PERMISSION VOLUNTARY AND MAY I CHANGE MY MIND?

Your permission is voluntary. You do not have to sign this form and you may refuse to do so. If you refuse to sign this form, however, you cannot take part in this research study.

You may completely withdraw from this study at any time. You also may choose to cease participation or skip any questions that you do not feel comfortable answering.

If you decide not to participate in this study or if you stop while the study is underway, the health care you receive from the UW-Madison and its affiliates will not be affected in any way.

K. HOW LONG WILL MY PERMISSION TO USE MY HEALTH INFORMATION LAST?

By signing this form you are giving permission for your health information to be used by and shared with the individuals, companies, or institutions described in this form. Unless you withdraw your permission in writing to stop the use of your health information, there is no end date for its use for this research study. You may withdraw your permission at any time by writing to the person listed below:

Lisa Cadmus-Bertram, Ph.D.
2000 Observatory Drive, Madison, WI 53706

Beginning on the date you withdraw your permission, no new information about you will be used. Any information that was shred before you withdrew your permission will continue to be used. If you withdraw your permission, you can no longer actively take part in this research study.

L. REGISTRATION AT CLINICAL TRIALS.GOV

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

M. WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

Please take as much time as you need to think over whether or not you wish to participate. If you have any questions about this study at any time, contact the Principal Investigator, Lisa Cadmus-Bertram at (608) 265-5946.

If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

AGREEMENT TO PARTICIPATE IN THIS STUDY AND PERMISSION TO USE AND/OR DISCLOSE MY HEALTH INFORMATION

I have read this consent and authorization form describing the research study procedures, risks, and benefits, what health information will be used, and how my health information will be used. I have had a chance to ask questions about the research study, including the use of my health information, and I have received answers to my questions. I agree to participate in this research study, and permit the researcher to use my health information as described above.

Name of Participant (please print):_____

_____ _____

Signature of Participant **Date**

Name of person obtaining consent and authorization (please print):_____

_____ _____

Signature of person obtaining consent and authorization **Date**

YOU WILL RECEIVE A COPY OF THIS FORM AFTER SIGNING IT