CONSENT TO TAKE PART IN A BEHAVIORAL RESEARCH STUDY

TITLE: The initial efficacy of FitEx for endometrial cancer survivors: A pilot randomized controlled trial of a walking promotion program with or without yoga

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

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 study staff. 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 and test 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 team 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 or potentially help other survivors improve their physical activity. You may join if you want to improve your physical activity habits, or if you are an endometrial have ideas about what sort of program would work best for endometrial cancer survivors like yourself.
- If you are a friend or loved one of someone with endometrial cancer, you were asked to join as part of the support team of an endometrial cancer survivor who enrolled in the study and was assigned to an intervention group.
- If you join the study as an endometrial cancer survivor and are assigned to the standard-of-care group, you will have the option to receive a Fitbit and will be sent a one-time educational newsletter. You will also receive questionnaires at various times during the study. You will not recruit friends and loved ones to form a team nor participate in Zoom meetings. You will be asked to wear your Fitbit for 7-days and then for an additional 8 weeks.
- Endometrial cancer survivors assigned to the intervention group will recruit up to 5 support team members to form a team, with the endometrial cancer survivor serving as the team captain.

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- If you join the study and are a participant assigned to an intervention group, you will have the option to receive a Fitbit and will be sent weekly newsletters and participate in the intervention as part of a team. You will also be strongly encouraged to participate in weekly recorded Zoom meetings consisting of virtual physical activity and social support with other teams. You will also receive questionnaires at various times during the study. You will be asked to wear your Fitbit, track your activity, and report your fruits and vegetables intake for 7-days before the study interventions starts and then for the 8-week duration of the study intervention.
- Six months after the study ends, participants in the standard-of-care and both intervention groups will again be asked to wear Fitbit for 7 days. Participants in the intervention group will be asked to track their activity and fruits and vegetables intake, fill out questionnaires, and participate in a semi-structured exit interview. Afterwards, 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, 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 or other gynecologic oncologists.
- Being in the study will not cost anything although 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.

Please read this consent form carefully.

WHAT IS INFORMED CONSENT?

You are being asked to take part in a research study because you you are either:

a) An endometrial cancer survivor interested in participating in the study OR
b) A friend or loved one ("support team member") of an endometrial cancer survivor who is participating in the study

The research is funded by the National Institute of Health. The person running this study locally is Shannon Armbruster, MD and Samantha Harden, PhD.

Before you can decide whether to take part in the research, you should be told about the possible risks and benefits with this study. This process is known as informed consent.

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This consent form will give you information about this study and your rights as a research subject.

This consent form may have words or information you do not understand. The research staff will explain anything that you do not clearly understand. Please ask as many questions as you need to make sure that you know what will happen to you in this study and why you are being asked to be in it.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this study is to determine whether a physical activity tracking program called FitEx would be more useful to endometrial cancer survivors than standard-of-care. 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 their physical activity and improve their fruit and vegetable intake. 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.

WHAT WILL HAPPEN IN THIS RESEARCH STUDY?

In this study, participants in the intervention groups will form teams of endometrial cancer survivors and their friends and loved ones ("support team members"). Endometrial cancer survivors assigned to the standard-of-care group will not form teams.

All participants will have the option to receive a Fitbit, a wearable watch that tracks how many steps you take. Participation in our study lasts roughly 10 weeks with a follow up 6 months afterwards. Participants with Fitbit devices who have not synced their Fitbit devices after 6 days will receive up to two automated SMS-based reminders per week.

Each team in the intervention groups will be composed of one endometrial cancer survivor and up to 5 friends or loved ones ("support team members"). Each day, participants in the intervention groups will track their physical activity and fruits and vegetables intake for 7-days before the study interventions starts and then for the 8-week duration of the study intervention. FitEx may or may not help people with endometrial cancer improve their daily physical activity and improve their health and quality of life.

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.

There are three groups in this study. 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. The chance of being assigned to one group is equal to your chance of being assigned to any of the other groups.

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Each endometrial cancer survivor who enrolls in the study will be randomized into one of three groups: 1) standard-of-care, 2) FitEx intervention, or 3) FitEx plus yoga intervention. Each endometrial cancer survivor in either intervention group may recruit up to 5 friends or loved ones, who will also be enrolled into the study as support team members, to form their individual teams within their respective study intervention.

If you are eligible for the study and decide to participate, you will have the option to receive a wearable Fitbit pedometer for the duration of the study that we ask you to wear every day, even to sleep. Participants in all three groups will have the option to receive and wear this Fitbit.

If you are assigned to an intervention group, you will receive a baseline questionnaire and be asked to wear your Fitbit, track your activity, and report your fruits and vegetables intake for 7-days before the study interventions starts. You will have the options to track physical activity and fruits and vegetables intake through the FitEx-ECS portal within Fitabase or on FitEx Individual Log sheet. You will also be asked to complete some other questionnaires to get an idea of why you are participating in the study and how you are feeling in your daily life.

For the following 8 weeks, participants in the standard-of-care group will be asked to track their activity with Fitbit while participants in the intervention groups will be asked to wear their Fitbit, track physical activity, and report fruits and vegetables intake for the duration of the 8-week intervention. All participants will receive questionnaires related to physical activity and quality of life, and endometrial cancer survivors may receive an additional questionnaire related to their cancer.

Endometrial cancer survivors in the standard-of care group will receive a one-time educational newsletter and again, will not recruit support team members.

Endometrial cancer survivors and their teams in intervention groups will receive weekly newsletters and be strongly encouraged to meet once a week for 8 weeks. The weekly 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. Friends and loved ones will be encouraged to participate in the meetings for group accessible movements and will be asked to make space for the endometrial cancer group discussion. As these **Zoom meetings will be audio recorded**, participants will be verbally reminded of audio recording at the beginning of each session. Additionally, the physical activity portion of the Zoom meeting will be video recorded, but the video will only include video and audio of the FitEx instructor, not you or the other participants. Please note that there may be certain risks inherent in Zoom for privacy and security.

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At week 9 of the study, participants in the intervention groups you will receive a certificate of completion for FitEx, and there will be another meeting to celebrate team achievements. Endometrial cancer survivors and support team members will be given repeat questionnaires to determine if anything changed over the course of the study. Participants in the intervention group will also be interviewed about their experiences with FitEx.

Six months afterwards, all participants will be asked to track their activity with a Fitbit for 7 days. Participants in the intervention group will also be asked to track their other physical activity and report their fruits and vegetables intake as they did in the beginning of the study. This information will be used to see if the study interventions helped improve their physical activity habits, even after the study was over.

The study ends for most participants after this point. The FitBit is yours to keep and you may choose to continue wearing it.

For participants, the potential benefits of this research are related to evaluating a physical activity program that could be beneficial for endometrial cancer survivors. 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 physical activity. There are also potential societal benefits of being in a group based physical activity intervention. Benefits of social support may also arise as friends or loved ones take on the journey with endometrial cancer survivors to improve 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).

WHAT ARE THE RISKS OF BEING IN THIS RESEARCH STUDY?

For participants in one of the intervention groups, 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.

For all participants, some of the questionnaire items 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. Please also note that there may be certain risks inherent in Zoom for privacy and security.

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For all participants, 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 the FitEx 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.

For all participants, 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.

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.

Please 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.

WHAT ARE THE BENEFITS OF BEING IN THIS RESEARCH STUDY?

Although you may not personally benefit from taking part in this study, the knowledge gained may benefit others. You may or may not benefit directly from this study since the benefits of this research are related to physical activity, and participants may feel numerous benefits related to continued physical activity 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.

ARE THERE ANY OPTIONS TO BEING IN THIS RESEARCH STUDY?

Options include not participating or participating.

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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.

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 physical activity 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 ABOUT CONFIDENTIALITY?

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research. One exception is if you agree that we can give out research information with your name on it. Other exceptions are information about child abuse or neglect and harm to yourself or others.

Your name will not be used in any publication or presentation about this research. Your data will be securely stored within the FitEx server, Carilion Clinic's server, and within a program called REDCap. The research records, including questionnaires and audio recordings from the Zoom sessions, will be kept on the REDCap database or on a Carilion

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password-protected secure server. All research data will be coded with a unique number. Your name and medical record number will be linked to the code number on a master list of those who take part in the study. This master list will be kept separate from the research database and will be securely stored in the REDCap database. This master list will only be used by the researchers or organizations that govern research quality and safety oversight. Your identity will not be used in any sort of published report.

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

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 personal level of physical activity and fruits and vegetables intake, self-compassion, flourishing, habit formation, social support, endometrial cancer, weight, barriers to physical activity adherence, and quality of life outcomes

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.
- 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 the following non-Carilion facilities: Virginia Tech and University of Virginia.
- The Office of Human Research Protections (OHRP), Food and Drug Administration (FDA), or other government agencies that oversee research with humans.
- The following sponsor or funding agency for the research: National Institute of Health

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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.

WILL I BE PAID FOR TAKING PART IN THIS RESEARCH?

After enrollment: At the beginning of the study, you will receive a wearable Fitbit Charge 5TMs pedometer for you to keep. If you already own a Fitbit that you wish to use, you will instead have the option to be given an $99 reimbursement for using your personal Fitbit for the study. You will be asked to wear your Fitbit over the course of the study.

Post-intervention: Upon completion of the post program exit interview, participants in the in the intervention groups will receive $10.

At the 6-months follow up: Upon completion of both filling out the 6-month post-program survey and wearing their Fitbit for one week, all participants in any of the three groups will be compensated $20.

In order to receive compensation for your participation, you will be asked to complete an Internal Revenue Service (IRS) W-9 form. Your social security number will be required to complete the IRS form. Compensation to study subjects greater than $600 in a calendar

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year is considered taxable compensation and is reportable to the Internal Revenue Service (IRS). Carilion will be required to provide your name, social security number, address, and amount of payment to the IRS. You will be issued a 1099 tax form by Carilion if you meet this reporting threshold. This information and your payment amount will be kept secure and confidential in our research financial records and Carilion's financial office. This information will not be associated with the study name or the research data you provide as a participant.

NOTE: If you would like to participate in the study without filling out a W-9 form, you will be given the option to participate in the study without receiving a Fitbit or other compensation. You still be able track self-reported physical activity without a Fitbit by entering data into the FitEx-ECS portal.

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 are assigned to one of the intervention groups and 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.

ARE RESEARCHERS BEING PAID TO DO THIS STUDY?

This study does not have any sponsors. However, it is funded by an integrated Translational Health Research Institute of Virginia (iTHRIV) grant through the National Institute of Health.

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.

WHO ARE THE CONTACT PERSONS?

If you encounter complications or have any questions about the study, you may call: Dr. Armbruster at 540-581-0160

This research is being overseen by an 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:

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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.

ZOOM

This research study is using Zoom as the virtual web conferencing platform for weekly meetings. I understand that the meetings conducted during this study will be recorded by the researcher using the audio and video recording capabilities available in the Zoom videoconferencing platform. These recordings are necessary so researchers can analyze the information provided during the meetings. It is important to know that Zoom should not be considered fully secure. There are risks of Zoom saving copies of the recording and sharing copies of the recordings with unknown third parties, or unknown third parties accessing recordings without Zoom's approval. Carilion Clinic and its researchers have no control over how Zoom or other unknown third parties use, access, and or disclose the information from these meetings. Therefore, privacy and confidentiality is not guaranteed due to the nature of the virtual web conferencing platform used in this research study.
_____ Yes, I understand.

IRB SURVEY:

The IRB committee is a group of people that reviews research to protect the rights of research subjects. One job of the IRB is to make sure the research is done in a way that is respectful to subjects. If you agree, the Carilion IRB may select you to receive a survey asking about your experiences while taking part in this research study. If your name and address are given to the Carilion IRB in order to mail the survey, the Carilion IRB will keep this information confidential. You do not have to put your name or other identifying information on the survey unless you choose to do so or request to be contacted regarding your experiences. You do not have to give permission to allow the Carilion IRB to send you this survey. Please check below whether you agree to allow the Carilion IRB to send you a survey:

_____ Yes, I agree to Carilion IRB sending me a survey about my experiences while taking part in research.
_____ No, I do not want Carilion IRB to send me such a survey.

CONSENT SIGNATURES:

RESEARCH SUBJECT: The research study described in this consent form, including the risks and benefits, has been explained to me and all of my questions have been answered. I consent to take part in this research study. My consent is given willingly and

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voluntarily. I may withdraw my consent at any time. I will receive a signed copy of this consent form.

_____
Printed Name of Research Subject (18 years or older)

_____ _____
Subject's Signature Date

PERSON OBTAINING CONSENT: I certify I was present for the informed consent discussion. The subject or legally authorized representative had an opportunity to ask questions about and appeared to understand the information presented. The subject or legally authorized representative agreed to take part voluntarily in the research and I obtained his/her signature.

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

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