

**Innovative Approaches to Adolescent Obesity Treatment:
Exploring the Role of Parents**

NCT02586090

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YOUTH ASSENT FORM
Use for Subjects 12 through 16 years

TITLE: Innovative Approaches to Adolescent Obesity Treatment: Exploring the Role of Parents

VCU IRB NUMBER: HM20005235

SPONSOR: National Institutes of Health

This form may have some words that you do not know. Please ask someone to explain any words that you do not know. You can take home a copy of this form to think about and talk to your parents about it before you decide if you want to be in this study.

What is this study about?

The purpose of this study is to find out how parents of teenager in a weight management program can best help their teen change their health behaviors and improve their health.

What will happen to me if I choose to be in this study?

In this study, you will:

- Be seen by doctors, diet specialists, exercise specialists and behavior specialists. If you are a boy, the doctor will do an examination for a hernia, like the one done by your doctor for sports physicals.
- Have your physical activity measured by a small device worn on your wrist for approximately 4-7 days (tested at entry and again at 4 months and 7months).
- Answer some questions on paper forms and at individual meetings with a dietitian and behavior specialist that will help us to understand things like your eating habits, exercise choices, what your life is like and how you feel about things.
- Come to weekly meetings with the behavior specialists and the dietitian for 4 months. For most of these meetings, you will also be with other teens in the program at the same time. Separate meetings will be held for boys and girls. These meetings will occur once a week in the afternoons or evenings and last about 1 hour. During the meetings, staff will help you learn about healthy eating and exercise, help you set goals to improve your health and lose weight, and see how you are doing in reaching these goals. Your parents will be invited to attend some or all of the meetings that focus on healthy eating and nutrition to help them learn too.
- Learn and follow an exercise program that will be designed for you and exercise at the program's gym at least one time a week for about an hour for 4 months.
- Attend an exercise orientation session at the YMCA with other teens and parents in the study.

- Attend a cooking class with other teens and parents in the study.
- Keep track of your eating and exercise choices each day by writing in a log book. You will need to bring your log book to the weekly meetings and go over the information with the nutrition or behavior specialists.
- Have your weight measured every week to monitor your progress.

If you stop participating in the study before finishing the final testing at 7 months, someone may contact your parent to ask questions about the reason you have stopped. The answers to the questions can help us make the program better.

After your participation in the study ends, some follow-up questions may be mailed to your parents. The questions will ask about your health and health behaviors and how you liked the program. When this form arrives, you and your parent can fill it out together. However, you do not have to answer the questions if you do not want to.

If you decide to be in this study, you will be asked to sign this form. Do not sign the form until you have all your questions answered, and understand what will happen to you.

What might happen if I am in this study?

Your condition may not get better or may become worse while you are in this study. There is no guarantee that you will lose weight from being in this study. You may lose weight, stay the same, or gain more weight while you are in this study.

It might make you feel upset to talk about things that bother you. You may feel embarrassed to talk about your body size, eating and exercise habits. If you have not exercised before, you might feel tired or sore after you have been to the gym. You may feel a little bit dizzy, short of breath or sick to your stomach after participating in exercise, but this should not last very long. If a part of your body starts to hurt after you exercise, or if you feel dizzy or sick, you should tell one of the program staff and your parent about it.

If you have asthma, your wheezing, or shortness of breath may become worse during or after exercise. You will need to bring your rescue medications to all exercise sessions. Tell the exercise staff at the study Gym if your asthma becomes worse during an exercise session.

If the doctor or behavioral specialist finds a medical or behavioral problem during one of the program's meetings, you may be required to see your own physician or another behavioral specialist before you are allowed to start or continue with the program.

The benefit of this study is to help doctors find out about the best way to help adolescents your age (12-16) who have problems with their weight improve their health. You may lose weight during the program. You may improve other areas of your overall health by following the exercise and nutrition goals.

What do I get if I am in this study?

You will have access to a free membership to your local YMCA. This is only during the time that you are in the study. Study staff may give away small prizes worth less than \$30 during the groups sessions when you or the entire group reach certain goals. Your parents will be provided with up to \$20 when your family completes testing at 2 months, up to \$40 when your family completes testing after 4 months and up to \$50 when your family completes testing after 7 months. You can talk to your parents about how your family would like to use this money.

Other ways to get help.

You may find other ways to find help from your doctor, a dietitian, an exercise program or a person that is trained to help you with making changes in your behavior. You and your parent can choose to find this kind of help from other sources in your community.

Will you tell anyone what I say?

We will not tell anyone that is not part of the study team the things you say in the sessions, the answers you give us to the questions. If we talk about this study in speeches or in writing, we will never use your name. If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law requires us to let people in authority know so they can help you. If a court of law sends us a legal paper asking for your personal information, program faculty or staff are required to comply and produce the requested information. When you are in a group with other adolescents and parents, they will hear what you say, and may or may not tell someone else.

If you and your parent decide to exercise at the YMCA as part of the complementary TEENS membership we will send information about your level of physical fitness and your specific TEENS exercise plan to their staff to help make sure you exercise safely.

Do I have to be in this study?

You do not have to be in this study. If you choose to be in the study, you may stop at any time. No one will blame you or criticize if you drop out of the study. Your decision will not change your future medical care if you are a patient at the VCU Health System.

Questions

If you have questions about being in this study, you can talk to the following persons or you can have your parent or another adult call:

Melanie K Bean, PhD
Study Principal Investigator

VCU Department of Pediatrics
P.O. Box 980140
Richmond, VA 23298-0140
(804) 527-4756

Edmond Wickham, M.D., M.P.H.
Study Medically Responsible Investigator
VCU Departments of Internal Medicine and Pediatrics
P.O. Box 980111
Richmond, VA 23298-0111
Telephone: (804) 827-0453

If you have questions about your rights as a research subject, you may contact:

Office of Research and Innovation
Virginia Commonwealth University
800 East Leigh Street, Suite 3000
P.O. Box 980568
Richmond, VA 23298
Telephone: (804) 827-2157

Do not sign this form if you have any questions. Be sure someone answers your questions.

Assent: I have read this form. I understand the information about this study. I am willing to be in this study.

Youth name printed

Youth signature

Date

Name of Person Conducting Informed Assent Discussion/Witness (printed)

Signature of Person Conducting Informed Assent Discussion/Witness

Date

Principal Investigator signature (if different from above)

Date