Changing Health and Lifestyle Behaviors in Offspring Following Maternal Bariatric Surgery (HALO-2)

Clinicaltrials.gov NCT05350267

Unique Protocol ID 2021-0601

Informed Consent Version 4.4 (01/04/2024)

Title of research study: **Changing Health and Lifestyle Behaviors in Offspring Following Maternal Bariatric Surgery**

(HALO-2 Study)

Key Information:

Investigator: Dr. Meg Zeller

Contact Info: 513-636-2712

Funding: NIDDK; Grant R01DK128525

The following is a short summary of this study to help you decide whether to be a participant in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

COMBINED Parental Permission/Assent: If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this form, we mean you or your child; "we" means the study doctor and other staff.

Reason for the study:

The main reason for this research study is to test a new program (Health and Lifestyle Behaviors in Offspring, or "HALO") designed for mothers who recently had bariatric surgery who have a school-aged child. HALO focuses on providing each mother with education and parenting strategies to improve her child's healthy lifestyle behaviors, such as her child's eating and physical activity, while she is engaged in her own lifestyle behavior change after bariatric surgery. For this part of the HALO program development, mothers will be randomly assigned to one of two groups. Group 1 will receive monthly mailings that include educational handouts focused on healthy eating, physical activity, screen time, and sleep habits for children ages 6-12 years. Group 2 will have access to a special HALO website with customized educational materials and activities and meet with a Health Coach, weekly online. Ultimately, we are testing whether participating in the HALO program results in improved health habits and/or weight for her child. To date, there are no other family-based treatments designed for mothers who recently had bariatric surgery focused on also improving child health outcomes.

Procedures:

To start the study, all mothers and children will schedule and complete two study visits. First, members of the HALO team will come to your home and mothers will fill out questionnaires on a HALO provided laptop, and complete a home food inventory via paper/pencil. If eligible you and your child will be invited to participate in an optional Part 2 of the study, called HALO-E. HALO-E involves completing additional questionnaires. Both you and your child will have your heights and weights measured. You and your child will be provided with a waist-worn activity tracker which you will wear for one week, which you will return via a provided pre-paid mailing envelope.

For the second visit, you and your child will meet with the HALO-Coordinator via video-conferencing from your home. During this visit you will talk with a dietician about what you and your child typically eat over a 24-hour day (a "dietary recall"). Two additional phone-based dietary recalls (for a total of three 24-hour dietary recalls), scheduled at a

time convenient for you during the following week, will be completed by phone with the dietician. You will then be shown two videos which explain more about how the study works and introduces you to the HALO-Pediatrician, who will explain the goals of HALO and how they relate to your child's health.

Once these study visits are completed, you will be randomly assigned to one of two study groups. Over 26 weeks, participants in Group 1 will receive monthly mailings that include educational handouts focused on healthy eating, physical activity, screen time, and sleep habits for children ages 6-12 years. Over 26 weeks, participants in Group 2 will have access to a HALO iPad and a HALO website with customized educational materials and activities. They will also meet with Health Coach, weekly online. All participants (i.e., both groups) will repeat the home-based study visit (questionnaires, home food inventory, dietary recalls, activity tracking) again at the end of the 26 weeks.

All participants will complete a final follow-up home-based study visit again at 52 weeks (I.e., 1 year), marking the end of the study.

Participation requires that women:

- Have recently undergone a bariatric surgery procedure (e.g., Roux-en-Y gastric bypass, sleeve gastrectomy) that did not involve a device (e.g., balloon, gastric band)
- Are 3-12 months post-surgery at enrollment
- Read, write, and speak in English
- Are not currently pregnant
- Live within 75 miles of the CCHMC main campus
- Have a biological child aged 6-12 years who lives in her home $\geq$ 75% of the time (at least 5 days a week). For HALO-E women must have a biological child aged 8-12 years old

Participation requires that her child:

- Has a body mass index (BMI, a weight to height ratio) $\geq$ the 70th and < 120% of the 95th percentile for their age and sex
- Is not currently participating in supervised weight management care (behavioral, medication-assisted)
- Has no other chronic medical condition or developmental disabilities
- Is willing to participate

We expect that you and your child will be in this research study for 52 weeks (i.e., 1 year).

More detailed information about the study procedures can be found under ***"(Detailed Procedures)".***

Risks to Participate:

There are minimal risks to participate in this study. The questionnaires used in this study have been used in research without any reported negative effects. You can refuse to answer questions for any reason during the study. More detailed information about the risks to participation can be found under "(Detailed Risks)".

Benefits to Participate:

We cannot promise any benefits to you or others from your taking part in this research. However, potential benefits may include improved knowledge of nutrition and physical activity for you and your child. Additional benefits may include improved health habits and/or weight for your child. The information learned from this research study may improve future interventions designed for people who have undergone bariatric surgery and have children living in their home.

Other Options:

Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you or your child receive. Your alternative to participating in this research study is to not participate.

Cost to Participate:

There are no costs for participating in this research study, with the exception of the time spent to complete study procedures.

Payment:

If you agree to take part in this research study, and whether in Group 1 or Group 2, we will pay you up to $326 for your time and effort. The payment schedule for completed study visits is included in the table below on page 5 within the Detailed Procedures section. You will receive payments 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, Cincinnati Children's 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 will need to complete a Federal W-9 form for this income tax reporting. This form requires your child's Social Security number. This form will be given to the Cincinnati Children's Hospital business office. It will not be kept as part of your child's study chart. If you move, you will need to complete another W-9 with an updated address.

Additional Study Information:

The following is more detailed information about this study in addition to the Key Information. ***If I have Questions or would like to know about:***

Who to talk to…	**You can call …**	**At …**
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Dr. Meg Zeller** Principal Investigator	Phone: 513-636-2712
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Jennifer Knox** Study Coordinator **Daniella Hamden** Study Coordinator	Phone: 513-415-4805 Phone: 513-846-3645

• Your child's rights as a research participant	**Institutional Review Board** This is a group of scientists and community members who make sure research meets legal and ethical standards.	Phone: (513) 636-8039

Total number of participants:

Approximately 50 women who recently underwent bariatric surgery who have a child between the ages 6 and 12 years will be enrolled in the HALO study. Of the 50 women enrolled in HALO-2, 30 women with children 8-12 years old will be enrolled in HALO-E.

Detailed Procedures:

Baseline Study Visits For All Participants: For the first study visit, study staff will come to your home and assist you with completing questionnaires about you, your child, your family, and the foods in your home for HALO-2 and HALO-E (if eligible and willing to participate). You will also sign a "release of information", allowing study staff to contact your bariatric surgery program to obtain your last recorded height and weight before you had surgery. Your and your child's heights and weights will also be measured. Finally, you and your child will each be provided with a waist-worn activity tracker and instructions for use, which are to be worn daily for one-week when you are awake. You will be asked to return the activity trackers to study staff in a pre-paid mailing envelope. For the second visit, you and your child will meet with the HALO-Coordinator via video-conferencing from your home computer. During this visit you will talk with a dietician about what you and your child typically eat over a 24-hour day (a "dietary recall"). Two additional phone-based dietary recalls (for a total of three 24-hour dietary recalls), scheduled at a time convenient for you during the following week, will be completed by phone with the dietician. You will then be shown two videos which explain more about how the study works, and introduces you to the HALO-Pediatrician, who will explain the goals of HALO and how they relate to your child's health. In the event you do not have a home computer, the HALO Coordinator will return to your home with a laptop to complete this visit.

After these study procedures are complete you will be randomly assigned to either HALO Group 1 or HALO Group 2. Which group you get assigned to will be by chance, like flipping a coin. Neither you nor the study investigator will choose which group you get. You will have an equal chance of being in either group. You will be told which group you are in.

HALO Group 1 (Weeks 1-24):

- ***If you are assigned to Group 1,*** each month you will receive HALO mailings that will include educational handouts on supporting healthy eating, physical activity, screen time, and sleep habits for children ages 6-12.
- Each month you will be asked to complete a brief online questionnaire.
- You can reach out to the HALO study team via email if there are questions about

the materials provided.

HALO Group 2 (Weeks 1-24):

Daily

If you are in Group 2, you will track HALO focused eating and activity behaviors through an electronic tracker ("eTracker") accessed on a study-issued iPad or personal smart device.

Weeks 1-16

- You will meet with a HALO Health Coach via telehealth. During this visit you will access the HALO website using your study-issued iPad to watch a HALO educational video, immediately followed by a brief online questionnaire. Videos focus on healthy eating, physical activity, screen time, and sleep habits for children ages 6-12.
- Then you will talk about the video and how to apply what you've learned to make changes to your child's eating and activity behavior.
- At week 10, members of the study team will come to your home to measure your child's height and weight.

Weeks 16-24

- You will complete up to four additional biweekly online Health Coach sessions (planned for Weeks 18, 20, 22, 24) for continued support and answer questions you may have.
- At week 26 you will return the study issued iPad to the HALO team.

Follow-up Study Visits For All Participants: At week 26 and again at week 52, study staff will come to your home and you will complete follow-up questionnaires and have your and your child's heights and weights measured. At both time-points the study dietician will call you to complete a set of three phone-based 24-hour dietary recalls at a time that is convenient for you. Additionally, you and your child will wear a waist-worn activity tracker while awake for one week. To learn more about the experience of mothers and their families, after the study is completed, we will use your zip code and match it to U.S. national census data to identify geographic and socioeconomic characteristics of people living in your area. No follow up will be conducted for Part 2 of the study (HALO-E). HALO-E procedures will only occur at the baseline visit. Finally, no genetic testing will be done during this study.

<table>
<tr><td rowspan="3">At Home</td><td rowspan="3">Baseline Study Visit 1 with HALO Staff</td><td>Height and Weight Measured
Study Questionnaires
Home Food Inventory  </td><td rowspan="2">$30</td></tr>
<tr><td>Wear Activity Trackers for 1-week
• Return Activity Tracker by provided FedEx packet or Coordinator pick-up</td></tr>
<tr><td>HALO-E Study Questionnaires (Opt-in if qualify)</td><td>$25</td></tr>
<tr><td>At Home</td><td>Virtual Baseline Study Visit 2</td><td>Video call with Study Dietician
Watch Videos, Introduction to HALO-Pediatrician</td><td>  </td></tr>
</table>

		Dietary recalls by phone 	$25
		You will be randomly assigned to **Group 1** or **Group 2** (Like flipping a coin)	
Group 1	Months 1-6	**Group 1:** Mailed monthly educational materials. Online questionnaire, monthly across 6 months at $16 each	**Group 1:** Up to $96
Group 2	Weeks 1-16	**Group 2:** HALO educational videos and Health Coach sessions Week 10 Child Height Weight Measure. Online questionaires, weekly across Weeks 1 -16 at $6 each	**Group 2:** Up to $96
At Home	Week 26	Height and Weight Measured Study Questionnaires Home Food Inventory 	$70
		Dietary recalls by phone Wear Activity Tracker Return Activity Tracker by provided FedEx packet or Coordinator pick-up	
At Home	Week 52	Height and Weight Measured Study Questionnaires Home Food Inventory 	$80
		Dietary recalls by phone Wear Activity Tracker Return Activity Tracker by provided FedEx packet or Coordinator pick-up	

Will I be involved in future research studies? There may be other studies in the future that you would be eligible for. By signing this consent form, you are agreeing for researchers at CCHMC to contact you to offer you the opportunity to participate in future research projects. By signing this consent form you ARE NOT agreeing to participate in any future projects, you are only agreeing that you may be contacted.

Change of Mind/Study Withdrawal:
You and your child can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can document that you are no longer interested in participating in the study.
The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include: the study pediatrician determines that it is in you and/or your child's medical best interest, the study ended early for any reason, or new information becomes available.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

Detailed Risks:

LESS COMMON, LESS SERIOUS
• Psychological risk: Discomfort while completing study questionnaires or intervention participation due to content or time commitment (rare). • Physical risk: Risk of an injury resulting from increasing physical activity or minor discomfort while wearing the waist-worn activity tracker (rare). • Privacy risks: Loss of confidentially (rare). • Unknown or unforeseen risks associated with study participation.

Privacy:

In the HALO study, to learn more about the experience of mothers and their families we will use your zip code only and match it to U.S. national census data to identify geographic and socioeconomic characteristics of people living in your area. No other identifying data such as your name, date of birth, full address, phone numbers, or social security number will be used in the HALO study.

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. That your family is a participant in this study will be included in your child's medical record. We will make every effort to keep confidential all research information in the medical record that identify you/your child to the extent allowed by law. We cannot promise complete privacy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

In order to maximize protection of privacy and confidentiality, HALO study staff will execute the following study procedures. Informed consent documents with identifying information will be locked in file cabinets separate from any data. Each participant will be assigned a unique study identifier code (ID). This unique identify code will be used to log into the HALO website. A master key linking identifying participant information and study ID will be secured in a locked computer file, separate from the data. All questionnaires will be coded only with this ID number. These original forms will also be stored in locked file cabinets. Only study personnel will have access to the offices and file cabinets. Recordings of the Health Coach sessions will be kept on a password-protected electronic file that is stored on a secured server. When utilizing the web-site, only participant identification numbers provided by the HALO Coordinator will be used. Intervention sessions will be delivered via Zoom for Healthcare™, a HIPAA-compliant videoconferencing software.

There are some limitations to confidentiality for the research study. If a participant (child and mother) reveals intent to harm themselves or others or actual harm (e.g., abuse, neglect, suicidal behaviors), we must disclose this information to ensure your and your child's safety.

Additionally, because the HALO baseline assessment (visit #2) and program (Group 2 only) are delivered virtually via telehealth, we will need some identifying information (i.e., cell phone number, email address) to send you study questionnaires and invitations to Zoom for Healthcare™ sessions. We will make every effort to keep these confidential but cannot guarantee that they will be. For Group 2, your Health Coach will also need this information to contact you during the intervention period.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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?

Cincinnati Children's Hospital Medical Center (Cincinnati Children's) will need to use and share your PHI as part of this study.

This PHI will come from:

- Your Cincinnati Children's medical records
- Your research records
- Study questionnaires, dietary recalls, and activity tracker

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications

Who will share, receive and/or use your protected health information in this study?

- Staff at all the research study sites (including Cincinnati Children's)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

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.

Will your child's other medical care be impacted?

By signing this document, you / your child agree to participate in this research study and give permission to Cincinnati Children's to use and share you/your child's PHI for the purpose of this research study. If you refuse to sign this document you/your child will not be able to participate in the study. However, you/your child's 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/your child should participate in this research, you will document your permission 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 / Parental Permission — Date

_____ _____
Signature of Parent or 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