Full Plate Living Nutrition Program
NCT07271940

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# University of Wisconsin-Madison
# Consent to Participate in Research and Authorization to Use Protected Health Information for Research

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**Study Title for Participants:** Full Plate Living Nutrition Program

**Formal Study Title:** Full Plate Living Nutrition Program

**Lead Researcher:** Kathryn Miller, MD

**Institution:** University of Wisconsin-Madison

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## Key Information

The information in this section is to help you decide whether or not to be a part of this study. You can find more detailed information later on in this form.

### Why are researchers doing this study?

Dr. Kathryn Miller is doing research on an 8-session nutrition education program focused on fiber intake. The purpose of the research is to evaluate the acceptability and feasibility of implementing this program in a general internal medicine clinic. This program emphasizes a fiber-rich, whole foods diet consisting of fruits, vegetables, legumes, whole grains, nuts and seeds. Such interventions can improve diabetes management and lead to weight loss.

You are being invited to participate in this research study because you are a UW Health patient between the ages of 22 and 65 who has diabetes, prediabetes, or a body mass index (BMI) between 30 and 42, and you may be interested in learning more about nutrition.

Session facilitators include:

- Kathryn Miller, MD
- Brittany Galusha, MD
- Beth DeGarmo, PA
- Lauren Knoche, PA

### What will I need to do in this study?

The research team will ask you to attend 8 weekly nutrition education sessions. The nutrition education program sessions will take place with other participants within a shared medical visit. Shared medical visits are group appointments where 8-12 patients meet with two doctors or providers to receive care together. Shared medical visits are billed to insurance like a regular primary care office visit. They have the same co-

payments. The cost of the co-payment will not be covered by the study. Each session will last 60 minutes. In addition to the 8 sessions, there will be an informational session at the beginning to go over the program, ask questions, and complete some paperwork. You will not be charged a co-payment for this session.

As part of the study, we will take your weight at each visit. We will also ask you to complete a series of surveys at home. The surveys will ask you to record your daily food intake in an online food diary and will ask you questions about your quality of life. We will also ask you to come into the office 3 months after the last session to have your weight taken during a medical assistant appointment.

You can find detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

## What are some reasons I might – or might not – want to be in this study?

| **You may want to be in this study if you are:** | **You may NOT want to be in this study if you:** |
|---|---|
| • Comfortable participating in the nutrition education program with other patients.<br>• Willing to complete surveys throughout the course of the study, including surveys that ask about your physical health, well-being, and food consumption.<br>• Willing to have your weight taken.<br>• Willing to participate in the study for several months. | • You do not have time to attend 8 sessions over the course of 8 weeks.<br>• You do not have time to complete the study surveys.<br>• You are uncomfortable attending a nutrition education session with others.<br>• You are uncomfortable answering questions about your physical health or well-being or answering questions about what you ate.<br>• You are uncomfortable having your weight taken.<br>• You uncomfortable with your medical record being reviewed and extracted. |

## Do I have to be in the study?

No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights. You can ask all the questions you want before you decide.

# Detailed Information

The following is more detailed information about this study in addition to the information listed above.

## Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to the research team at allmaras@wisc.edu.

If you have concerns about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. UW Staff not part of the study team will work with you to address concerns and assist in resolving any complaints.

## If I take part in the study, what will I do?

If you take part in this study, you will attend 8 1-hour nutrition education sessions and one informational session before the start of the program. The sessions will occur once a week. The sessions will take place at a UW Health General Internal Medicine clinic. During the sessions you will learn about nutrition with up to 8-12 other patients.

In each session, you will learn about the benefits of fiber and how to add fiber to your diet. Sessions will be led by session facilitators who will deliver the content through PowerPoint slides. Sessions will also include opportunities for you to participate in group discussions about how to identify and eat foods that are rich in fiber. The sessions will last 60 minutes. As part of the sessions, you will set goals for making changes. Each visit builds incremental knowledge and change by strengthening motivation and skills. You will have access to the Full Plate Living website and will be provided with a patient guidebook.

The session providers will take your weight. Throughout the study we will ask you to complete several surveys. The surveys will ask you about your quality of life and your food intake. Each survey will take about 20 minutes to complete. You will receive an email invitation and email and text reminders to complete each survey. You will receive up to 5 reminders for each survey. Surveys will be sent out at the beginning and end of the study. We will also send out some surveys 3 months after the conclusion of the study. We will also ask you to come into the office 3 months after the last session to have your weight taken during a medical assistant appointment.

As part of the study we will interview 10 participants. The research team will use purposeful sampling to select potential interview participants. Sampling will be based on your attendance in the program and any changes you made as a result of the program. The interview will ask about your experiences in the program and will help us better understand what worked well, what could be improved, and how the program impacted your health and nutrition.

If you are asked to complete an interview, we will collect audio recordings of you during the interview procedures to aid with note taking. You are not required to participate in the interview if you are asked. It is possible you may not be asked to participate in an interview. Interviews will be conducted via Zoom and will last approximately one hour. A written copy of the recordings will be made for use in the research. The audio recordings will be destroyed once the audio files have been transcribed. We will record demographic information as part of the interview. Further information will be provided in a separate consent form if you are asked to participate.

**Protected health information (PHI) used in this study**
Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Information currently in your medical records as well as information added to your medical records during the course of this study. This information could include your medical history, your diagnosis, your medications, your weight, your insurance type, and your demographics. We will get this information from your health care providers.

## What happens if I say yes, but I change my mind later?

You can leave the research at any time. If you choose to leave the study, your choice will not affect your healthcare or any services you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights. If you no longer take part in the study, we will use your data already collected unless you specifically request to the study coordinator that it not be used.

Your authorization for researchers to use your protected health information (PHI) will last until the research study is done. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Kathryn Miller, MD, at 20 S Park St., Madison, WI 53715-1348.

## What are the study risks?

The risks of this study are minimal. There is a risk of a confidentiality breach. To minimize this risk, data will be stored securely according to campus policy.

Confidentiality cannot be guaranteed in a group setting. You are encouraged to not say identifiers out loud.

Taking part in this research study may lead to added costs to you. Shared medical visits are billed to insurance like a regular primary care office visit. They have the same co-payments. The cost of the co-payment will not be covered by the study. There will be a total of 8 sessions.

## Who has access to the information collected for the research?

We have strict rules to protect your personal information and protected health information (PHI). We will limit the use and disclosure of your personal information, including research study and medical records, as described in this consent form. A breach of confidentiality is unlikely.

We will share information with individuals or organizations identified in this consent form. Federal or state laws may also permit or require us to show information to university or government officials responsible for carrying out or monitoring this study. This includes University of Wisconsin and its representatives and affiliates, including those responsible for ensuring compliance, such as the Human Research Protection Program.

Authorizing the research team to use your PHI means that we can release it to the people or groups listed in this form for the purposes described in this form. Once we share your identifiable health information outside UW-Madison, the HIPAA Privacy Rule may no longer protect it. However, we try to make sure that everyone who sees your health information keeps it confidential.

## Will information from this study go in my medical record?

Your medical record might say that you participated in this study, and a copy of this consent and authorization form might go in your medical record. Some of the information we collect for this study will go in your medical record, including your weight and self-reported fiber intake. Both you and your UW Health providers will be able to see these results.

# What else do I need to know?

### Will I receive anything for participating?

If you agree to take part in this research study, we will pay you up to $250 for your time and effort. Compensation will be prorated for each survey or activity that is completed outside the session. If you are selected to participate in an interview, you will receive an additional $50.

**Compensation Schedule:**

| When | What | $ | |
|---|---|---|---|
| Baseline | Intro Visit (Weight + Sf-12) | $ | 30.00 |
| Baseline | ASA24 | $ | 20.00 |
| Baseline | ASA24 | $ | 20.00 |
| End | Assessment 2 (Sf-12 + ASA24) | $ | 30.00 |
| End | ASA24 | $ | 20.00 |
| End | Interviews | $ | 50.00 |
| 3-month post | Assessment 3 (Sf-12 + ASA24) | $ | 50.00 |
| 3-month post | ASA24 | $ | 30.00 |
| 3-month post | Weight | $ | 50.00 |

**Permission to communicate about the study by email**
We are requesting your email address and mobile phone numbers so we can email and text you invitations and reminders to complete study-related surveys. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email or text. Email and text should also not be used to convey information of an urgent nature.

**How many people will be in this study?**
We expect up to 48 people will be in this research study.

## Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study. If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

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|---|---|
| Signature of participant | Date |
| Printed name of participant | |
| Signature of person obtaining consent | Date |
| Printed name of person obtaining consent | |