INNOVATIONS IN MANAGEMENT OF OBESITY AND INACTIVITY IN PEDIATRIC PRIMARY CARE APPLICATION FOR STUDY

NCT #02724839

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Informed Consent Form
Cincinnati Children's Hospital Medical Center
3333 Burnett Ave., Cincinnati, OH 45229

STUDY TITLE: INNOVATIONS IN MANAGEMENT OF OBESITY AND INACTIVITY IN PEDIATRIC PRIMARY CARE

STUDY NUMBER: _____

Principal Investigator: Kristen Copeland, MD Telephone Number: 513-636-1687

INTRODUCTION

We are asking you to be in a research study so that we can learn new information that may help others. If you decide not to be in this study, we will still take good care of you. If you decide to be in this study, you may change your mind at any time during the study and you can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to be in the study. You can ask questions at any time.

WHY ARE WE DOING THIS RESEARCH?

In this research study we want to learn more about management of obesity and inactivity for children ages 6-12 year old.

We are asking you and other people with a child(ren) between the ages of 6 and 12 years old to be in the research, because we want to learn more about effective methods of providing advice and guidance for your child's health and well-being.

WHO IS IN CHARGE OF THE RESEARCH?

Dr. Kristen Copeland is the researcher at Cincinnati Children's Hospital Medical Center (CCHMC) that is in charge of this study.

WHO SHOULD NOT BE IN THE STUDY

You can not be in this study if you do not have an interest in bettering your nutrition and activity habits.

WHAT WILL HAPPEN IN THE STUDY?

The research staff will explain each visit to you and may give you a handout that explains each visit in more detail. You will be able to ask questions to make sure that you understand what will happen.

These are the things that will happen to you while you are in the study:

People taking part in this research will be put into two groups: the intervention group and the control group. The groups are selected by chance, as if by tossing a coin. Participants in the intervention group will participate in 6-10 peer led nutrition group sessions. Participants in the control group will not participate in the peer led group sessions.

All participants, both parent and child, will receive a Fitbit. Participants in the intervention group will receive their Fitbit during the study and have their activity level monitored using the Fitbit device. Participants in the other group will receive the Fitbit and intervention materials after the intervention group finishes.

All participants will be weighed and heights taken at beginning and end of the study. They will be asked to complete a few simple surveys regarding your child's quality of life, quality of sleep, and eating habits. We will then compare which of the two group has the best results.

The research staff will continue to monitor your clinical records after the study ends.

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

Being in this research may help you learn practical tips to improve your diet, where to buy inexpensive fruits and vegetables, how to reduce use of screen time and the location of safe and fun parks to play at. This research may also help other children in the future who suffer from childhood obesity.

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

There is minimal risk with this study. You may become frustrated if you are asked questions during testing that you do not know how to answer. You do not need to answer any question that you do not wish to answer and you can stop at any time. Also, there is a minimal risk of loss of privacy. Your information will remain confidential.

There may be other risks that we do not know about yet.

WHAT OTHER CHOICES ARE THERE?

Instead of being in this study, you can choose not to be in it.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE?

Making sure that information about you remains private is important to us. To protect your privacy in this research study we will keep all survey responses and information in a secured location which only the researchers have access to.

WHAT IF WE LEARN NEW INFORMATION DURING THE RESEARCH?

The study doctor will tell you if they find out about new information from this or other studies that may affect your health, safety or willingness to stay in this study.

WILL IT COST YOU ANYTHING EXTRA TO BE IN THE RESEARCH STUDY?

There is no cost to you to participate in this research study.

WILL YOU BE PAID TO BE IN THIS RESEARCH STUDY?

You will be reimbursed for your time, effort and travel while you are in this research study.

Those in the intervention group will be paid $10 for attending the first nutrition group session and $10 for completing an exit interview at the completion of the pilot phase of the study. For those who are in the control group, you will receive $10 for completing the first interview, weigh-in session, and surveys and $10 for completing the follow-up weigh-in session and surveys. Additionally, the Fitbit devices given to you and your child for the research study (one to each participant) will be yours to keep.

You will receive payment for this study in the form of a reloadable debit card (Clincard). We will give you a handout that will explain how to use the card. Because you are being paid for your participation, CCHMC is required by the Internal Revenue Service (IRS) to collect and use your social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay you. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your Social Security number. This form will be given to the CCHMC business office. It will not be kept as part of your study chart. If you move, you will need to complete another W-9 with an updated address

WHAT HAPPENS IF YOU ARE INJURED FROM BEING IN THIS STUDY?

If you believe that you have been injured as a result of this research you should contact the Dr. Copeland as soon as possible to discuss the concerns. Treatment for injuries is available at CCHMC. If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in a research study. If possible, you should give them a copy of this consent form.

CCHMC follows a policy of making all decisions about compensation for the medical treatment of physical injuries that happened during or were caused by research on an individual basis.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions, concerns, or complaints about this research study you can contact the study person listed on page 1 of this document.

If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the CCHMC Institutional Review Board at 513-636-8039.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?
CCHMC will need to use and share your PHI as part of this study. This PHI will come from:

- Your CCHMC medical records
- Your research records

How will you know that your PHI is not misused?
People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?
You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?
Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

Will your other medical care be impacted?
By signing this document you are agree to participate in this research study and give permission to CCHMC to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research you will document your consent by signature below.

You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent — Date

_____ _____
Signature of Legally Authorized Representative* — Date

_____

* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____

Signature of Individual Obtaining Consent Date