



Study Title: Healthy Eating for My Infant: A Community- Informed Infant Obesity Prevention Program
Addressing the Impact of Maternal Mental Health on Eating and Feeding

NCT Number: not yet assigned

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Parent Permission for Child's Participation in Research
University of Cincinnati
Department: Psychology
Principal Investigator: Cathleen Stough, PhD

Title of Study: Reducing Health Disparities through an Adaptive Healthy Eating Program for Underserved Infants in a Home Visiting Program (Phase II)

Introduction:

You are being asked to take part in and allow your child to take part in a research study. Please read this paper carefully and ask questions about anything that you do not understand.

This research is sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases.

Who is doing this research study?

The person in charge of this research study is Cathleen Stough, PhD, of the University of Cincinnati (UC) Department of Psychology. There may be other people on the research team helping at different times during the study.

What is the purpose of this research study?

We have made a program to help support families in healthy eating for their babies. Some families will receive the program and other families will not, and we will look to see how the program might be helpful for children's health. The program will talk about things like what to feed your baby, how to feed your baby, and common challenges families run into when trying to do these things. The program also helps to support and empower families to make the changes they are interested in making and set their own goals.

Who will be in this research study?

About 60 children will take part in this study. Your baby may be in this study if they are 2 months old at the time of your first study visit, were a single birth (not a twin or multiple birth) and have no major medical conditions requiring specialized feeding. You (the parent) must also be a fluent English or Spanish speaker and an adult (over age 18). You must also not currently be receiving grocery home delivery.

What will you and your child be asked to do in this research study, and how long will it take?

All families will do 3 study visits when your baby is 2, 15, and 21 months old. The first visit will take about 90 minutes. The other visits will take about 60 minutes. In the visit you will:

- In the first visit, you will complete informed consent.
- You will complete a survey about basic information about yourself and your baby (such as age, gender, race), your feeding of your baby, your babies eating behavior, your stress and adjustment as a parent, and access to food/food security.
- We will also measure your baby's weight and length. We may also access measurements of your baby's weight and length from health care visits they have at Cincinnati Children's Hospital Medical Center or their pediatrician's primary care office.
- Within 2 weeks of each of the visits, you will complete 3 interviews about what your baby ate the day before by phone.

Some families will also be part of a healthy eating program for 24 sessions, but some families will not do



this part. It is decided at random who does the program; it is like a coin toss. You will find out at the first visit whether your family will be part of the program. Which group you are in will not change anything about the *Every Child Succeeds (ECS)* program you are already in. All families will continue to be in the *ECS* program.

If you are in our healthy eating program, you will do twenty-four 1-hour long visits when your child is 3-14 months of age, with 2 sessions per month. These visits will happen in addition to your usual *ECS* visits. You will have 2 counselors who will work with you, a peer counselor and someone from the UC study team. We will talk about child nutrition, feeding your child, what to do at mealtimes, and things that can make it harder for your family to reach their healthy eating goals (e.g., stress, mental health). We will work with you to help you set goals for your baby that you want to work towards. The program also includes assistance with groceries through free Kroger delivery and \$35 every other week for purchasing Kroger groceries. We will have you login to your Kroger account at each session and will directly load the \$35 payments for each session into your account. We will make audio recordings of the treatment sessions so we can look at how well our staff are giving the program. This recording will not be stored with your name. Recording will be listened to only by our research staff, who are paying attention to the interventionists' work rather than family responses (e.g., like a shadow visit for an *ECS* visit). Families who receive the program will also give feedback on how they liked the intervention at their last study visit. Families receiving the program and grocery delivery will also be asked to provide us information about purchases made using the grocery delivery at the post-treatment and 6 month follow-up visits. At those visits, you will log into your Kroger account, and we will download purchase data for the grocery delivery orders. We will only collect information about the grocery deliveries and will not collect any other information from your account.

Families who are not participating in the healthy eating program will complete monthly phone calls with study staff lasting approximately 10 minutes each. During these phone calls, we will ask you questions about your child's health and how you feel about feeding your child.

Being in the study will take about 30 hours if you receive the intervention and about 6 hours if you do not receive the intervention.

We may contact you in the future about being part of future research studies (e.g., to see how your baby is growing and doing after being part of our study). We will use the most recent contact information *ECS* has for you to reach out to you. If you do not want to be contacted about possible future research opportunities, tell us at your last study visit. This will not have an impact on whether you can participate in this current study or in the *ECS* program.

Are there any risks to being in this research study?

People from our study will come to your home to do the study. This may make some people uncomfortable. People from our study will take safety precautions when coming to your house to avoid bringing illness into your home, but this is still a risk.

If you do the program, you will talk about things like mental health and stress, which may make some people feel uncomfortable. We can provide you information about supports to help you get care for your mental health. Part of the intervention will be done by a peer counselor, who may be someone who lives in your community. We will try to make sure this is someone you do not know. All peer counselors learn how to keep people's information private in case they do see you in a different place outside the



intervention or if they do already know the person.

There may be other risks we do not know about yet. There is an outside person not involved with our study who will help us identify if there are any risks of the program.

Are there any benefits from being in this research study?

You may not get any benefit of being in this study. If you are in the program, you will receive information about how to help your child eat healthy. Being in this study may help people in the future with ways to help their child be healthy and may help reduce later risk for obesity.

What will you get because of being in this research study?

You will receive either a 1-year membership to the Kroger boost program (value ~\$100) or a \$100 gift card for completion of the first visit. You will also receive a \$50 gift card for completing the second visit, and a \$100 gift card for completing the final visit.

Do you and your child have choices about taking part in this research study?

If you do not want to take part in this research study, there will be no impact to your ability to receive services in the *ECS* program. You may simply choose not to participate.

How will your and your child's research information be kept confidential?

Information about you will be kept private by using a study ID number on the research forms instead of using your name or your child's name. We will keep a list of names and study ID numbers in a separate place than the research forms. Only the research team and peer counselors will know your identity and information will be kept private. The only exception to maintaining your information private is if we notice during the study that a child is being abused or neglected.

We will do these things to keep your data safe and confidential:

- Your information will be kept in a research lab at UC.
- Paper copies of data will be kept in a locked filing cabinet in the research lab at UC.
- Electronic data will be stored on either password protected computers or a secure network drive.
- Audio recording of treatment sessions will be stored electronically on the secure UC network drive. These will be stored in a separate folder from any other participant data or names. Only study staff will have access to these recordings.
- Consent forms will be stored separately from study data.

All data will be de-identified following completion of study analyses and publication with the exception of the document linking study ID numbers to participant names and the audio recordings.

- Paper copies of data, consent forms, and the document linking study ID numbers to participant names will be destroyed through secure shredding 5 years following the last publication of study results.

The data from this research study may be published; but we will not say who the participants were. People at the University of Cincinnati and the National Institutes of Health may look at the study records. De-identified data from the project will also be deposited in UCFigshare, a University of Cincinnati (UC) data repository for NIH-sponsored research at UC. UCFigshare is a platform for accessible and interoperable data sharing and available publicly at <https://uc.figshare.com/>.

**What are your and your child's legal rights in this research study?**

You keep all your legal rights in this study. The researchers, people funding the research, and the institutions are responsible if something happens (e.g., breach of confidentiality).

What if you or your child has questions about this research study?

If you have any questions or concerns about this research study, you should contact Cathleen Stough, PhD, at Cathleen.Stough@uc.edu or 513-556-5589.

The UC Institutional Review Board reviews all research projects that involve human participants to be sure the rights and welfare of participants are protected. This research study has been registered on ClinicalTrials.gov, a private U.S. registry of clinical trials.

If you have questions about your child's rights as a participant, complaints and/or suggestions about the study, you may contact the UC IRB at (513) 558-5259. Or you may call the UC Research Compliance Hotline at (800) 889-1547, or write to the IRB, 300 University Hall, ML 0567, 51 Goodman Drive, Cincinnati, OH 45221-0567, or email the IRB office at irb@ucmail.uc.edu.

Do you or your child HAVE to take part in this research study?

No one has to be in this research study. Refusing to take part will NOT cause any penalty or loss of benefits that you or your child would otherwise have.

You may give your permission and then change your mind and take your child out of this study at any time. To take your child out of the study, you should tell Cathleen Stough (Cathleen.Stough@uc.edu, 513-556-5589) or tell the research assistant when they call you about a visit.

Agreement:

I have read this information and have received answers to any questions I asked. I give my permission for my child to participate in this research study. I will receive a copy of this signed and dated Parent Permission form to keep.

You Child's Name (please print) _____

Your Child's Date of Birth _____ (Month / Day / Year)

Parent/Legal Guardian's Signature _____ Date _____

Signature of Person Obtaining Permission _____ Date _____