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Study Title: Whole Food for Prediabetes: A Precision Nutrition Approach to Test the Feasibility of a Family-Based Whole Foods Diet in Adults with Prediabetes and their Offspring

Document Date 7/20/2022

Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Nadia M. Sneed, PhD, APRN, FNP-BC **Version Date:** 7/20/2022
Study Title: Whole Food for Prediabetes: A Precision Nutrition Approach to Test the Feasibility of a Family-Based Whole Foods Diet in Adults with Prediabetes and their Offspring
Institution/Hospital: Vanderbilt University

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
This study will last for two weeks. Being in the study is free to you. We do not believe that being part of this study puts you at risk. This study will help us learn if adults with prediabetes and their children are interested in participating in and adopting a family-focused healthy diet. Throughout the entire 2-weeks of the program, all meals and snacks will be provided for you and your family (up to 4 people) at no cost to you. During the study, you will speak with a Registered Dietitian Nutritionist two times (1-2 hours each session) to discuss how to plan, prepare, and cook the foods provided to you. You will be provided with menus and some cooking tools to help you plan and prepare meals. We will ask that children participate in the meal planning, preparation, and cooking (if age appropriate). We will also ask you to eat meals together as a family. You will have the opportunity to ask the Registered Dietitian Nutritionist any questions you may have about your diet plan. During the study, you will be asked to meet in person two times (120-150 minutes each session). At each visit, we will ask you detailed questions about you and your child's diet, and we will measure you and your child's weight and height and waist circumference. At each visit we will also ask you to complete surveys. We estimate that the total time commitment of this study is 4 ½ hours each week (up to 9 hours total) plus time to prepare and cook meals (about 1-2 hours daily).

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you indicated you have prediabetes and are a biological parent of a child ages 6-17.

The purpose of this study is to learn if adults with prediabetes and their children are interested in participating in and adopting a family-focused healthy diet.

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.

Procedures to be followed and approximate duration of the study:

The study will last for 2 weeks.

During the study, you and your child(ren) will learn how to prepare and enjoy healthy meals together as a family. Once you are enrolled in the study, we will ask you to meet in-person with your child(ren) two times for up to 2 ½ hours each time at a designated recruitment site on Vanderbilt University's campus. Free parking will be provided for each session. At each of these sessions, we will ask you specific questions about what you and your child(ren) ate the day before the session. We will record the information in a secure diet program that helps us calculate how many calories you ate and helps us understand more about what you and your child(ren) normally eat. We will also measure you and your child's waist circumference, height, and weight. We will also ask you to complete surveys about you and your child(ren).

During the study you will speak with a Registered Dietitian Nutritionist two times (at the beginning of the study and at the start of week 2). The meeting can be scheduled in-person during each of the two study visits or they can be conducted over the phone or via a secure Zoom conference session. During these session with the Registered Dietitian Nutritionist, you and the dietitian will discuss how to plan, prepare, and cook the foods provided to you. Each session with the dietitian may take 1- 2 hours of your time. During the study, we plan to have all groceries delivered to your home. In the event that food delivery is not available in you location, we will contact you to ask you to pick up the foods at a designated site on Vanderbilt Campus. We will attempt to have these groceries ready at your two study visits if foods cannot be delivered. These **groceries will be provided at no cost to you and your family** and enough food will be provided for **three meals and two snacks to feed up to a family of 4 for two weeks**. You will be provided with menus and some cooking tools to help you plan and prepare meals. We will ask that you only consume the foods provided for the two weeks you participate in the study. We will encourage your child to eat the meals and snack provided when they are home (not during school hours unless you would like to pack the food for their lunch). This includes when children are home during the weekends. You or a partner/spouse in the household will be responsible for preparing and cooking all meals and following the menu instructions. We will also ask that you keep a food diary each week. At each visit we will provide you with a printed piece of paper for you and your child(ren) where you will be able to record what you ate in a 24-hour period. We will ask that during each meal or snack, you record everything you and your child(ren) ate and drank. We will ask you to fill out the food diary three times a week for two weeks. If your child is able, they can fill out their own food diary, but we ask that you assist them to make sure they are writing down all the foods they ate and drank during the day. This food diary will be used by our Registered Dietitian Nutritionist and research team to understand what foods or beverages you are regularly eating during the study.

The diet for this study is based on the United States Department of Agriculture diet recommendations provided in the 2020-2025 Dietary Guidelines for Americans report. The Dietary Guidelines for Americans is updated every 5 years and provides evidence-based recommendations for a healthy diet for all children and adults living in the United States. During the study, you and your child(ren) will receive individual instructions from our study team about how many calories from foods you will need to eat daily. This will be based on how much energy from food your body needs to maintain your current weight. The goal of this diet is to provide fresh and packaged foods that support a healthy diet pattern. The diet will follow calorie recommendations that are based on age and gender groups. The diet will be broken down into how many calories from carbohydrates, fats, and

proteins you need to eat daily. Each day, your diet will consist of 45% of your calories coming from carbohydrate foods, 30% of your calories coming from dietary fats, and 25% of your calories coming from protein. The diet will have low amounts of added sugars and saturated fats and no "junk foods" or sugary beverages. Menus will be created to help you and your child(ren) follow recommend intakes of carbohydrates, fats, and protein each day.

We will ask that children participate in the meal planning, preparation, and cooking. The study team will provide age-appropriate recommendations to encourage children to participate in the meal preparation and cooking. We will also ask you to eat meals together as a family as often as possible during the study.

You will have the opportunity to ask the Registered Dietitian Nutritionist any questions you may have about your diet plan during your sessions with the Registered Dietitian Nutritionist. If you have additional questions, an optional follow-up session with a study team member or the Registered Dietitian Nutritionist will be provided. This optional session can be conducted over the phone or via a secure Zoom video conference session.

After the study is over, you will be invited to attend an optional 2-hour family focus group session. You will be encouraged to bring your child(ren) and spouse/partner; however, their attendance is optional and you will still be compensated if you choose to participate in the focus group session alone. During the focus group session, we will gather feedback about your participation in the study and 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 participants 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 or your child(ren)'s 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.

If you agree, our research staff will use Google Voice to text or call you to discuss the study and/or schedule a time for us to call you to complete surveys. Google Voice is a web-based, third-party service. Vanderbilt does not have a contract with Google to keep your information private, and the study team does not have full control over internet security, Google privacy policies, or phone carrier privacy policies. Text messages will be sent using SMS, which are not encrypted. There is no assurance of confidentiality of information communicated by an unencrypted text message. However, we will make every effort to keep your information confidential by creating a Whole Food for Prediabetes Study Google Voice Account.

We would like to ask for your permission to continue to contact you in case we have studies in the future that you and your family might be interested in. You can decide at that time if you are interested. If you agree to allow us to remain in contact with you, we will ask you to update your phone numbers, your address, and your additional contacts (in case we are unable to reach you at your phone number(s) or your address). If you agree to allow us to remain in contact with you, we may call or text you and we may send you updates via mail. This is optional and you can mark your choice at the end of this form.

Expected costs:
There is no cost to you to participate in this study.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

We do not believe that being part of this study puts you at risk. There is a possibility that with trying new foods a food allergy could occur. We believe this is unlikely; however, in the event that you, your child, or a non-enrolled family member develops a new food allergy reaction while participating in this study, we ask that the affected person seeks immediate medical attention. We will also ask that the affected person stops eating any foods provided from the study and that you contact a member of our study team to let us know about the incident as soon as possible.

The main inconvenience to you will be the time it takes to be part of the study. You may feel uncomfortable about some of the questions on the surveys, but you can decide not to answer any questions that make you feel uncomfortable. There is also the risk of potential loss of confidentiality. However, we will protect this information as best we can, as described below.

The foods and menus provided in this study are evidence based and healthy for both you and your child.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt [or the Sponsor] to give you money for the injury.

Good effects that might result from this study:

a) **The benefits to science and humankind that <u>might</u> result from this study.** This study may help us learn if adults with prediabetes and their children are interested in participating and adopting a healthy diet and eating together as a family. We also hope to learn if families are interested in preparing and cooking foods together.

b) **The benefits you might get from being in this study.** You and your child may learn about 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.

Study Results:
After we have finished the study, we may write a report and tell others about what we have learned. We will not use your name or your child(ren)'s name in the report when we tell others what we have learned.

Alternative treatments available:
You do not have to sign this consent form for you or your family to receive care at Vanderbilt University Medical Center. If you do not sign this consent form, you will not be able to participate in the Whole Food for Prediabetes study.

Compensation for participation:

You will get a small gift during your two in-person sessions to help you apply what you learn (example: cooking utensils). You are required to attend each in-person session to receive these small gifts.

If you agree to take part in this research study, you will receive up to $75 dollars for one enrolled child/adolescent or up to $95 dollars for two enrolled children/adolescents upon completion of the study for your time and effort. Payment will be received in the form of an electronic gift card (bank deposit for foreign nationals) within 2-4 weeks upon the completion of the necessary payment documentation. We will provide your payment at the end of the study when we measure you and your child's weight, height, and waist circumference and after we do the final surveys (times shown on the chart below). You will be invited to attend an optional family focus group session. You will be encouraged to bring your child(ren) and spouse/partner; however, their attendance is optional, and you will still be compensated if you choose to participate without them in the focus group session.

Table 1.

Study Time Points for Data Collection	Completing of all Baseline Requirements	About How Long Data Collection Will Take
T1 (Baseline)	Food provisions for study	120-150 minutes
T2 (2-weeks)	$40 (index parent and one child/adolescent) **or** $60 (index parent and two children/adolescents)	120-150 minutes
Family Focus Group	$35 (requires index parent with or without child/adolescent participation)	60-120 minutes

All participants who wish to accept payment for their participation will be required to submit a payment form that requests personal information (e.g., name, address, email, phone, citizenship status, etc.).

Study payments given to VU employees count as taxable income and will be reported to VU by study personnel to be included on Form W-2.

In addition to the payment form, foreign nationals receiving payment will be required to register as a VU supplier and complete a GLACIER record prior to receiving payment as federal and state tax withholdings apply. Payments made to human subjects who are foreign nationals are reported on Form 1042-S. All payments to foreign nationals are subject to 30% federal income tax withholding and sent via direct deposit.

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study; however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

If you receive $600 or more from the university in a calendar year, VU must report the amount you receive to the Internal Revenue Service (IRS) on the form 1099-MISC. This form tells the IRS that payment was made to

you, but it does not say that you were paid for taking part in this research study. You should talk to your tax advisor regarding the proper use of this form 1099-MISC.

Circumstances under which the Principal Investigator may withdraw you from study participation:
We do not plan to ask participants to stop being in the study. If we decide to ask you to stop being in the study (withdraw you from the study), we will let you know why we decided to do this.

What happens if you choose to withdraw from study participation?
You may stop being in (withdraw from) the Whole Food for Prediabetes study at any time. You may stop being part of the study at any time and for any reason, without this causing any problem for you. Any research data collected before you took back (withdrew) consent may still be used for reporting and research quality. Research data collected will be stored for at least 3 years.

Contact Information:
If you should have any questions about this research study or possibly injury, please feel free to contact the Principal Investigator, **Dr. Nadia Sneed** at **615-421-8563.**

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:
All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Your study information will be kept on paper records and on a computer database. The paper records will be kept in locked cabinets. Each person in the study will be given a number to identify you in the place of your name. The computer records will only include this number and will be on a secure site (safe place) that only people on the study team can get to. Only the Principal Investigator and certain research staff will be able to get to your information and to the file that links your number with your name, which will also be on a secure site (safe place) on the computer. We will not include your name or any identifying information in any reports we write about this study. After we remove all information that could identify you or your child, your data may be shared with a third party for analysis.

Certificate of Confidentiality:
This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Your information may be shared with Vanderbilt or the government, such as the Vanderbilt University Institutional Review Board or Federal Government Office for Human Research Protections if you or someone else is in danger or if we are required to do so by law. Vanderbilt may give or sell your data without identifiers for other research projects not listed in this form. There are no plans to pay you for the use or transfer of this de-identified information.

Authorization to Use/Disclose Protected Health Information:
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use, or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed."

Principal Investigator: Nadia M. Sneed, PhD, APRN, FNP-BC **Version Date:** 7/20/2022
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Institution/Hospital: Vanderbilt University

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

I give my permission to be in this study.

☐ Yes ☐ No

I give the study team permission to contact me directly to collect information about me and my child for the study.

☐ Yes ☐ No

I give the study team permission to contact me or other people that I identify directly so we can stay in contact throughout the 2-weeks of the study.

☐ Yes ☐ No

I give the study team permission to contact me about other study opportunities that I might be interested in.

☐ Yes ☐ No

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title