Redesigning Pediatric Primary Care Obesity Treatment: Virtual House Calls

NCT06078774

07.12.2023

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Redesigning Pediatric Primary Care Obesity Treatment: Virtual House Calls

VCU INVESTIGATOR: Melanie K. Bean, PhD, Associate Professor of Pediatrics and Psychiatry, 804-527-4765

NOTE: In this consent form, "you" always refers to the research participant. Both children and caregivers will be participants in this study. Tasks specific to children and caregivers are detailed in this form.

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

Why is this study being done?

The purpose of this study is to evaluate the feasibility and effectiveness of the Virtual HouseCalls intervention to reduce youth body mass index. Specifically, this study is examining the achievability of a telehealth-based behavioral weight management intervention in conjunction with pediatric primary care. Virtual HouseCalls will engage participants with content through screen sharing, tailor counseling to the patient's home and community context, and use items in the home as part of the visit to create real-time feedback and support.

What will happen if I participate?

If you are a **child** participant, you will be asked to do the followings things as part of this study:

1. Have your health care provider complete a medical clearance form that states it is safe for you to participate in a weight management program that focuses on improving your eating choices and increasing your physical activity.
2. Answer questions about your eating and health behaviors.
3. Week 1, attend a virtual session for ~60 minutes.
4. Weeks 1-12, attend weekly, virtual sessions for ~30 minutes.
5. Weeks 13-24, attending bi-weekly, virtual sessions for ~30 minutes.
6. Participate in weekly 30-minute virtual exercise sessions for 24 weeks
7. Visit your pediatrician for a primary care visit 3 times throughout the study (baseline, 3-months, and 6 months).
8. Weigh yourself weekly.
9. Complete study assessments at baseline, 3-months, and 6-months which consists of a height and weight measurement and completing online questionnaires.

If you are a **caregiver** participant, you will be asked to do the followings things as part of this study:

1. Have your health care provider complete a medical clearance form that states it is safe for you to participate in physical activity.
2. Provide demographic information about yourself and your child as well as information about you and your child's behaviors and your home food environment.
3. Week 1, attend a virtual session for ~60 minutes.
4. Weeks 1-12, attend weekly, virtual sessions for ~30 minutes.
5. Weeks 13-24, attending bi-weekly, virtual sessions for ~30 minutes.
6. Participate in weekly 30-minute virtual exercise sessions for 24 weeks with your child.
7. Participate in 3, 60-minute individual visits with coach throughout the program.
8. Bring your child to their primary care visit 3 times throughout the study (baseline, 3-months, and 6-months).
9. Complete study assessments at baseline, 3-months, and 6-months which consists of completing online questionnaires.

Feedback will be provided at weekly meetings to help you and your child progress toward goals. All virtual sessions will occur with your health coach and will focus on weight management strategies and other health behaviors. Your participation in this study will last up to 6 months. Approximately 60 individuals will participate in this study.

What alternative treatments or procedures are available?

If you decide not to enter this study, you can receive the usual care that you would receive even if you were not in the study. This includes services available to assist children and families with weight management through Children's Hospital of Richmond at VCU. The study staff will discuss these options with you. You do not have to participate in this study to receive usual standard of care through pediatric primary care.

What are the risks and benefits of participating?

There are both risks and benefits of participating in research studies.

Risks and Discomforts	Benefits to You and Others
• Mild to moderate physical activity may cause sore or pulled muscles, heart problems, physical discomfort, and/or accidental injuries such as falling. You or your child may also experience some physical discomfort such as increased heart rate, chest pain, shortness of breath, headache, nausea, and/or fatigue. Increased physical activity may worsen existing medical conditions. • Weight change may require adjustments to medications. • A focus on weight could be upsetting for some people, and might result in increased depression, or resorting to unhealthy behaviors in attempts to succeed at weight loss. • Participation in research might involve some loss of privacy. There is a small risk that someone outside the study could see and misuse information about you or your child. • The study questionnaires ask personal questions that are sensitive in nature and may make you feel uncomfortable.	There is evidence that lifestyle intervention with exercise, nutrition education and behavioral support are effective in helping people lose weight. However, it is unlikely that it will work with everyone, and we cannot promise that it will help you and your child. This study may help the investigators learn things that may help other people in the future. There is no guarantee that you or your child will receive any benefits from being in this study. However possible benefits include improved health and fitness. We hope the information learned from this study will provide more information about better ways to treat children with overweight.

WHAT ARE THE COSTS?

Your insurance plan will need to pay for the costs associated with routine medical visits with your primary care provider. This includes your insurance co-pays and deductibles.

All other costs associated with the study will be covered by the study sponsor.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will be compensated by cash or check for completing study assessments. Families will each receive $25 at 3-months and $50 at 6-months for completing the study assessments.

Total payments within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

Please be aware that the investigative team and the University may receive money for the conduct of this study.

CAN I STOP BEING IN THE STUDY?

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

We may withdraw you from the study if:
• the study staff thinks it is necessary for the subject's mental health and safety;
• the sponsor stops the study; or
• administrative reasons

HOW WILL INFORMATION ABOUT ME BE PROTECTED?

VCU has established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services

It will be noted in your protected electronic health record at VCU Health that you are in this study. Information about the study will be included in the record. This information is protected just as any of your other health records are protected.

In general, we will not give you any individual results from the study. Once the study has been completed, we will send you a summary of all of the results of the study and what they mean.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know. Study staff that hears such information will report it to the Principal Investigator who will submit a report to the appropriate services and resources will also be provided to you so that you can engage in additional care, as needed.
In the future, identifiers might be removed from the information and samples you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will ask you to permit us to access existing information from your healthcare records. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?
The following types of information may be used for the conduct of this research:

- Complete health record
- History and physical exam
- Diagnosis & treatment codes

Who will use or share protected health information about me?
VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Data Coordinators

- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?
This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Statement of Privacy Rights
You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at Principal Investigator at Melanie Bean, BOX 980140, Richmond, VA 23298

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

Melanie Bean, Study Principle Investigator
804-527-4765
melanie.bean@vcuhealth.org

and/or

Sarah Farthing, Study Coordinator
804-527-4756
sarah.malone@vcuhealth.org

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
Phone: (804) 827-2157
https://research.vcu.edu/human-research/hrppirb/research-participants/

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT AND/OR PARENT/LEGAL GUARDIAN PERMISSION

I have been provided with an opportunity to read this consent form and permission form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form and permission form] I have not waived any of the legal rights or benefits to which I and/or my child otherwise would be entitled. My signature indicates that I freely consent to participate and/or give permission for my child to participate in this research study. I will receive a copy of the consent form and permission form for my records.

Signature Block for Enrolling Adult Participants	
_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date

Signature Block for Enrolling Child Participants - Parent/Guardian Permission	
_____ Name of Child/Youth Participant	
_____ Name of First Parent/Legal Guardian (Printed) *Study team – verify that this individual is the child's parent or legal guardian.*	
_____ **Required** First Parent/Legal Guardian Signature	_____ Date
_____ **Optional** Second Parent /Legal Guardian's Signature	_____ Date
_____ Name of Person Conducting Parental Permission Discussion (Printed)	
_____ Signature of Person Conducting Parental Permission Discussion	_____ Date
_____ Principal Investigator Signature (if different from above)	_____ Date

Enrolling Child Participants (Ages 9-13) – Verbal Assent by Child
STATEMENT OF ASSENT BY CHILD PARTICIPANT The person doing this research study has explained what will happen to me if I participate in this study. Saying "yes" means that I want to be in this study. I can decide not to be in this study if I do not want to. Nothing will happen to me if I do not want to participate.