



Social and Behavioral Study

Research Consent

eProtocol ID: U21-12-4630

IRB Approval Date: July 31, 2022

Digitally signed
by Inova
Date:
2022.08.01
15:14:54 -0400

STUDY INFORMATION

Title of Study | **Buen Provecho**

Principal Investigator | Elyssa Wood

Service Line/Department | Nursing

Study Site | Inova Health System, 44045 Riverside Pkwy, Leesburg, VA 20176

Key Information about This Research Study

You are being asked to participate in a research study. Participation is completely voluntary. It is your choice whether or not you take part in this research study. Your choice will in no way impact the care you receive at HealthWorks for Northern Virginia.

You are encouraged to ask any and all questions you have to the study team related to participating before agreeing to join this research study.

Why is this study needed?

The purpose of this research is to find out if education about nutrition, exercise and lifestyle habits changes how families behave at home.

You are asked to be in this study because you and your child receive care at HealthWorks for Northern Virginia and your child is between the ages of 6 and 12 years.

What does participation in this research study involve?

Your participation in this research will involve receiving counseling by your doctor at HealthWorks about the nutrition, exercise, and lifestyle habits that effect weight. This counseling will take place during your child's doctor visit during the next 12 weeks. We will give you 2 surveys during this study. One survey right before your first counseling session, and the second survey several weeks after your last counseling session.

We expect about 50 families from HealthWorks Northern Virginia will be part of this study.

What are the risks and benefits of this research study?

Almost all research studies involve some risk. Risks of this study are minimal. Risks are described in detail later in this document.

Here are some possible benefits:

Help the researchers better understand how to counsel families about nutrition, exercise and lifestyle habits that effect weight.



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You may learn some information about nutrition, exercise and lifestyle habits that effect weight.

Here are some possible risks and difficulties:

You will need to return for follow-up appointments, and these may be inconvenient for you.

What are my other choices if I do not take part in this study?

You do not have to be in this research study. If you decide not to take part in this study, you can choose to not be in the research study.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions you need to help decide whether or not to join this study.

How is this research funded?

This research is being funded by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1TR003015.

What happens if I say “yes, I want to be in this research”?

If you say yes to being part of this research study, someone will call you before your next clinic appointment to ask you survey questions about diet, nutrition and exercise. The next time you come for a doctor's visit your doctor will talk with you and your family about nutrition, exercise and lifestyle habits that effect weight. A few weeks later, we will call you and ask you the same survey questions again over the phone. We will also collect some data from your medical chart.

Although there will be over 50 families completing this study, half will receive one type of educational session, and half will receive another type of educational session. Both sessions include the same information, but the style of teaching will be different. You are being offered the sessions that take place during your doctor visits.

What are the risks and discomforts involved?

There are minimal risks to participating in this research. We are being very careful with your private health information. In addition to your survey answers, we will be collecting some other information gathered during your doctor visit, like your weight. Instead of attaching your name to this private information, we will create a code for you. Only the researchers will understand how the code can be linked to your name and private information. The researchers will keep this code safe, so no one besides the researchers know that the survey answers and private health information belong to you.

Will being in this study benefit me or others in any way?

Even if the study does not help you directly, your participation in this study may help other people in the future by helping us learn more about how to best educate families about nutrition, exercise and lifestyle



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habits that effect weight. The study may also benefit you because you may learn some information about nutrition, exercise and lifestyle habits that effect weight.

What if new information becomes available?

We will tell you about any new information developed during your participation in this research if the information could relate to your willingness to continue to participate in this study.

Will I be paid or receive anything for being in this study?

We will not pay you to take part in this study or pay for any out of pocket expenses related to your participation, such as travel costs.

What happens to the information collected for the research?

Some organizations may be required to inspect and request a copy of study information including the IRB and other Inova Health System representatives responsible for the management or oversight of this study. However, no identifiable information about you is being collected. We will only link the special study code to your information, not your name.

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you.

We may publish and present what we learn from this study, but none of this information will identify you. Information which can identify you is removed from the data we collect, and the data could be used for future research studies or provided to another researcher for future research without additional informed consent.

The following is a list of individuals who may access the anonymous survey you complete:

- Members of the research team
- Offices and committees responsible for the oversight of research
- Collaborating researchers outside of the Inova Health System

The research team may publish the results of this research. However, there is no identifying information being collected from you.

Will information be used for other research?

Information collected about you and collected from you will be used for this research and may also be used for other research studies here at the Inova Health System. There may also be collaborative research efforts with other entities, such as universities, the government, and private companies where we may share your



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VOLUNTEER IN A HUMAN RESEARCH STUDY

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information. The individuals performing the research will not know who the information came from. We will not ask for additional consent from you to use your information for the additional research.

What happens if I want to leave the study?

If you decide to leave the research, contact the study team so the investigator can work with you to create a safe plan for your withdrawal.

Can I be removed from the research without my OK?

The researchers may take you out of the study, even if you want to continue, if:

- You do not follow the study rules or you no longer meet the requirements to be in the study; or the study is stopped by the sponsor or researchers.

Contact Information

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Study Contact:

Study Contact PI | Elyssa Wood

Phone Number | 703-858-6731

Inova's Office to help protect you in this Research Study is called Human Research Protections Office (HRPO). You are welcome to call HRPO if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Human Research Protections Office (HRPO) | 1-888-534-6682

This research has been reviewed and approved by an Institutional Review Board ("IRB"). The IRB of Record for this study is:

IRB of Record | IRBGroup D

Phone Number | 1-888-534-6682

PARTICIPANT'S STATEMENT/SIGNATURE

- *I have read this form and the research study has been explained to me.*
- *I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.*
- *I agree to be in the research study described above.*



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-
- I will receive a copy of this consent form after I sign it.*

Signature of Participant

Printed Name

Date

Signature of Person Conducting Informed Consent
Discussion*

Printed Name

Date

**The person conducting the informed consent discussion has signed above as witness.*



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The purpose of this research is to find out if education about nutrition, exercise and lifestyle habits changes how families behave at home.

You are asked to be in this study because you and your child receive care at HealthWorks for Northern Virginia and your child is between the ages of 6 and 12 years.

What does participation in this research study involve?

Your participation in this research will involve receiving counseling by your doctor at HealthWorks about the nutrition, exercise, and lifestyle habits that effect weight. This counseling will take place during your child's doctor visit during the next 12 weeks. We will give you 2 surveys during this study. One survey right before your first counseling session, and the second survey several weeks after your last counseling session.

You and your child will also participate in a 12 week program online called Inova Healthy Plate Club. This program is held online, for a one-hour session once a week. It is important that you and your child attend as many of these sessions as possible.

We expect about 50 families from HealthWorks Northern Virginia will be part of this study.

What are the risks and benefits of this research study?

Almost all research studies involve some risk. Risks of this study are minimal. Risks are described in detail later in this document.



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Here are some possible benefits:

- Help the researchers better understand how to counsel families about nutrition, exercise and lifestyle habits that effect weight.
- You may learn some information about nutrition, exercise and lifestyle habits that effect weight.
- You and your family will receive a box of vegetables, free of charge, every other week while you are in this study, as part of a program called the Inova Healthy Plate Club.

Here are some possible risks and difficulties:

- You will need to return for follow-up appointments, and these may be inconvenient for you.

What are my other choices if I do not take part in this study?

You do not have to be in this research study. If you decide not to take part in this study, you can choose to not be in the research study.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions you need to help decide whether or not to join this study.

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You will also receive information to schedule your Inova Healthy plate club sessions. These sessions happen once a week, for 12 weeks. For some of the sessions, you and your family will receive a box of healthy vegetables to cook with during the class session. You and your family can keep any extra vegetables or fruits in the box to eat during the week. The food boxes will be delivered to your home, or you can come pick them up before the sessions.



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Will being in this study benefit me or others in any way?

Even if the study does not help you directly, your participation in this study may help other people in the future by helping us learn more about how to best educate families about nutrition, exercise and lifestyle habits that effect weight. The study may also benefit you because you may learn some information about nutrition, exercise and lifestyle habits that effect weight. You will receive a box of vegetables and fruit every other week (6 boxes total) during this study.

What if new information becomes available?

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- *I agree to be in the research study described above.*
- *I will receive a copy of this consent form after I sign it.*

Signature of Participant

Printed Name

Date

Signature of Person Conducting Informed Consent
Discussion*

Printed Name

Date

**The person conducting the informed consent discussion has signed above as witness.*