Study title: *The feasibly, efficacy, and acceptability of FitEx for endometrial cancer survivors: A pilot randomized controlled trial of walking with or without yoga*

Study PI: Shannon Armbruster, MD, MPH

NCT ID: Not yet assigned

RESEARCH eCONSENT FORM

The feasibly, efficacy, and acceptability of FitEx for endometrial cancer survivors: A pilot randomized controlled trial of walking with or without yoga

PI: Shannon Armbruster, MD, MPH and Samantha Harden, PhD

IRB-21-1256

SUMMARY

This consent form contains important information to help you decide whether to take part in a research study. You should read and discuss all the information in this consent form with the research study doctor. A brief summary of the study is provided below.

- Being in this research study is voluntary; it is your choice.
- If you join this study, you can still stop at any time.
- Do not join this study unless all of your questions are answered.
- The study is being conducted to evaluate the relationship between endometrial cancer survivors and physical activity. To date, there is no ideal program for endometrial cancer survivors who are looking to improve their weekly physical activity. This study is being used to develop a program for endometrial cancer survivors that incorporates things that they value into a program specifically designed for survivors.
- Individuals who are eligible to join the study are endometrial cancer survivors and their friends and loved ones ("support group members") who wish to support them on their wellness journey.
- An individual with endometrial cancer may choose to participate if they want to improve their physical activity levels. You may join if you want to create a team composed of your family and friends in order to exercise with other survivor teams to improve your physical activity habits together, or if you have ideas about what sort of program would work best for endometrial cancer survivors like yourself.
- If you are a loved one of someone with endometrial cancer, you were asked to join by an endometrial cancer survivor who enrolled in the study as part of their support group.
- The study intervention lasts 8 weeks. If you join the study, you will receive a pedometer. You'll be asked to track how much you walk for 5 days before the 8 week study starts.
- When the study starts, the endometrial cancer survivor and up to 5 support group members will be placed within a team, with the endometrial cancer survivor serving as the team captain.
- You will be asked to record how many steps you walk and how many fruits and vegetables you consume every day for 8 weeks. There will also be optional weekly Zoom meetings consisting of virtual physical activity and social support with other teams. You will also receive questionnaires at various times during the study. Six months after the study ends, you will receive more questionnaires and be asked to track how much you walk for 5 days. Afterwards, your participation in the study will conclude.
- Your participation is expected to last for about 8 months total.
- The most important benefits that you may expect from taking part in this research include benefits related to sustained physical activity and exercise, such as improved quality of life.

- The most likely risks to you are discomfort during the study and the possibility of a data breach.
- Your options other than participating are to not participate. This will not affect your care at Carilion Clinic or with Dr. Armbruster.
- You or your insurance will be billed for standard medical care and you will be responsible for any medical costs your insurance does not cover.

The study staff will explain this study in detail to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

WHY AM I BEING ASKED TO PARTICIPATE IN THIS RESEARCH?

You are being asked to participate in this research because you are either:

a) An endometrial cancer survivor interested in a physical activity intervention OR

b) A friend or loved one ("support group member") of an endometrial cancer survivor who is participating in the study

There are different groups of participants in this study. You may be an endometrial cancer survivor being asked to recruit members of your team, or you may be a friend, loved one, or family member of someone with endometrial cancer who asked you to participate.

Endometrial cancer survivors who enroll will be asked to recruit up to 5 friends or loved ones ("support group members") to join them over the duration of the study. Through involvement in the study, the endometrial cancer survivor and her support group members will become a team, supporting each other throughout this journey.

This study may be right for endometrial cancer survivors who are looking to improve their physical activity adherence or who wish to connect with other endometrial cancer survivors through a walking, goal-setting, and social support program. The study may be right for support group members looking to encourage and support their loved ones with endometrial cancer by exercising together.

INTRODUCTION

Informed consent is the process of learning the key facts about a research study before you decide whether or not to volunteer. Your agreement to volunteer should be based upon knowing what will take place in the research study and how it might affect you. Informed consent begins when the research staff explains the facts to you about the research study.

The research staff will assist you with the informed consent form that goes over these facts so you can decide whether or not you want to take part in the research study. These facts include details about the research study, tests or procedures you may receive, the benefits and risks that could result and your rights as a research volunteer.

You are being asked to join a research study. The person running this study locally is Dr. Armbruster. You are being asked to take part in this study because you are a survivor of endometrial cancer or you are a friend or loved one of an endometrial cancer survivor. The

main purpose of research is to create new knowledge for the benefit of future patients and society in general. Research studies may or may not benefit the people who participate. Being in this research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. The study is completely voluntary and choosing not to participate will not impact the care that you receive from Dr. Armbruster or any other providers at Carilion Clinic.

Be aware that the role of the study doctor is different from the role of your personal doctor. Your personal doctor decides how to treat your specific problem in order to help you. The study doctor treats all subjects under a specific protocol to obtain general knowledge that may or may not benefit you. Be sure to ask your doctors questions to help you know more about these different roles.

PURPOSE

The purpose of this study is to determine whether a physical activity tracking program called FitEx would be useful to endometrial cancer survivors. Dr. Armbruster is working with Dr. Harden, the co-investigator and the principal investigator of FitEx, to improve people's health through physical activity and movement. FitEx is a program used to encourage adults to improve their fruit and vegetable intake, while increasing their physical activity. FitEx works by having its participants join a team with their friends and loved ones, so they can support one another in meeting their goals. In this study, we will form teams of endometrial cancer survivors and their loved ones and provide you with a pedometer, a wearable watch that tracks how many steps you take. Each team will be composed of one endometrial cancer survivor and up to 5 friends or loved ones ("support group members"). Each day, participants record how much exercise, how many fruits, and how many vegetables they've eaten that day for a total of 8 weeks. Participation in our study lasts roughly 10 weeks, and you will be followed for 6 months afterwards. We think that FitEx may help people with endometrial cancer improve their daily physical activity, and slowly improve their health.

PROCEDURES

If you would like to participate in the study, you will be screened to make sure you are an eligible candidate. As part of this screening, you will be asked for personal information such as age, race, height, weight, educational status, employment status, and other relevant demographics.

Each endometrial cancer survivor who enrolls in the study may recruit up to 5 friends or loved ones to join their team while on the study. If you are eligible for the study and decide to participate, you will receive a wearable pedometer for the duration of the study that we ask you to wear everyday, even to sleep. All participants will wear this pedometer. Each day, you'll be asked to record how many steps you've walked that day. When the study begins, you will be asked to track your daily steps for 7 days. You will also be asked to complete some

questionnaires to get an idea of why you are participating in the study and how you are feeling in your daily life. Once we have an idea of how much you walk normally, the FitEx program will begin.

Since you now have 7 days of steps recorded, you will be randomly assigned to one of two groups of participants within FitEx. Both groups will be made up of other endometrial cancer survivors. Within each group, there will be individual teams. A team consists of one endometrial cancer survivor and up to 5 friends or loved ones, who will also be enrolled into the study. During enrollment into FitEx, you will receive a baseline questionnaire and you will be asked to fill out a questionnaire with your steps walked and your fruit and vegetable intake each week. You will also receive other questionnaires related to exercise. Endometrial cancer survivors will receive questionnaires related to their cancer.

The groups will meet once a week for 8 weeks, and participation in the meetings is voluntary. The meetings will take place over Zoom and will consist of 15 minutes of group discussion and 15 minutes of group accessible movements, such as light stretching and posture improvement, for a total of 30 minutes each week. The friends and loved ones will be invited to the meetings for group accessible movements, and will be asked to make space for the endometrial cancer group discussion. After each session, you will be asked to complete more questionnaires to see how you felt about the activities and track your progress.

It is not clear which group assignment is better. For this reason, the group given to you will be assigned on chance using a method called randomization. Randomization means that the group you are in will be assigned by chance, like the flip of a coin. Your chance of receiving the ECS group is equal to your chance of receiving the ECS plus yoga group.

At week 9 of the study, you will receive a certificate of completion for FitEx, and there will be another meeting to celebrate your achievement with yourself and other members of your team. Endometrial cancer survivors will be given the same questionnaires that they got when they signed up for the study to determine if anything changed over the course of the study.

Six months afterwards, you will be asked to record how much you are walking for 7 days, just like you did when the study started. This information will be used to see if the study helped improve your physical activity habits, even after the study was over. You will also be given more questionnaires to fill out. The study ends after this point. The FitBit is yours to keep and you can choose to continue wearing it.

For participants, the benefits of this research are related to exercise. Participants may feel numerous benefits related to continued exercise over the course of 8 weeks. We hope the study will help us understand more about barriers as well as identify areas to help survivors of endometrial cancer with dietary modification and exercise. There are also potential societal benefits of being in a group based physical activity intervention. You may feel the benefits of

social support with your friends or loved ones as you take on the journey of improving your physical activity adherence together.

As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality will occur. The researchers have procedures in place to lessen the possibility of this happening (see "What about confidentiality?" section below).

WILL I RECEIVE NEW INFORMATION ABOUT THIS RESEARCH STUDY OR ABOUT MY STUDY RESULTS?

In general, we will not give you any individual results from the study because the clinical significance may not be known. It is possible though that we will discover information of medical importance that is unrelated to the purpose of this study. If we believe that the information is of urgent medical importance, we will share this information with you.

Sometimes new information comes out during a research study that may affect your health, welfare, or willingness to stay in a study. If that happens, the researchers will tell you about the new information. If you decide you no longer wish to participate, they will also tell you about other options for your care. You may need to sign another form with your consent to continue in the study.

RISKS

The movements that we practice are designed to be very safe in order to prevent injury. You will mostly remain seated and we will ensure that the movements are inclusive to all of our participants. You will be surveyed before the study begins to make sure that exercising is safe for you. However, as with any movements such as walking, there is a risk of injury.

The survey questions may be personal. Some of the questions might be embarrassing or uncomfortable. You may skip any question that makes you feel uncomfortable. Your name will not be used in any publication or presentation about this research. The other risks in this study relate to the confidentiality of your health information. For endometrial cancer survivors, we will combine your survey results and personal information with information from your medical records on your condition, your treatment, and your surgery.

When we analyze the data, we will replace your name with a code number to protect your privacy. The list that connects your code number to your name will be kept in a secure location. Research results shared will have your name and other direct identifiers removed to protect your identity. The risk for someone outside of the research study to learn of your participation or responses is low. Your name will not be used in any publication or presentation about this research. Your data will be securely stored within FitEx's server, Carilion Clinic's server, and within a program called REDCap. All of these programs are encrypted and password protected. Only members of the study team will have access to your identifiable data.

Identifiers on your research data might be removed so that your identity can no longer be linked to them. Your private information may then be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. Even though your identifiers will be removed, there still may be a chance that someone could figure out that the information is about you.

AUTHORIZATION TO USE YOUR HEALTH INFORMATION:

NOTE: This health information section only applies to participants who are endometrial cancer survivors. HIPAA authorization is not necessary for support group members. We will not view the medical records of support group participants.

There is a federal law that protects the privacy of health information. This law is known as HIPAA. HIPAA stands for the "Health Insurance Portability and Accountability Act." Because of this law, your health information cannot be looked at, collected or shared with others without your permission.

Signing this consent and authorization form means you allow the Principal Investigator for this study and members of the investigator's research team to create, get, use, store and share information that identifies you for the purposes of this research.

This is the information about you that researchers will use:

- Personal identifiers such as name, address, telephone number, or medical record number.
- Demographic information such as age, race, gender.
- Current and past medications or therapies.
- Family medical history.
- Results of physical exams, laboratory tests, x-rays and other diagnostic procedures.
- Tests and procedures that will be done in the study.
- Other personal health information that will be obtained from other sources to use in the research, including past medical history, tests or records from other sites.
- Information from surveys or questionnaires done for this study.
- The following information specific to this study: knowledge of endometrial cancer, barriers to exercise adherence, personal level of physical activity, physical/mental health, life after cancer treatment, yoga self-efficacy, fear of cancer recurrence, motivational factors that drive exercise habits.

The investigator and research team may share information about you with:

- The Carilion Clinic Institutional Review Board, a research protection group that provides ongoing review of the research project or other groups authorized to monitor the study.

- Authorized employees of Carilion Clinic who need the information to perform their duties to provide treatment, to ensure the integrity of the research or to do accounting and billing.
- Research collaborators at Virginia Tech.
- Government agencies that oversee research with humans
- The Office of Human Research Protections (OHRP), Food and Drug Administration (FDA), or other government agencies that oversee research with humans.
- Committees that monitor research data and safety or other groups authorized to monitor the study

Health information that could allow you to be identified is called protected health information or PHI. The investigator and research team will share only the PHI listed above with the individuals/agencies listed above. If the investigator needs to share other PHI or needs to share PHI to other individuals/agencies not listed above, then you will be asked for your permission in writing again.

Carilion Clinic and its affiliates are required under law to protect your PHI. However, the individuals or agencies who receive your PHI may not be required by the Federal privacy laws to protect it. They could share your PHI with others without your permission, if permitted by the laws governing them.

You will not be eligible to participate in this study if you do not sign this consent and authorization form. You have the right to stop sharing your PHI. To end your permission to share your PHI, you must do so in writing to the Principal Investigator at the address listed on the first page of this form. If you want the researchers to stop collecting your PHI for the research, you may be removed from the study. If you are removed from the study, it will not affect your ability to receive standard medical care or any other benefits you are entitled to receive. PHI collected for the research study prior to you ending your permission will continue to be used for the purposes of the research study. Research information continues to be analyzed or monitored after the study is finished so it is difficult to say when use of your PHI will stop. There is not an expiration date for this authorization to use and disclose your PHI for this study.

WILL IT COST ME MONEY TO TAKE PART IN THIS RESEARCH?

Taking part in this research will not cost you any money. However, if you are injured during the study, your insurance is responsible for taking care of hospital charges or doctor's appointments related to your injury.

WHAT IF I WANT TO STOP BEING IN THE STUDY BEFORE IT IS FINISHED?

Being in this research is voluntary. You may refuse to take part or you may withdraw at any time. Your decision not to take part or your decision to withdraw will not affect your ability to get care from your doctors or from Carilion.

If you decide to withdraw from the study, please let Dr. Armbruster know so that the study team can safely discard your data and ensure that your data is not retained with other participant data.

If you decide to leave the research early, there are potential adverse consequences. You may feel discomfort leaving a team, or you may feel discouragement. Leaving a team of friends and loved ones may be difficult.

CAN I BE REMOVED FROM THIS RESEARCH WITHOUT MY APPROVAL?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have an injury that requires stopping the research
- You become pregnant
- The research is canceled by the FDA or the sponsor
- You are unable to participate in research exercises such as walking or yoga
- You are unable to consistently log your study data
- You are unable to find at least one participant to join your team (if you are an endometrial cancer survivor)
- You or your team do not adhere to the procedures of the study

The reason for any exclusion will be explained to you.

WHAT WILL HAPPEN IF I HAVE COMPLICATIONS OR IF I AM INJURED BY THIS RESEARCH STUDY?

If you have a medical problem that happens because you are in this study, you will be able to get treatment. If you need emergency care, call 911 or go to your nearest hospital or emergency room right away. It is important that you tell the doctors at the hospital or

emergency room that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

The treatment will be billed to you or your insurer at the usual charge. The study does not make any provisions for the payment of these costs. You will not receive any other financial compensation, nor payment for any wages you may lose due to your injury. However, you do not give up any legal rights to seek compensation for injury by signing this consent form.

Call the person in charge of this study as soon as you are able. They will need to know that you are hurt or ill.

BENEFITS

You may benefit directly from this study. For participants, the benefits of this research are related to exercise. Participants may feel numerous benefits related to continued exercise over the course of 8 weeks. Researchers hope that the information collected from this study may be useful in future development and/or adaptation of a lifestyle modification intervention designed for survivors of endometrial cancer.

WILL I BE PAID FOR TAKING PART IN THIS RESEARCH?

At the beginning of the study, you will receive a wearable FitBit pedometer. You will be asked to wear this pedometer over the course of the study. You will not be compensated for your participation in this study outside of the FitBit Charge, which is for you to keep.

Payments and gifts made to you as compensation for your participation will be tracked by the research team. This information will be submitted to Carilion's financial department for central tracking. If you receive greater than $600 from Carilion in a calendar year, this is considered taxable compensation and will be reported to the Internal Revenue Service (IRS). You will be issued a 1099 tax form by Carilion if you meet this reporting threshold.

ARE RESEARCHERS BEING PAID TO DO THIS STUDY?

This study does not have any sponsors. It does not have any funding. None of the investigators or research staff will receive money or other types of payment from this study.

QUESTIONS

Before you sign this form, a member of the research team should answer all your questions. There are also some teach back questions for you to answer. If you do not know the answer, we can discuss the study further to clarify your understanding.

- What will you be doing during the study?
- How often should you input your steps?
- For how many weeks will we have weekly meetings?

- Are the weekly meetings optional?
- How often do you wear the pedometer?
- How long does the study last?
- Who will you be on a team with during the study?

You can talk to the study PI, Dr. Armbruster at 540-581-0160 if you have questions, suggestions, concerns, or complaints after signing this form.

This research is being overseen by the Carilion Clinic Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (540) 853-0728 if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

CLINICAL TRIAL STATEMENT

This study will be listed as a Clinical Trial. 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.