

Ages 13-17 Child Assent Document for Research Study

Principal Investigator: Nadia M. Sneed PhD, APRN, FNP-BC

Version Date: 10-01-2025

Title of Study: Whole Foods for Teens: A Pilot Dietary Intervention to Reduce Body Adiposity in Adolescents with Obesity

Institution/Hospital: Vanderbilt University

This assent document applies to children ages 13-17

Name of participant _____ Age____

Below are the answers to some of the questions you may have. If you have any questions about what is written below or have any other questions about this research, please ask them. You will be given a copy of this consent form.

1. Why are you doing this research?

Vanderbilt University School of Nursing is doing a Whole Foods for Teens research study to learn if adolescents and their families want to learn to eat healthy meals together and if eating healthy foods can help support a healthy weight in adolescents. Also, we want to learn if eating whole foods can make families' diets better.

2. What will I do and how long will it take?

During the study, you and your parent or caregiver will learn about eating healthy meals together as a family. Once you are enrolled in the study, we will ask you to meet in person with your parent or caregiver 2 times for up to 2 1/2 hours each time at our facility on Vanderbilt University's campus. At each visit, we will measure you and your parent or caregiver's waist, height, and weight. We will also ask you and your parent or caregiver to complete surveys. We will ask you and your parent to report what you eat each week during the study using a food diary. The information will be recorded in a secure diet program to help us understand more about what you and your parent or caregiver normally eat.

We will also ask you to complete two body scans at the Vanderbilt Institute for Imaging Sciences on the Vanderbilt University Medical Center campus during the beginning and end of the study. This scan, called DXA (i.e., Dual-Energy X-ray Absorptiometry), uses low-dose X-ray technology to measure your body composition (e.g., bone mass and body tissue mass). During the scan, you will be asked to wear lightweight clothes without metals, or the radiology technician will give you a gown to wear. During the scan, a radiology technician will ask you to lie still on your back for 5-10 minutes on a flat table and he/she will operate the scanner which includes a small device like an arm that will move above you to scan your body. [Read for female adolescents only: We may ask to collect a urine sample to rule out the possibility of pregnancy before completing the scan. If there is the possibility of pregnancy, we will not be able to complete the scan and we will also be required to report this information to your parent or caregiver.] Each visit should take between 30 minutes to 1-hour to complete.

You and your parent or caregiver will be randomly selected to participate in one of two groups:

Whole Teens Counseling group: If you and your parent or caregiver are asked to be in the *Whole Teens Counseling* group, we will ask you and your parent or caregiver to meet with a Registered Dietitian Nutritionist up to 3 times to learn about how to eat a healthy diet that follows the current United States Department of Agriculture MyPlate Plan.

Whole Teens MyPlate group: If you are asked to be in the *Whole Teens MyPlate* group, we will create a personalized MyPlate plan for you and your parent/caregiver to use. We will ask you and your parent/caregiver to cook healthy meals for you and your family for 8 weeks and you and your parent or caregiver will be asked to speak with the study dietitian 4 times during the study. These meetings will be over the phone or on a virtual secure Zoom conference call. The Registered Dietitian Nutritionist will help you and your parent or caregiver determine what to eat each week and how to plan and prepare your meals. He/She may also provide cooking tips to help with the meal planning/preparation. Each session with the dietitian may take 1- 2 hours. During the study, we will send some groceries to your home or your parent or caregiver may be asked to pick them up. Groceries will be provided at no cost to you and your family and will include mostly fruits and vegetables to help you and your family meet your

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recommended MyPlate daily food group goals. You and your parent/caregiver will be asked to record your food group goals on your personalized MyPlate plans each day. You will receive a folder to help you keep track of your daily MyPlate goals. At the end of the study, we will invite you and your parent or caregiver to attend a 2 to 2.5-hour family focus group session. During the focus group session, we will gather information about your participation in the study and ask you and your family what you thought about the diet. All focus groups will be recorded with either an audio recorder or a secure teleconference platform so we can listen to them at a later date to gather information about what you and others thought about the study. Because the focus groups will take place in a setting with other participants, we will not be able to keep your identity confidential from the group. However, information collected during the focus group session will remain confidential and will only be accessible by the Principal Investigator and study team members.

Participants in both the *Whole Teens Counseling* group and the *Whole Teens MyPlate* group will be asked to provide detailed information about their diets. You and your parent or caregiver will be asked to fill out a food diary some days during the study to help us learn more about your family's eating habits. We will also collect height and weight from you and your parent or caregiver, and we will measure your waist and your parent's or caregiver's waist two times during the 8-week study. We will also ask you some questions about yourself and your daily activity levels and will ask you to follow the recommended activity levels outlined in your MyPlate plan (60 minutes daily) as you are able.

The dietary advice provided to you and your family is based on dietary recommendations from the United States Department of Agriculture's Dietary Guidelines for Americans. MyPlate encourages a variety of fruits, vegetables, whole grain products like breads, rice, and pasta, a variety of proteins like meat, fish or beans, and dairy products like milk, cheese, or yogurts. Snack foods and drinks with added sugars or saturated fats and sodium will be strongly discouraged and if you are randomized into the *Whole Teens MyPlate* group, we will ask you and your family to limit their consumption during the 8-week study. We will encourage you to help plan, prepare, and (if appropriate) cook the meals with your parent or caregiver and family members. We will also encourage you to eat the meals and snacks we recommend when you are at home (not during school hours unless you or your parent or caregiver would like to pack your lunch). We will also ask you to eat meals together as a family as often as possible during the study and not use media (e.g., phones, TV, tablets) at the table while eating.

This study will last for 8 weeks. We estimate that the total time commitment of this study is 2 to 4 ½ hours weekly (up to 36 hours total) plus time to prepare and cook meals (about 1-2 hours daily) if you are in the *Whole Teens MyPlate* group. We estimate that the total time commitment of this study is 10-12 hours total if you are in the *Whole Teens Counseling* group.

3. Do I have to be in this research study and can I stop if I want to?

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether you still want to be in this study.

4. Could it make me sick [or sicker]?

We do not believe that being in this research study will make you sick. The diet recommended in this study is evidence-based and healthy for both you and your family.

There is a possibility that with trying new foods a food allergy could occur. We do not believe this is likely; however, if you do develop a severe allergic reaction from any food consumed as part of participating in this study, you need to seek medical attention immediately and stop eating any foods provided to you from the study. We will ask your parent or caregiver to tell us about what happened as soon as possible.

5. Will anyone know that I am in this research study?

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Only your parent or caregiver and the study team will know you are in this study. If you and your parent or caregiver attend the group meeting at the end of the study, the people in the group will also know you are in the study. However, we will ask everyone in the group not to talk to others about who was at the meeting. After we have finished, we will write a report and tell others what we have learned. We won't use your name in the report when we tell others what we have learned. If we find out that someone has been hurting you, we cannot keep that private.

6. How will this research help me or other people?

You and your family may learn how to plan, prepare, and cook healthy foods together, eat together as a family, and learn more about how to choose, prepare, and eat healthy foods.

This study may help us learn if a whole foods diet can help teens achieve a healthy weight and if the diet can make families' diets healthier.

7. Can I do something else instead of this research?

You do not have to be a part of this study and nothing bad will happen to you if you do not want to be in the study.

8. Who do I talk to if I have questions?

You can ask me any questions that you have now about this study. If you have questions later, you can ask a study team member.

You will also have the opportunity to ask the Registered Dietitian Nutritionist any questions you may have about your diet during your sessions with him/her. If you have more questions after your meeting, you and your parent or caregiver can schedule another meeting to speak with the Registered Dietitian Nutritionist. This optional session can be conducted over the phone or via a secure Zoom video conference session.

Writing your name on this page means that the page was read (by you or to you) and that you agree to be in the study.

Date

Signature of patient/volunteer

Assent obtained by:

Signature

Printed Name and Title