

Ages 10-12 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 10-12.

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 program 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?

A study team member will meet with you and your parent or caregiver once at the beginning of the program and once at the end of the program to ask you questions about you and your family and what types of foods you like to eat. A study team member will talk to you and your parent about how to eat a healthy diet together as a family.

You will also be asked 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 your regular clothes, 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 adolescent's only: We may ask to collect a urine sample to rule-out the possibility of pregnancy before completing the scan.] Each visit should take between 30-minutes to 1-hour to complete.

You and your parent or caregiver will be put into one of two groups: the *Whole Teens Counseling* group or the *Whole Teens MyPlate* 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/caregiver to meet with a study dietitian up to 3 times to learn about how to eat a healthy diet that follows the United States Department of Agriculture MyPlate plan. 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 also send some healthy foods to your family 4 times during the study and will give you and your family kitchen tools and menu's to follow during the program. We will ask you and your parent/caregiver to cook healthy meals for you and your family for 8 weeks and talk with the study dietitian 4 times during the study. We may also invite you and your parent to meet with other parents/caregivers and adolescents to tell us what you liked or did not like about the program.

We will ask everyone in both groups to write down what they eat and drink during the program to help us understand more about your diet. You and your parent/caregiver will be asked to use a food diary to write down what you ate on some days during the program. We will also collect your height and weight and we will measure your waist two times during the 8-week program. We will also ask you questions about yourself and your physical activity levels and encourage you to follow the daily physical activity guidance encouraged in your MyPlate plan.

This program will last for 8 weeks. If you are in the *Whole Teens MyPlate* group, we estimate that the total time it will take to be in this program 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 Counseling* group, we estimate that the total time commitment of this study is 10-12 hours total.

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

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You can choose not to be part of this program at any time. Nothing bad will happen to you if you don't want to be part of this program or want to stop being part of the program later on.

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

Being in this research program will not make you sick.

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

Only your parent or caregiver and the study team will know you are in this program. If you and your parent are asked and choose to attend a group meeting at the end of the program, the people in the group will also know you are in the program; 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?

This research will help you and your family learn how to eat healthy meals together and help us learn if eating healthy foods can support a healthy weight in teens. Also, we hope to learn if eating healthy foods can make families' diets better.

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

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

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

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

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