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Title of Study: Creating Healthy Environments for Chicago Kids – The CHECK Trial

Sponsor: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

RUSH

Subject Information Sheet and Consent Form

Introduction

Note: If you are the parent, guardian, or legal representative of a minor or person who is not able to consent for themselves the terms "you" or "your" refer to you and/or the person being asked to participate in this research.

You are being invited to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the information in this form carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions and the study doctor or study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate. Before anything is done for this study, you must sign this form. A copy of this signed form will be given to you.

You do not have to take part in this study. You are free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who take part in research are called "subjects" instead of "patients".

Why are you being invited to participate in this study?

You are being asked to take part in this study because you are a child between 6-12 years old and your body mass is in the overweight or obese range. This study focuses on lower-income and middle-income households in the greater Chicago area.

What is the purpose of this study?

Childhood obesity has become widespread in Chicago, and across the country. The first-line therapy for childhood obesity consists of behavioral programs that focus on healthy eating, getting enough sleep, and increasing physical activity. Childhood weight management programs are most effective when the entire family participates. The purpose of this study is to compare two different approaches to delivering family-based childhood weight management programs.

How many study subjects are expected to take part in the study?

Altogether, 266 families are expected to participate in this study.

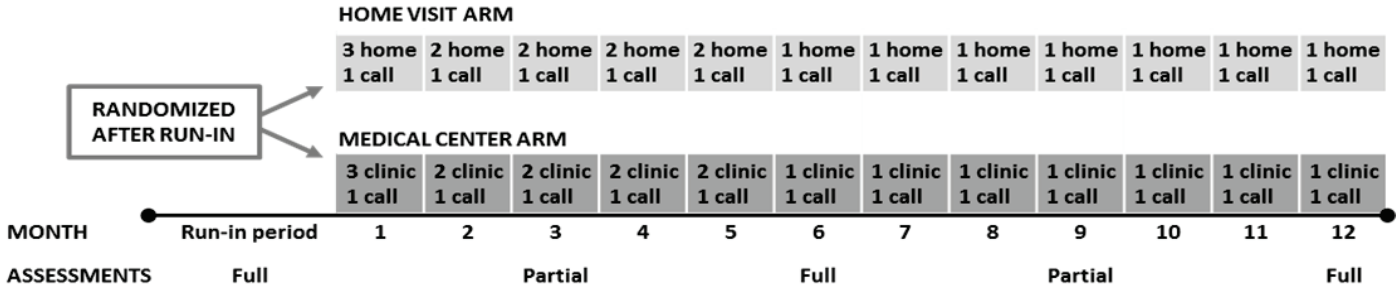
What will you be asked to do?

The first part of this study is a two-week screening process. The screening process is needed to find out if you are eligible for the study. You will be asked to meet with researchers two times for about 60 minutes per visit. The first visit will take place at Rush University Medical Center, and the second visit will take place in your home. At these meetings, researchers will ask you questions about your household, and measure the height, weight, and waist girth of everyone in your home. Your child will be asked to wear a small activity monitor (about the size of a wristwatch) on his or her waist during the daytime for one week. At night, your child will wear the device on his or her wrist, just like a watch.

All families who complete the screening and are found eligible will receive a family-based childhood weight management program for 12 months. Your family will be randomly assigned (like the flip of a coin) to receive this treatment either at Rush University Medical Center (the Medical Center Group) or in your home (the Home Visit Group). Both groups will receive the same program – the only difference will be in the location where the program is delivered.

The childhood weight management program you will receive is called ***Creating Healthy Environments for Chicago Kids (CHECK)***. Altogether, you will meet with a trained weight management counselor 18 times over one year. The program focuses on making healthy changes to your family routines and the foods and activities available in your home. Your counselor will provide information on child nutrition, sleep needs, and physical activity guidelines, and will tailor aspects of the program to your family. Your counselor will also provide support through regular telephone calls that happen between in-person visits.

All participating families will complete four assessment visits during the study (in addition to the screening visits). All of the assessment visits take place in your home – you will not need to travel to Rush. The assessment visits that occur at the middle (month 6) and end (month 12) of the study will last about 90 minutes. Researchers will ask you questions about your child's diet and your family's routines, and will take an inventory of the foods and activities available in your home. Your child will wear the activity monitor for 7 days at each of these assessments. The height, weight, and waist girth of your family members will be measured. The two assessment visits at the 3-month and 9-month time points will be shorter, and should take less than 30 minutes. At these visits, researchers will only take height, weight, and waist girth measurements, and ask you about any medical expenses or medical problems you may have had in the past several months. As discussed below, you will be paid for completing the assessment visits. All of the activities that take place at assessment visits are being done to answer the scientific questions that this study is designed to address. You should only enroll in this study if you can commit to completing all assessment visits. You are expected to complete the assessment visits even if you choose to stop participating in the weight management program.



How long will you be in the study?

Your participation will last about 54 weeks (2 weeks of screening, plus 52 weeks of weight management treatment). You may be removed from this study without your consent. Possible reasons may be that the study doctor decides that continued participation in the study will be harmful to you, or the study is canceled.

What are the possible risks of the study?

There are no major health risks associated with participating in this study. Being involved in a weight loss study can sometimes make children feel ashamed. To reduce this risk, your meetings with your counselor will always take place in a private setting, and the program focuses on the health of the entire family (rather than focusing on just the overweight child). There are no foreseeable legal or financial risks associated with participation. Researchers will be interacting with your entire family and will be visiting your home at least several times. As employees of Rush University Medical Center, the researchers are required to report suspected child abuse or neglect; elder abuse, neglect, or exploitation; and immediate risk of significant harm to one's self or others to the appropriate authorities. If the researchers learn that you or a family member is experiencing suicidal thoughts, we will first attempt to provide appropriate resources, and only contact emergency personnel if needed.

Are there benefits to taking part in the study?

Your child will receive a child obesity treatment that may help to bring his or her weight into a healthy range. Prior studies have found that overweight family members of children who participate in weight loss programs may also lose weight. However, results vary from person to person, and you may not directly benefit from participating in this study. The knowledge gained from this study will advance the scientific understanding of childhood obesity treatment.

What other options are there?

Instead of participating in this study, you may choose to participate in other child obesity programs available through healthcare facilities and commercial providers. You may choose to ask your child's pediatrician about these options before you agree to participate in this study.

What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. No names or other identifying information will be linked to the research information that you provide. Instead, researchers will use identification numbers. All of the information collected will be stored on password-protected computers or in locked file cabinets. Only the research team, the study sponsor (NIDDK), research collaborators at University of Illinois Chicago and University of Minnesota, and the Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects. Additionally, a small committee of scientists called a Data Safety Monitoring Board will oversee subject safety for this study, and may have limited access to your files in the event of a safety concern. Your identity will not be revealed on any report, publication, or at scientific meetings.

If you withdraw from this study, the data already collected from may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

In order to conduct the study, the study doctor (Dr. Appelhans) will use and share personal health information about you. This includes information already in your medical record, as well as information created or collected during the study. Examples of the information that may be shared include your medical history, physical exam and laboratory test results. The study doctor will use this information about you to complete this research.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

A description of this study will be available on http://www.CLINICALTRIALS.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at anytime.

What are the costs of your participation in this study?

There is no cost for participating in this study. The family-based childhood weight management program will be provided at no charge. You will not be billed for any of the assessments performed for this study. All costs that are part of your usual medical care, such as visits with your child's pediatrician, will be charged to you or your insurance company. You will be responsible for all costs that are not paid by your insurance company. You should check with your insurance company before you enroll in this research study.

What financial disclosure(s) apply to this study?

Rush University Medical Center is being paid by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to conduct this research. A portion of this money may go to the study doctor to compensate for other institutional research related costs.

Will you be compensated or paid?

You will be paid for completing the five assessment visits that occur during this study. You will receive $50 total for completing both screening visits, and $50 for completing the assessment visits at the 6-month and 12-month time points. You will also receive $25 for completing the brief visits at the 3-month and 9-month time points. Again, these five assessment visits take place in your home. If your family is randomly assigned to the Medical Center Arm, you will be reimbursed for parking or public transportation (up to $8 per visit) to Rush for those treatment visits associated with this study. You may be required to provide your Social Security Number to be paid. If your payment for study participation exceeds $600 per year, this information must be reported to the Internal Revenue Service (IRS).

Your participation in this research study may contribute to the development of commercial products from which the Sponsor company or others may derive economic benefit. You will have no rights to any products, patents or discoveries arising from this research, and you will receive no economic benefit.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Please check with your insurance company regarding coverage.

If you have any medical problems during the study, please contact the study doctor. He will explain your treatment options to you and/or help you find a place to get treatment.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) also has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you tell emergency personnel of your participation in this study and notify the study doctor as soon as possible.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: Brad Appelhans, PhD (312-942-3477). Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

SIGNATURE BY THE SUBJECT:

☐ Check here when the child assent form has been completed

_____

Name of Subject (child)

_____

Parent, Guardian or Legal Representative's Signature Date of Signature

OPTION TO BE CONTACTED FOR FUTURE RESEARCH:

Please initial one of the following to indicate your choice:

_____ (initial) I **AGREE** that researchers may contact me in the future to ask me questions about my health or to ask me to participate in research.

_____ (initial) I **DO NOT AGREE** that researchers may contact me in the future to ask me questions about my health or to ask me to participate in research.

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject or the subject's legally authorized representative. I further attest that all questions asked by the subject or the subject's legal representative were answered to the best of my knowledge.

_____ _____
Signature of Individual Obtaining Consent Date of Signature

☐ *Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject or the subject's legally authorized representative and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).*

SIGNATURE BY WITNESS
(for use when the person obtaining consent is not the witness):

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the subject or the subject's legally authorized representative and the person signing the form has done so voluntarily.

_____ _____
Signature of Witness Date of Signature

☐ Check here if a separate witness signature is not necessary.

SIGNATURE OF THE PRINCIPAL INVESTIGATOR
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

_____ _____
Signature of the Principal Investigator Date of Signature

☐ Check here if Principal Investigator obtained consent and a separate signature is not required.