Principal Investigator: Matthew Haemer MD MPH
COMIRB No: 21-3721
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Study Title: Family Inclusive Childhood Obesity Treatment Designed for Low Income and Hispanic Families

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You and/or your child are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about how the Healthy Living Program (HeLP) compares to counseling about weight by your child's medical provider. The results will compare how well the two programs help you and your child make healthy lifestyle changes and either make progress toward, or stay at, a healthy weight.

You are being asked to be in this research study because you have a child between the ages of 2-16 years of age at or near an unhealthy weight who was referred to the study by your child's primary care provider.

Up to *658* people will participate in the study:

Up to 329 will participate in the Healthy Living Program FIRST.

Up to 215 children: unhealthy weight

Up to 114 children: siblings of the child who was referred

Up to 329 will participate in visits to their primary care provider, FIRST, followed by the Healthy Living Program.

Up to 215 children: unhealthy weight

Up to 114 children siblings of the child who was referred

What happens if I join this study?

If you join the study, you will either participate in the Healthy Living Program right away or visits with your child's doctor to set healthy lifestyle goals for 18 months. **If you start the study with visits with your child's provider, you will be able to participate in the Healthy Living Program after 18 months.**

<u>If you join the study you and your children will:</u>

- Complete 6-7 surveys at the beginning of the study and at 12 months:

- Demographic survey: Race, ethnicity, country of origin, income, education level, number of adults and children in home, public vs. private health insurance, use of public benefits (WIC, SNAP, TANF), and food insecurity.
- Two Surveys about cultural and family values
- A survey about the weight related quality of life of your child
- A survey about the mental health of your child
- Two surveys about your home environment and attitudes and habits around food

- Have your weight, height, and waist circumference measured up to 3 times in 18 months. It is up to you if you want to know your measurements. Your measurements will be taken privately and stored securely so that only the research team sees them.

Authorization for parental height, weight, waist circumference:

Parent #1: _____

Parent #2: _____

- Children 10 years and older will be asked to complete up to 4 surveys during the study (beginning, 12, and 18 months).
  - A survey about their weight-related quality of life
  - A survey about their mental health
  - Two surveys about the home environment and attitudes and habits around food
- children that are 2-16 years old will get their weight and height measured every 1 to 2 months for up to 18 months.
- children that are 7-16 years old will do exercise tests that are similar to what they do in a typical school gym class.
- During the course of your participation in this study, you may have one visit with your Primary Care Provider that will be audio recorded.
  - Recordings will be stored on a secure server at the University of Colorado Anschutz Medical Campus; transcripts will be kept under lock and key. If you do not consent to be audio recorded, you may still participate in the study.

Please initial here if you agree to be audio recorded: _____

Researchers will look at changes in BMI, lifestyle habits and attitudes around food over a period of 18 months. They will also have access to your children's electronic health records to learn about BMI and blood test changes during this period of time.

If you are in the Healthy Living Program you and your children will participate in:

- Twelve weekly 2 hour evening classes at a Rec Center where you and your family will join five to ten other families to:
  - Learn parenting skills, nutrition, and family fitness.
  - Children 3-6 years old will attend their own classes where they will learn about new foods and exercises.

- Researchers will ask you to report any food allergies before offering any foods. Children will be offered the food. Children will not be forced to eat in any way.
- Children 7 and up will participate in fun physical activity sessions with a trained fitness professional.
- Parents and children 7 and up will learn how to shop for, prepare, and cook healthy food.
- Children 10 and up will participate in mindfulness training designed to reduce stress.

- Participate in 3 Healthy Living Program reunion classes with your group within 18 months.

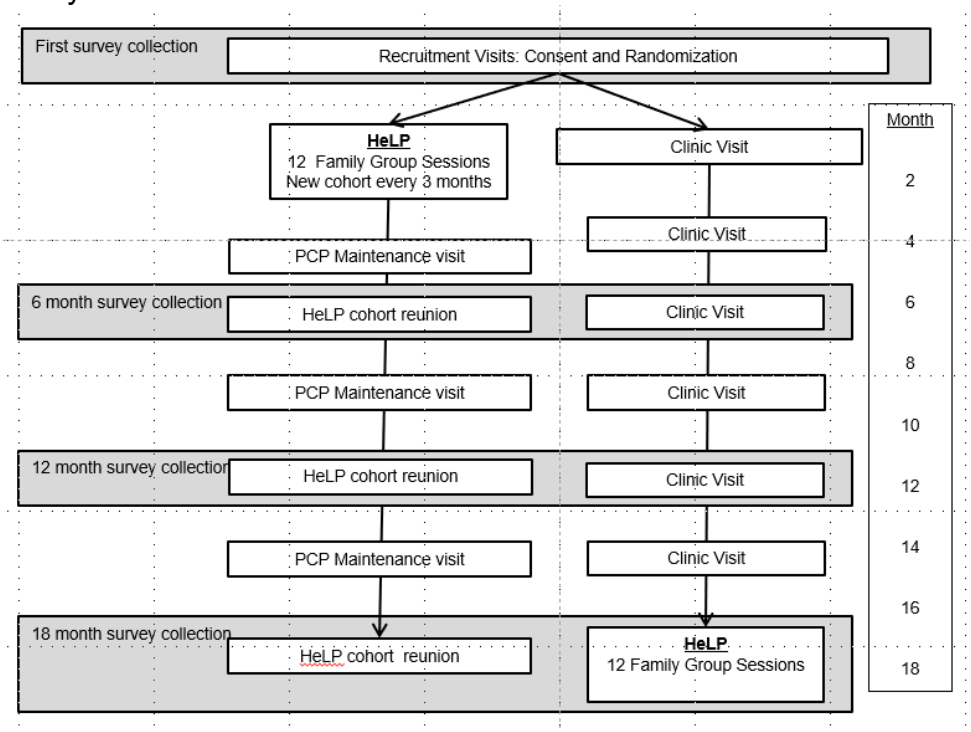
<u>If your family is randomized to start with visits with your child's primary care provider, you will:</u>

- Bring your child to your primary care clinic for check-ups every 3 months.
- Set healthy lifestyle goals with your child's primary care provider.
- Participate in the Healthy Living Program after 18 months of visits with your child's provider.

Length of Study:

Study participation will last up to 36 months.

Study Timeline:



What are the possible discomforts or risks?

Discomforts your children may experience while in this study include mild discomfort in performing the physical fitness test. These fitness activities are similar to what many children perform in school gym class. The test includes push-ups, sit ups, stretching, and running or jogging. Trained fitness professionals will guide your child to complete the test. Sprains, strains, and fractures are rare but possible in any physical fitness program. The Healthy Living Program fitness tests are designed to minimize these risks.

Other possible risks include what you may experience while participating in a cooking class. These risks include accidents and injuries related to food preparation, cooking, and eating. Families will be using kitchen tools, knives, stoves, and electronic kitchen equipment as well as eating raw or uncooked foods (example: salads, vegetables).

If the results of the questionnaires indicate that your child may be at risk of mood or behavior problems, we will inform you and the child's primary care provider so that you can seek additional diagnosis and care if needed. If you or your medical provider have concerns that your child needs extra mental health support, this is available through your child's primary care clinic at Kid's First Health, Clinica Family Health, or Every Child Pediatrics.

What are the possible benefits of the study?

Possible benefits for parents who participate in this study include more knowledge about healthy lifestyle and how to make healthy changes with their families.

Possible benefits for children who participate in this study include improved health related to their weight status, improved quality of life, and reduced risk of contracting chronic illnesses related to unhealthy weight (i.e. Type 2 Diabetes and heart disease)

This study is designed for the researcher to learn more about how to help families make healthy eating and activity changes in the community setting.

Are there alternative treatments?

If you choose not to sign the consent or if your child develops a severe medical problem due to obesity like diabetes, your child may be able to receive care for their weight gain or obesity through avenues within Children's Hospital or with their Primary Care Provider.

Who is paying for this study?

- This research is being paid for by the National Institute of Health (NIH), a branch of the U.S. Department of Health and Human Services and is dedicated to improving health for Americans.

Will I be paid for being in the study? Will I have to pay for anything?

You will be paid $50 at the enrollment visit, and visits at 6 months, 12 months, and 18 months for a total of $200 by the time you have completed the study.

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

- If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study? The Principal Investigator may decide to stop your participation without your permission if they think that being in the study may cause you or your child harm, if your child is not a patient at one of the participating clinics (Kids First Health clinics, Clinica Family Health, and Every Child Pediatrics), or for any other reason.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. Matthew Haemer at 720-777-7474. Healthy Living Program staff will communicate with your primary care provider about any injury suffered during the program to arrange follow-up care.

- The University has no plan to pay for a physical or psychological injury.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Matthew Haemer. You may ask any questions you have now. If you have questions later, you may call Dr. Matthew Haemer at 720-777-7474 or Program Manager Emily Steen at 303-214-8091.

You may have questions about your rights as someone in this study. You can call Dr. Matthew Haemer with questions. You can also call the Multiple Institutional Review Board (IRB) at 303-724-1055.

Certificate of Confidentiality

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research,
- If required by Federal, State or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and the health systems it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver

We cannot do this study without your permission to see, use, and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate health systems may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Matthew Haemer
Pediatrics/Section of Nutrition
University of Colorado Denver
12631 E. 17th Ave F561
Aurora, CO. 80045

Both the research records that identify you and the consent form signed by you may be looked at by others.

- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- *National Institutes of Health (NIH)*, who is the company paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

- Some things we cannot keep private. If you give us any information about child abuse or neglect we have to report that to Social Services. Also, if we get a court order to turn over your study records, we will have to do that.
- If you tell us you are going to physically hurt yourself or someone else, we have to report that to the state police. Also, if we get a court order to turn over your study records, we will have to do that.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study has been completed.

Information about me and/or my child that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of my previous and current Medical Records that are relevant to this study, including but not limited to diagnoses, physical measurements, laboratory studies, nutrition and activity screening forms
- Research Visit and Research Test records
- Psychological tests
- Billing or financial information
- Responses to questionnaires

What happens to Data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you and your children during this study are important to this study and to future research. If you join this study:

- The data that are given by you to the investigators for this research and so no longer belongs to you.
- Both the investigators and the National Institutes of Health, the sponsor of this research, may study data collected from you.
- If data are in a form that identifies you or your child, the University or the health systems involved in this study may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a copy of this consent form.

Child's Name: _____

Print Parent/Guardian Name:_____

Parent/Guardian #1 Signature:_____Date:_
_____

Print Parent/Guardian #2 Name: _____

(If available) Parent/Guardian #2 Signature:
_____Date:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Researcher:_____ Date:_____

[BELOW: Signature Line for studies with children ages 13-18 who can read this form (children 7-13 should sign a SEPARATE assent form; for children 0-7, the parents are consented.)

_____ Date_____
Child

Consent form explained by: _____

Print Name _____ Date_____

Researcher _____ Date _____