Main Informed Consent Form

# Official Study Title: ACTIVATE: A pilot randomized Activity Coaching Trial to Increase Vitality and Energy during post-operative pelvic radiation therapy for endometrial cancer Main Informed Consent Document

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# Consent Form to Volunteer in a Human Research Study

## *STUDY INFORMATION*

**TITLE**: A pilot randomized **A**ctivity **C**oaching **T**rial to **I**ncrease **V**it**a**l**i**ty and **E**nergy during post-operative pelvic radiation therapy for endometrial cancer

**PROTOCOL NO.:** INOVA-2024-91
WCG IRB Protocol #20243810
INOVA-2024-91

**SPONSOR:** Inova Schar Cancer Institute

**INVESTIGATOR**: Avani Rao, MD
8081 Innovation Park Drive
Fairfax, Virginia 22031
United States

**SERVICE LINE/ DEPARTMENT**: Inova Schar Cancer Institute/Department of Advanced Radiation Oncology and Proton Therapy

**STUDY-RELATED PHONE NUMBER(S):** 571-472-4724 (24 hours)

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

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A person who takes part in a research study is called a research or study participant. In this consent form "you" always refers to the research participant.

You are encouraged to ask any questions you may have and obtain answers before you decide.

## *Key Information about This Research Study*

The following is a short summary of this study. It will help you decide whether to take part. More detailed information is given later in this form.

You are being asked to take part in a research study. Doing so is voluntary. The purpose of this study is to see if incorporating an activity coaching program is helpful in improving treatment-related fatigue for women undergoing pelvic radiation therapy (RT) for endometrial cancer.

As part of the activity coaching program, you will have ten weekly check-ins with a certified exercise coach. During check-ins, you and the exercise coach will set weekly goals. You will try to incorporate activities that are easy and enjoyable for you. You will receive a follow-up email with the plan you discussed with the coach. The email will also have links to exercise videos you can stream if you are interested. You may also choose to use the MedBridge app to view your exercise program and videos. You can schedule these weekly visits with the exercise coach at your convenience.

If you join this research study, you will be placed in the **Immediate Start Activity Coaching Program** or the **Delayed Start Activity Coaching Program**.

If you are in the:

- **Immediate Start Group:** Your sessions with the exercise coach will start during the first week of radiation therapy and continue until you have completed radiation.
- **Delayed Start Group:** Your sessions with the exercise coach will start 6-8 weeks after you have completed radiation and continue 16-19 weeks post-radiation.

All Participants who agree to join this study will be asked to:

- **Participate in a program** with an exercise coach to set weekly goals for activity. The timing of when you start the program will be based on which group you are assigned to.

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- **Receive a Fitbit** to track how active you are, your heart rate and how many steps you have taken. The goal is to wear it daily until your last follow-up on study at 16-19 weeks post-radiation. Someone from the research team will call you to see if you have any questions or problems with your Fitbit, or if you need help fixing anything. The Fitbit will be given to you for free, and you will be able to keep the device after the study has ended.
    - Please make sure to keep the Fitbit on your wrist for at least 8 hours of your day while you are awake.
- **Complete 4 surveys** that ask about your quality of life, symptoms, and side effects of therapy. They should each take about 20 minutes to complete. You will receive a $25 gift card for each survey you complete.
- **Complete a short 6-minute walking test** to see how your heart and lungs respond to light exercise. This test will be done during clinical visits. You will complete this test 4 times throughout the study.
- **Participate in an interview** with the study investigator at the end of the study to hear your feedback on how we can improve the next study.

If you decide to join this study, then you will spend about 6 months in this study**.** Taking part in the study involves little to no risks. Some of the risks that you may experience include Physical Activity Risks (such as having higher fatigue) and Data Security Risks. These risks are described in detail later in this document.

No direct benefit can be promised to you for being in this study. Instead of being in this research study, you may choose to decline to take part.

## *Detailed Information*

Research has shown that for women who are undergoing pelvic radiation therapy, fatigue is a common side effect. Fatigue that occurs during radiation therapy can make it harder to perform daily living activities.

While there are studies that recommend exercise as a treatment for fatigue in cancer patients and survivors, there are currently no studies that focus on the role of exercise for women undergoing pelvic radiation therapy.

The purpose of this study is to is to see if incorporating an activity coaching program is helpful in improving treatment-related fatigue for women undergoing pelvic radiation therapy for endometrial cancer. This is a pilot study designed to guide the design of a larger follow-up study.

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We expect 16 patients to be included in this study. 8 patients will be assigned to the Immediate Start Group, and 8 will be assigned to the Delayed Start Group.

## *What happens if I say yes, I want to be in this research?*

This study is divided into 5 Phases:

1. Screening
2. Enrollment
3. RT Simulation
4. Radiation
5. Post-Radiation

Information about each phase is described in detail below.

***Phase 1: Screening:*** You will meet with a research coordinator to see if you can participate in this study. During this visit, the research coordinator will:

- Discuss the study with you and answer any questions you have.
- Once you have agreed to join the study, you will sign this form. A copy of this form will be given to you.

You will then be asked to:

- Give your health history. The study staff will review your medical history to see if you can be part of this study.
- Ask you about the medications you are taking.

***Phase 2: Enrollment:***

Will occur before you start radiation (7 days before or after simulation). During this visit, the following procedures will occur:

- Your weight and height will be collected.
- You will be provided with a Fitbit device. The research coordinator will teach you how to use it.
- You will perform the 6-minute walk test.
- You will complete the **first** of the 4 surveys.

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- You will be assigned to the Immediate Start Exercise Coaching Program or the Delayed Start Coaching Program. This random assignment will be based on a 50/50 chance, like the flip of a coin. If you are in the:
    - **Immediate Start Group:** your sessions with the exercise coach will start during the first week of radiation therapy and continue until you have completed radiation. You will be set up with ten weekly visits with an exercise coach. The first visit will occur during the planning of the radiation therapy. The first visit will last 60 minutes. The remaining nine visits are 30 minutes each. You and the coach will discuss your activity level during these check-in visits. You will also explore ways to enhance your activity in the week ahead. This could be in-home exercise ideas, walks, or other online or in-person options.
    - **Delayed Start Group:** your sessions with the exercise coach will start 6-8 weeks after you have completed radiation and continue 16-19 weeks post RT. You will be set up with ten weekly visits with an exercise coach. The first visit will occur 6-8 weeks after radiation therapy. The first visit will last 60 minutes. The remaining nine visits are 30 minutes each. You and the coach will discuss your activity level during these check-in visits. You will also explore ways to enhance your activity in the week ahead. This could be in-home exercise ideas, walks, or other online or in-person options.

***Phase 3: RT Simulation:***

During this visit, the following procedures will occur:

- Fitbit data will be collected.

***Phase 4: Radiation: Week 1-4 of pelvic RT (Fraction 1-20)***

During this visit, the following procedures will occur:

- Fitbit data will be collected.

***Phase 4: Radiation: Week 5 of pelvic RT (Fraction 21-25)***

During this visit, the following procedures will occur:

- Fitbit data will be collected.
- You will perform the 6-minute walk test
- You will complete the **second** of 4 surveys.

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***Phase 5: Post-Radiation: Week 5-7 Post-pelvic RT***

During this visit, the following procedures will occur:

- Fitbit data will be collected.
- You will perform the 6-minute walk test
- You will complete the **third** of 4 surveys.

***Phase 5: Post-Radiation:* Week 16-19 Post-pelvic RT**

During this visit, the following procedures will occur:

- Fitbit data will be collected.
- You will perform the 6-minute walk test
- You will complete the **last** of 4 surveys.
- You will be scheduled to have a recorded exit Interview with the Principal Investigator if you choose to participate.

## *Do I have to be in this research?*

No. Your participation in this study is voluntary. You do not have to be in this study if you do not want to, and you can leave the study at any time. You will not lose any services, benefits, or rights you would normally have if you chose not to be in the study or if you leave the study early. You can work with an exercise coach without being in this study.

## *Is there any way being in this study could be bad for me? (Detailed Risks)*

All research studies have some degree of risk or discomfort. If this happens, we are here to support you. Some of the discomforts that you may experience include Physical Activity Risks, and Data Security Risks, which are explained below:

**Physical activity risks**

- There may be a risk of higher fatigue with more activity.
- There may be a risk of muscle aches and pains due to physical activity.

**Risks of Six-Minute Walking Test (6MWT)**

Risks of a 6MWT include shortness of breath (dyspnea), chest pain, dizziness, or fatigue. Please let a member of the research team know if you experience any of these symptoms.

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**Data security risks**

- Your activity will be measured using the Fitbit. An automatic data collection service will be used to store your Fitbit data. The research coordinators will enroll your Fitbit into this system using an anonymous account.
- At the end of the study, the account will be deleted. The Fitbit will no longer be used by the study for data collection. You can keep the device if you wish. You will be able to register the device to your personal account.

## *What are the benefits to being in this study?*

You may not directly benefit from this research; however, we hope that your participation in the study may improve the side effects of radiation treatment, such as fatigue. Information from the study may help others by contributing to the overall knowledge of exercise therapy programs for patients undergoing radiation treatments.

## *What happens to the information collected for the research?*

We will do our best to limit the use or disclosure of your personal information, including information from this research study and from your medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Some organizations may be required to inspect and copy your information including the IRB and other Inova Health System representatives responsible for the management or oversight of this study.

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you.

We will remove identifiable information from the data we collect about you. After we remove all the identifiers, we will place a code on the information. The code will be linked to your identity, but the link will be kept in a location that is separate from your study data. We will maintain your study data on encrypted computers and access to the information will be limited to only members of the research team who need access to properly conduct the study. The information we send to collaborators will not include information that directly identifies you. Instead, a code will be applied to the data and link between the code and your identity will be kept at the research site.

The following is a list of individuals who may access your records:

- Members of the research team

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- Offices and committees responsible for the oversight of research
- Regulatory Authorities from other countries
- Third party vendors such as Fitbit and the data collection server that will be used to store your Fitbit data.

The principal investigator and research team may publish the results of this research. However, they will keep your name and other identifying information confidential.

If you are, or have been, a patient at an Inova Health System facility, you will have an Inova Health System medical record. We use an electronic medical record system known as Epic, which improves access to information important to your medical care. Epic will show that you are in a research study and a copy of this signed consent form will be included. To provide as complete a record as possible, some or all your study-related research information may also be placed in Epic. Including this information in Epic is intended only to give information to caregivers providing treatment for you while you are on this study.

This information will be available to Inova Health System doctors, nurses and other authorized staff who may not be part of the research team but who are involved in providing you with medical care, or who are otherwise allowed to access your information. The confidentiality of the results and other documents in Epic will be governed by laws, such as HIPAA, that concern medical records. We suggest that you tell any non-Inova Health System doctors that you are in a research study and that more information may be made available to them at your request. The research team may use your information to notify you of appointments, send you appointment reminders, or schedule additional appointments.

Federal law provides additional protections of your medical records and related health information. These protections are described in the Inova Health System HIPAA Research Authorization, which you will be provided with and asked to sign separately.

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.

## *Will the information collected be used in future research?*

Information collected about you will be used for this research and may also be used for other research studies here at the Inova Health System. There may also be collaborative research efforts with other entities, such as

universities, the government, and private companies where we may share your information. Before using the information for other research, the study team will remove information that identifies you so the individuals performing the research will not know who the information came from. We will not ask for additional consent from you to use your information for the additional research.

## *Payment*

We will pay you $25 in the form of a gift card when you complete each of the 4 surveys and $25 if you choose to participate in the Exit Interview totaling up to $125 at the following phases:

- Surveys completed at:
  - Enrollment visit
  - Week 5 of pelvic RT (Fraction 21-25)
  - 5-7 Week Post RT Follow-Up Visit
  - 16-19 Weeks Post RT Follow-Up Visit
- Exit interview with the lead study investigator to learn about your experience and how we can improve the next study.

Federal tax law requires that payments you receive for research participation be reported as income to the Internal Revenue Service (IRS).

In order to receive $600 or more during a calendar year from Inova for participating in research, you will need to provide either your social security number or Individual Taxpayer Identification number (ITIN) and complete IRS Form W-9. Inova will then report these payments to the IRS, and you will receive a Form 1099-MISC for tax reporting purposes. The researchers will not use this information for other purposes without your permission.

If you are unable to provide a Form W-9 with a valid social security number or ITIN, you will not receive payments from Inova for research participation exceeding $600 in a calendar year.

## *What happens if I want to leave the study?*

If you decide to leave the research, contact the study team so the investigator can work with you to create a safe plan for your withdrawal.

If you stop being in the research, data that has already been collected will not be removed from the study database. Even if you stop being in the research study, you will be asked whether the principal investigator can collect data from your routine medical care. If you agree that the principal investigator can collect data

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from routine medical care after you stop being in the research study, this data will be handled the same as research data.

## *Can I be removed from the research without my OK?*

The researchers may take you out of the study, even if you want to continue, if:

- Your health changes and staying on the study is no longer in your best interest;
- You do not follow the study rules, or you no longer meet the requirements to be in the study; or
- The study is stopped by the researchers.

## *Contact Information*

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Study Doctor.

**Principal Investigator** |Avani Rao, MD **Phone Number** | 571-472-4724 (24 hours)

Inova's Office to help protect you in this Research Study is called Human Research Protections Office (HRPO). You are welcome to call HRPO if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

**Human Research Protections Office (HRPO)** | 1-888-534-6682

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. The IRB of Record for this study is WCG IRB. You may talk to them at (800) 562-4789, Researchquestions@wcgirb.com 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.

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## *PARTICIPANT'S STATEMENT/SIGNATURE*

- *I have read this form, and the research study has been explained to me.*
- *I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.*
- *I agree to be in the research study described above.*
- *I will receive a copy of this consent form after I sign it.*

| _____ | _____ | _____ |
|---|---|---|
| Signature of Participant | Printed Name | Date |

| _____ | _____ | _____ |
|---|---|---|
| Signature of Person Conducting Informed Consent Discussion | Printed Name | Date |

This witness line below may be left blank unless:

- The participant is a non-English speaker and the short form consent process will be used; or,
- This study is FDA-regulated and the participant is illiterate, in which case the witness must be impartial (i.e. unaffiliated with the study); or,
- The IRB has otherwise required the participation of a witness during the informed consent process.

| _____ | _____ | _____ |
|---|---|---|
| Signature of Witness | Printed Name | Date |

**Interpreter Information** (To be completed by Inova staff, if applicable)**:**
☐ In person ☐ Telephonic ☐ Video Interpreter name/ID number (if applicable)_____
☐ Patient/Designated Decision Maker was offered and refused interpreter ☐ Waiver signed