

Title: Eating Better Together: A Pilot Study

NCT #: NCT05028205

Document Date: 12/7/23

Consent for Research Participation

Research Study Title: Eating Better Together

Researcher(s): Hollie Raynor, PhD, RD, LDN, University of Tennessee Knoxville
Betsy Anderson Steeves, PhD, RD, Gretchen Swanson Center for Nutrition

Why am I being asked to be in this research study?

We are asking you to be in this research study because you have a child living in your house between the ages of 4 and 10 years and your child has overweight or obesity according to medical standards. We are looking for a total of 60 families to participate in this study.

What is this research study about?

The purpose of the research study is to determine if a family-based treatment program for children with overweight or obesity, that has goals for healthy eating and physical activity for both the child and adult caregiver, and includes a fruit and vegetable delivery program, can improve child weight and dietary intake at 6 months.

Who is conducting this research study?

This study is being conducted by researchers at the University of Tennessee, Knoxville, and researchers at Cherokee Health Systems.

How long will I be in the research study?

If you agree to be in the study, your participation will last for 9 months. It will involve 2 appointments with the research team, one before the program and one at the end of the program. It will also involve the treatment program with Cherokee Health Systems. The program includes 3 in-person or telehealth sessions, and 3 phone calls. The sessions and calls with Cherokee Health Systems will be one time per month.

What will happen if I say "Yes, I want to be in this research study"?

Due to COVID-19, health safety procedures may be put in place during you and your child's participation in the study. This could involve social distancing, wearing a face covering, completing health screening prior to appointments, and/or appointments or program meetings occurring remotely, which would involve online sessions with Zoom.

If you agree to be in this study, we will ask you to do two measurement appointments. These appointments will happen before the program and at the end of the program. These appointments can occur at the campus of the University of Tennessee, Cherokee Mills (a University of Tennessee site next to Cherokee Health Systems Cherokee Mills clinic), or via Zoom. At this appointment, you will complete questionnaires on information about you and your child (age, race, etc.), grocery shopping, and eating habits. This will take about 1 hour. You and your child's height and weight will also be collected. If your appointment is in person at the

University of Tennessee or Cherokee Mills, the height and weight measures can be collected at that time and will take an additional 15 minutes. If you complete your appointment via Zoom, a separate 15-minute appointment will be scheduled to collect you and your child's height and weight either at the University of Tennessee, Cherokee Mills, or your home. Appointments occurring at the University of Tennessee and Cherokee Mills will follow all required health safety procedures that are in place at the University at the time of your appointment. You will receive a \$25 gift card upon the completion of this first assessment.

Following completion of the appointment, you and your child will receive 6, monthly education newsletters on nutrition and activity topics by mail. You and your child will also be asked to come to 3, 30-minute appointments at your Cherokee Health Systems clinic (these will either be in-person or via telehealth, depending on health safety practices in place at Cherokee Health Systems at the time of your appointment) and to do 3, 20-minute phone calls. At each visit and phone call you will be working with a Behavioral Health Consultant at your Cherokee Health Systems clinic. The appointments and phone calls will be monthly, so month 1 will be an appointment, month 2 will be a phone call, etc. During the appointments and phone calls you and your child will work with the Behavioral Health Consultant to decrease sugar-sweetened beverage intake and TV watching time and increase fruit and vegetable intake and physical activity time. Over the 6-month program, you and your child will work towards meeting the following goals: < 3 sugar-sweetened beverage servings/week (child and adult); < 2 hours/day of TV watching time (child) or 10 hours/week of TV watching time (adult); $\geq 1\frac{1}{2}$ cups/day of whole vegetables and ≥ 1 cup/day of whole fruit (child) or $\geq 2\frac{1}{2}$ cups/day of whole vegetables and $\geq 1\frac{1}{2}$ cups/day of whole fruit (adult); and ≥ 60 minutes/day of physical activity (child) or 150 minutes of physical activity per week (adult).

You will also be asked to record your and your child's daily intake of sugar-sweetened beverages and fruits and vegetables, and daily minutes of physical activity and TV watching time for 6-months. You will be provided with forms to complete this. Additionally, you will be asked to measure your child's weight monthly. You will be provided tools to take home for this.

To help meet your diet goals, you will be able to order online up to \$60.00 in fresh fruit and vegetables from the Kingston Pike Food City grocery store (5941 Kingston Pike, Knoxville, TN 37919) to be delivered to your home by research staff. You can choose how to use the \$60.00 according to your family's needs (e.g., use all \$60.00 at once, use \$15.00 a week). Each week, you will receive a text message with available time slots for fruit and vegetable delivery, as well as what your remaining balance is for purchasing fresh fruits and vegetables. You will confirm your preferred delivery time via text and must send a response text by close of business (5:00PM) on the day prior to delivery to indicate your online order is complete and ready for review. When ordering online, you will be encouraged to include a note to the Food City shopper in your order that lists preferred substitutions for any out-of-stock items, as well as a request that substitutions be made in the same dollar amount as the out-of-stock item(s). You will receive one text message the morning of your fresh fruit and vegetable delivery. This text message will confirm the scheduled delivery time. Good faith efforts will be made to hand off the fresh fruits and vegetables to you in-person. However, if you are not home at the time of delivery, the produce will be left in cold storage bags on the front porch. At the end of week 4, the weekly text will also include a reminder that the \$60.00 will expire in one week if you have not spent the \$60.00 on fresh fruits and vegetables.

When you have completed the 6-month program, we will schedule another appointment with you at the campus of the University of Tennessee, Cherokee Mills, or via Zoom. Similar to the first appointment we will have you complete questionnaires and get you and your child's height and weight measurements. Appointments at the University of Tennessee and Cherokee Mills should take about 45 minutes. If you complete your appointment via Zoom, this will take about 30 minutes and a separate 15-minute appointment will be scheduled to collect you and your child's height and weight at the University of Tennessee, Cherokee Mills, or your home. You will receive a \$25 gift card upon completion of this appointment.

While participating in this study, you and your child will continue to receive your usual care at Cherokee Health Systems.

What happens if I say “No, I do not want to be in this research study”?

Being in this study is up to you. You can say no now or leave the study later. Either way, your decision won't affect your relationship with the researchers or the University of Tennessee or the care that you or any of your family members receive at Cherokee Health Systems.

Instead of being in the study, one option available to you is to talk to your child's health care provider for other ways to help with weight. Other ways that your health care provider may suggest include diets with lower daily calorie recommendations, drug interventions, and surgery.

What happens if I say “Yes” but change my mind later?

Even if you decide to be in the study now, you can change your mind and stop at any time.

If you decide to stop before the study is completed, you may contact the Healthy Eating and Activity Lab at 865-974-0752 to let us know you would no longer like to participate. Any of your information already collected for the research study will be returned to you if you request it.

Are there any possible risks to me?

It is possible that someone could find out you were in this study or see your study information, but we believe this risk is small because of the procedures we use to protect your information. The procedures are described later in this form. The diet goals provide a balanced diet, with approximately only 300-500 (child) or 500-1000 kcal (adult caregiver) per day decrease from usual intake, and so you should expect to feel hunger prior to meals. The physical activity goal is for your activity to be increased gradually over time to prevent injury. However, it is still possible that you or your child may become injured when starting to be more active, but this is a risk for any new physical activity program. A potential risk is that you and your child may not lose weight and maintain the weight loss while in the program. However, this is a potential risk in any overweight and obesity treatment program. You or your child may also lose weight too fast or report unhealthy practices for weight loss. The Behavioral Health Consultant at Cherokee Health Systems will check you and your child's weight loss and discuss with you healthy ways for weight loss. If you or your child continue to have too much weight loss or report unhealthy practices, the Behavioral Health Consultant may encourage other medical care at Cherokee Health Systems.

Are there any benefits to being in this research study?

There is a possibility that you and your child may benefit from being in the study, but there is no guarantee. Possible benefits for both you and your child include weight loss, eating a healthy diet, and being more active. Even if you don't benefit from being in the study, your participation will help us learn more about family-based childhood overweight and obesity treatment that will benefit others in the future.

Who can see or use the information collected for this research study?

We will protect the confidentiality of your information by removing any identifying information that would connect you to your data and responses. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information or what information came from you. Although it is unlikely, there are times when others may need to see the information, we collect about you. These include:

- The Institutional Review Board at the University of Tennessee, Knoxville oversees research to make sure it is conducted properly.
- Government agencies (such as the Office for Human Research Protections in the U.S. Department of Health and Human Services), and others responsible for watching over the safety, effectiveness, and conduct of the research.
- If a law or court requires us to share the information, we would have to follow that law or final court ruling.
- A description of this study will be posted on a public website, <http://ClinicalTrials.gov>, and summary results of this study will be posted on this website at the conclusion of the research. No information that can identify you will be posted.

What will happen to my information after this study is over?

We will keep your information to use for future research. Your name and other information that can directly identify you will be kept secure and stored separately from your research data collected as part of the study.

We may share your research data with other researchers without asking for your consent again, but it will not contain information that could directly identify you.

Will I be paid for being in this research study?

Families will receive a \$25 gift card to Walmart after completing the first assessment, and another \$25 gift card to WalMart when the 6-month assessments are fully completed. Gift cards will be provided after all measures have been collected at both the beginning and the end of the study. Participant name and address will be collected to assure proper delivery of the gift card.

In addition, you will receive home deliveries of fresh fruits and vegetables as part of the study. For the home delivery, you can receive up to \$60.00 worth of fresh fruits and vegetables during each month you complete a session with the Behavioral Health Consultant. If you do not

complete a session, you will not gain access to the fresh fruit and vegetable delivery program that month.

Will it cost me anything to be in this research study?

The only cost to you for this study is money spent on transportation to and from the program meetings, however, this can be offset if you choose to complete these activities by telehealth video calls.

This study is offered in addition to the medical care that you receive at Cherokee Health Systems. If you choose to receive any medical care from Cherokee Health Systems, you are responsible for the costs of medical care unless your insurance covers those costs.

What else do I need to know?

We may need to stop your participation in the study without your consent if you no longer meet the study's eligibility requirements or if the study is stopped for any reason.

If we learn about any new information that may change your mind about being in the study, we will tell you. If that happens, you may be asked to sign a new consent form.

If this study results in clinically significant results, these results will not be automatically disclosed to participants.

Who can answer my questions about this research study?

If you have questions or concerns about this study, or have experienced a research related problem or injury, contact the researchers, Dr. Hollie Raynor at 865-974-9126, ext. 1 or hraynor@utk.edu

For questions or concerns about your rights or to speak with someone other than the research team about the study, please contact:

Institutional Review Board
The University of Tennessee, Knoxville
2240 Sutherland Ave., Suite 2
Knoxville, TN 37919

Phone: 865-974-7697

Email: utkirb@utk.edu

Authorization to Collect Height and Weight

If you and your child choose to no longer participate and attend in-person sessions and/or assessments as part of this study, it would still be useful to us to know how you and your child does over the next 6 months. We'd appreciate it if you'd give your authorization for the principal investigator to continue to obtain you and your child's most current height and weight from your primary care provider.

Child height and weight

IRB NUMBER: UTK IRB-21-06251-FB
Page 5 of 8
IRB APPROVAL DATE: 12/07/2023
IRB EXPIRATION DATE: 03/15/2024

Initials _____

If my child and I choose to no longer attend in-person sessions and/or assessments as part of this study, you have my permission to collect my child's most current height and weight from my child's primary care provider.

If my child and I choose to no longer attend in-person sessions and/or assessments as part of this study, you do not have my permission to collect my child's most current height and weight from my child's primary care provider.

Caregiver height and weight

If my child and I choose to no longer attend in-person sessions and/or assessments as part of this study, you have my permission to collect my most current height and weight from my primary care provider.

If my child and I choose to no longer attend in-person sessions and/or assessments as part of this study, you do not have my permission to collect my most current height and weight from my primary care provider.

Use of Your Identifiable Health Information

A law, called the Health Information Portability and Accountability Act (HIPAA), protects your health information. When choosing to take part in this study, and providing your permission above, you are giving us permission to obtain and use your and/or your child's health information. This health information includes information in your medical records and information that can identify you (like your name, or phone number), so generally this information cannot be used in research without your written permission.

If you give your permission, your health information that will be shared with us and used in the study includes your child's height and weight and/or your height and weight.

Your health information above will be shared with us by your or your child's health care provider (as stated on the document that you complete for the study).

We may need to share your health information (height and weight) with other people or organizations. Below is a list of those people and organizations and the reasons why they may see or get your health information.

- Members of the research team and other authorized staff at the University of Tennessee, Knoxville who make sure it is safe for you to be in this study, conduct the study and analyze the research data.
- People at the University of Tennessee, Knoxville who oversee and evaluate research. This includes the ethics board and quality improvement program that work to ensure research is conducted properly.

- People from any agencies and organizations that perform independent accreditation and/or oversight of research, such as the Department of Health and Human Services, Office for Human Research Protections.
- Business offices at the University of Tennessee, Knoxville may be given your name, address, payment amount and related information.
- Groups monitoring the safety of this study.

Some of these people or organizations that may see or get your health information may not have to follow the same privacy laws and protect your information in the same way that we will. Your health information will not be shared with anyone else without your permission unless all information that can identify you is removed.

Your permission to use and share your health information for this study will continue until the research study ends and will not expire unless you cancel it sooner. Researchers continue to analyze data for many years, and it is not possible to know when they will be completely done.

Can I change my mind about the use of my health information?

At any time, you may change your mind and withdraw your permission for your health care provider(s) to share or use your health information (height and weight) for the research; however you cannot get back information that was already shared.

To takeback your permission, you must write the researcher and tell him or her of your decision. You should also send a copy of this written notification to your health care providers. In the letter, state that you changed your mind and do not want any more of your health information shared or collected.

Dr. Hollie Raynor, 1215 Cumberland Ave, 229 JHB, Knoxville TN, 37996; hraynor@utk.edu

Once you take away your permission, no new health information will be shared with us. However, health information that has already been collected or shared with us may still be used as necessary to maintain the integrity of the research and as required by law. Also, if you take away your permission, you may not be able to stay in the research study.

You do not have to allow use of your health information. If you do not allow use of your health information, it will not affect your relationship with the researchers, the University of Tennessee, your health care provider(s) or any of the services and benefits you and your family receive from them in any way.

You have the right to see and copy your health information that is shared or used in this study. However, in order to complete the research, your access to this information may be restricted during the conduct of the study to maintain the integrity of the research. When the study is completed, you will be able to access to this information.

STATEMENT OF CONSENT

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 contact. By signing this document, I am agreeing to be in this study. I will receive a copy of this document after I sign it.

Name of Adult Participant

Signature of Adult Participant

Date

Researcher Signature

I have explained the study to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to be in the study.

Name of Research Team Member

Signature of Research Team Member

Date