

<b>Official Title</b>	Mindfulness Intervention for Nutrition in the Digital Kitchen (MIND) Study: A pilot and feasibility study
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Fred Hutchinson Cancer Center

**Consent to take part in a research study:  
Mindfulness Intervention for Nutrition in the Digital Kitchen (MIND) Study: A pilot  
and feasibility 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 learn about the effects of a self-paced online educational nutrition and cooking course for breast cancer survivors. People who join the study will be asked to either participate in a 6-week self-paced online nutrition and cooking course through an online learning system or to continue with their normal diet and cooking patterns for 6 weeks. After the 6-week period, people who continued with their normal diet will be offered access to the 6-week course. Both groups will be asked to complete surveys at the beginning of the study, at week 6, and at week 12.

During the 6-week self-paced online course, participants will engage with chef demonstration videos, nutrition education videos and articles, learn cooking techniques to prepare 3-4 recipes per week at home, understand how mindfulness can play a role in overall health, and participate in weekly online live question and answer sessions with a registered dietitian and/or chef.

You do not have to join this study. Although we hope you will learn new information about nutrition and cooking skills, the study might not benefit you directly. We hope the information we learn from your participation will help us provide cancer survivors with the right tools to support a healthy diet and mental health.

Below is a more complete description of this study. We provide details about the purposes, procedures, risks, and possible benefits related to this study. We also provide you with other information that you need to make an informed decision about joining 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 an electronic copy of the form you signed to keep for future reference.

**We would like you to join this research study.**

This research study will help us learn how to increase fruit and vegetable intake, change at-home cooking habits, and improve mental health stressors, such as anxiety, in breast cancer survivors. Since you are a breast cancer survivor, we would like to ask you to join this study. We plan to enroll up to 100 breast cancer survivors in this study.

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.

### **What research tests and procedures are part of this study? / What will happen in this study?**

If you agree to be in this study, the following procedures will be done:

- **Screening & Consent:** Study staff will ask you some questions over the phone to determine if you are eligible for the study. If you are eligible, we will send you two forms to sign - an electronic consent form and a form that allows the study team to access and collect your data (the second form is called a HIPAA form – HIPAA stands for Health Insurance Portability and Accountability Act). You will sign the forms electronically on your smartphone, computer, or tablet.
- **Baseline Surveys:** Once the consent and HIPAA form are signed, we will send you surveys to complete online. The surveys will ask questions about what you eat, your cooking habits, and your quality of life. We will also ask you about your height and weight. You have the option to complete the surveys online on your own, or with study staff over the phone.

After completing the baseline surveys, you will be randomized (sorted) to one of the two groups:

- **Self-paced Online Nutrition and Cooking Program**  
If you are randomized to the online nutrition and cooking program group, you will spend about 4 hours a week for 6 weeks completing a self-paced online course with a weekly online live question and answer session. During the course, you will view videos, read articles, and be asked to cook 3 to 4 recipes per week at home. You will also have the option of participating in weekly online live question and answer sessions with a dietitian and chef. At week 6, we will ask you to complete online surveys similar to the baseline surveys. Once the week 6 surveys are completed, you will continue with your normal routine. If after week 6 you have not completed all of the self-paced online educational nutrition and cooking program activities, you will be able to continue to complete those at your own pace. At week 12, we will ask you to complete a final set of surveys similar to the baseline and week 6 surveys.
- **Waitlist Control Group**  
If you are randomized to the waitlist control group, you will be asked to continue your normal diet and cooking routine. After the 6 weeks, you will complete surveys like the baseline surveys and be offered to join the optional 6-week self-paced online nutrition and cooking program. If you decide to join the program, you will spend about 4 hours a week for 6 weeks completing a self-paced online course with a weekly online live question and answer session. During the course, you will view videos, read articles, and be asked to cook 3 to 4 recipes per week

at home. At week 12, we will ask you to complete a final set of surveys similar to the baseline and week 6 surveys. If after week 12 you have not completed all of the self-paced online educational nutrition and cooking program activities, you will be able to continue to complete those at your own pace.

### **How long will I be in this study?**

We think you will be in this study for about 12 weeks. You may be in the study longer if it takes you longer than 6 weeks to complete the self-paced nutrition and cooking skills program.

The study principal investigator may take you out of this study at any time. This would happen if:

- They think it is your best interest to drop out.
- You are unable or unwilling to follow study procedures.
- The whole study is stopped.

If you leave this study, your test results and information cannot be removed from the study records.

### **Risks of being in this study**

There are some potential risks with participating in this study. The potential risks are listed below. There may be some unknown risks linked with being in this study that are not listed.

- Discomfort: They may be some discomfort in answering personal questions about your health. You can decline to complete a survey or skip questions at your own discretion.
- Gas and bloating: Recommended dietary changes may include gas and bloating due to increased fiber consumption.
- Inconvenience: The timing and frequency of the program and remote data collection may be an inconvenience to participants' schedules.
- Distress: Being asked questions about anxiety and depression, and suggested stress management strategies may increase awareness of symptoms and increase distress.
- Loss of privacy: a risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having personal information shared with someone who is not on the study team and was not supposed to see or know about a participant's information.

### **What are the benefits?**

We do not know if this study will benefit all study participants. We hope the information we learn will be used to develop future nutrition and culinary programs for other cancer survivors.

Quality of life: Through improving diet quality and learning mindfulness techniques, participants may experience improvements in quality of life, including improvements in sleep and cognitive function and a decrease in anxiety, depression, and pain.

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

Some organizations may need to look at your research records for quality assurance or data analysis. These include:

- Researchers involved with this study.
- The study sponsor and their agents.
- Fred Hutchinson Cancer Center and University of Washington.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, and other agencies as required.

We will keep your personal information confidential. But we cannot guarantee total confidentiality. Your personal information may be disclosed if required by law. For example, we are required to report certain diseases and infections to public health authorities. We are also required to report suspected abuse or neglect of children and vulnerable adults. Workplace safety rules may require health workers to contact you about lab tests. Or a court may order that study information be disclosed. Such cases are rare.

We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

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.

If you join this study, information about your participation would be made part of your permanent medical record. This information would include a copy of this consent form. If an insurance company or employer or anyone else were authorized to see your medical record, they would see a copy of this consent form.

## **Will you pay me to be in this study?**

You will be compensated with a \$25 electronic gift card after completing all measures for a given timepoint (baseline, week 6, and week 12 data collection) for a total of up to \$75.

**How much will this study cost me?**

There may be some extra costs for being in this study. This study is being delivered electronically, which will require a device with access to the internet. Additionally, groceries, some kitchen tools, and foods will be suggested to prepare the recommended recipes in the program. You will not be compensated for the device, internet service, or food ingredients required for participating in this study.

**Your rights**

- You do not have to join this study. You are free to say yes or no. Your regular medical care will not change.
- If you join this study, you do not have to stay in it. You may stop at any time (even before you start). There is no penalty for stopping. Your regular medical care will not change.
- 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.
- During the study, we may learn new information you need to know. For example, some information may affect your health or well-being. Other information may make you change your mind about being in this study. If we learn this kind of information, we will tell you.

**For more information**

If you have questions or concerns about this study, you can talk to your doctor anytime. Other people you can talk to are listed below.

<b>If you have questions about:</b>	<b>Call:</b>
This study (including complaints and requests for information)	(206) 667-4502 Dr. Heather Greenlee, Principal Investigator (206) 667-5625 Jenny Whitten, Project Manager
If you get sick or hurt in this study	(206) 667-4502 Dr. Heather Greenlee, Principal Investigator
Your rights as a research participant	(206) 667-5900 or email <a href="mailto:irodirector@fredhutch.org">irodirector@fredhutch.org</a> - Director of Institutional Review Office, Fred Hutchinson Cancer Center

**What will my information be used for?**

Your information will be used for the purposes of this study. Your information, including medical records relating to your cancer diagnosis and treatment, and surveys you participate in for this study, will be used to better understand the effects of a self-paced online educational nutrition and cooking course for breast cancer survivors.

**Will my information be kept for future research?**

In addition, be aware that by agreeing to participate in this study, your information could be used for future research studies or sent to other investigators for future research studies without additional consent from you. These future research studies will be reviewed by an oversight group known as an institutional review board (IRB) if required by law. The information that identifies you will first be removed from your information.

Your information will be stored in a secure location. It will be used for research only. This research may be done by for-profit companies. Researchers will not report their results to you or your doctor. The research results will not appear in your health record. This will not affect your care.

Research on your information may help develop new products. If these products make money, there is no plan to share the money with you.

After the study we might want to contact you for future research. You are free to say yes or no.

Please read the question below and think about your choice. When you decide, please select Yes or No.

Do we have your permission to contact you for future studies? (select one)

**YES**

**NO**

Initials: \_\_\_\_\_

Date: \_\_\_\_\_

## 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 (age 18+):

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Printed Name

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Signature

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Date

MIND Study: FH IRB #20593

Current consent version: Version 2, 11/13/2024

Previous consent version: Version 1, 6/20/2024