

Official Title	Multicenter Pilot Study: Leveraging Digital Health to Promote Evidence-Based Physical Activity to Improve Symptoms Among Patients Undergoing Radiation for Breast Cancer (PRO-ACTIVE)
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University of Washington / Fred Hutchinson Cancer Center

Consent to take part in a research study:

PRO-ACTIVE Pilot Study

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Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to examine the acceptability and feasibility of electronic symptom surveys and wearing Fitbit for activity monitoring among people getting radiation for breast cancer. Some participants may also be eligible for a virtual mind-body movement-based program.

People who agree to join the study will be asked to fill out a symptom survey every 2 weeks for 12 weeks. They will also wear a Fitbit activity tracker on their wrist every day for 12 weeks. Some participants will gain access to the IM@Home program in which they are encouraged to participate in virtual mind-body movement-based classes for up to 12 weeks.

You must have a smartphone, a laptop, or a tablet like an iPad to participate.

You do not have to join this study. Although the study will not benefit participants directly, we hope the information we learn will help us deliver movement-based programs to cancer patients in the future.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

We would like you to join this research study.

We are doing this research to learn how to run a virtual mind body movement-based study in community cancer clinics like yours. We will use our findings to design a larger study to test if symptom questionnaires and programs like IM@Home can help patients undergoing radiation better manage symptoms and side effects of cancer treatment.

Since you are about to start, or are currently receiving, radiation treatment for breast cancer, we would like you to join this study. We will enroll up to 30 people.

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits if you say no. Whatever you decide, your regular medical care will not change.

If you agree to be in this study, you will be asked to:

- **Agree to have your contact information (name, address, phone number, and email) shared** with the study staff at the University of Washington and Fred Hutch Cancer Center so they may contact you about study activities, and, **to register for the IM@Home program if you are determined to be eligible for the study.**
- **Complete a baseline survey.**
 - You will get the first survey when you join the study. It should take about 15 minutes. This survey will ask you about you, your health, and your current symptoms.
- **Complete 6 additional symptom surveys, one every 2 weeks.**
- You will fill out a web-based survey about your symptoms once every 2 weeks. It takes about 5 minutes to complete. You can fill out the survey on a computer or on a mobile device like a smartphone or tablet with internet access.
- Depending on your responses to the survey, you may be eligible to participate in a virtual mind-body movement-based program (IM@Home). If you are eligible, **you will be contacted by someone from the UW/Fred Hutch study team to register.** Briefly, this is a zoom-based program of scheduled live (as well as pre-recorded) classes including cardio fitness, yoga, tai chi, dance therapy, and meditation. Classes are 30-60 minutes in duration, and you will be encouraged to participate in at least 2 classes per week.
- **Wear the Fitbit.** We will ask you to wear a Fitbit device daily for 12 weeks. The Fitbit is worn like a watch. It will automatically track measurements, such as activity and heart rate. We will ask you to wear the Fitbit during the day and charge it 1-2 times a week. At the end of the study, you may choose to keep the Fitbit or return it to your doctor's office.
- You will need to download the Fitbit app mobile application or "app" onto a smartphone or tablet. After the study, you may delete the app from your device. You will be asked to log in to your device using the Fitbit account provided to you for the study or your personal Gmail account.
- When you begin wearing the Fitbit, you will be asked to agree to share the data it collects with the study team for this research study. You will give your consent to share this data by completing an online consent form. You do not have to agree to share your Fitbit data, but you will not be able to participate in the study.

- **Complete a survey at the end of the study.** At the end of the study, we will send you a survey that asks about your experience being in the study.
- **Review of your medical chart.** We will also collect information about your cancer treatment plan from your medical chart. Under federal and state law, you must sign a separate HIPAA Authorization Form to give your permission for the research team to collect this information. If you do not sign the HIPAA Authorization Form, you will not be able to participate in the study.

If you agree to join this study, your participation will last for 12 weeks.

We may collect information from your medical records for up to one year after you enrolled in the study.

You can drop out of the study at any time. If you are thinking about dropping out, please tell us. If you leave the study, no further information from you will be collected, but information that was already provided cannot be removed from the study records.

What are the risks?

- Wearing the Fitbit may cause mild skin irritation and discomfort. The Fitbit should be worn according to the manufacturer instructions. If you experience skin irritation when wearing the Fitbit, remove it and consult your doctor.
- The questions we ask about your medical history and symptoms may make you feel uncomfortable. You may skip any questions you do not wish to answer.
- There is a slight risk of loss of confidentiality.

What are the benefits?

Wearing a Fitbit will allow you to track your own daily activity. Depending on your survey responses, you may also be eligible to get access to our virtual intervention that can help manage symptoms you experience during radiation treatment.

Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information

If you join this study, some people and organizations might need to look at your medical or research records for quality assurance or data analysis. They include:

- Researchers involved with this study.
- Institutional Review Boards (IRB), including the University of Washington and Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.

- Fred Hutchinson Cancer Center and University of Washington.

We will do our best to keep personal information collected for this study confidential. Your personal information may be disclosed if required by law, such as a court order. Such cases are very rare.

We will not use your personal information in any published reports about this study.

Will you pay me to be in this study?

If you participate for the full 12 weeks you will receive up to \$100. To thank you for completing the study procedures (including survey completion and wearing the Fitbit monitor), you will receive gift cards at study entry (\$50 including time for Fitbit setup), mid-study (\$25), and study completion (\$25).

How much will this study cost me?

You may pay data charges by your internet or phone provider if you choose to receive study text messages. There may be charges from your internet or phone provider to use the Fitbit application when not connected to WiFi. If you are concerned about these costs, please bring them up with the study team.

What if you get sick or hurt after you join this study?

If you have been injured or otherwise harmed by participating in this study, contact a member of the research team at 206-897-2121.

This study is being done for research purposes only. Your doctor will not see any information about your symptoms collected in the surveys or Fitbit.

If you have concerns about your health or your symptoms you should contact your doctor. If you have a medical emergency, call 9-1-1.

You will not lose any legal right to seek payment for treatment if you sign this form.

Your rights

- You do not have to join this study. You are free to say “yes” or “no”.
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- If you join this study, you would not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.

For more information

If you have questions or concerns about this study, you may talk to a member of the study team anytime. Other people you can talk to are listed below.

If you have any concerns about your health during this study, you should contact your doctor. If you have a medical emergency, call 9-1-1.

If you have questions about:	Call:
This study (including complaints and requests for information)	206-897-2121 (Study Office, staffed on business days from 9am-5pm)
Your rights as a research participant	206-543-0098 (Human Subjects Division, University of Washington)

What will my information be used for?

This study is being done for research only. Your information will be used to learn more about symptoms people experience while going through radiation treatment for breast cancer.

Will my information ever be used for future research?

The information that we obtain from you from this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, the information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

Signatures

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent;
and
- agree to participate in this study.

Participant:

Printed Name

Signature

Date

Researcher's statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature:

Printed Name

Signature

Date

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