Principal Investigator: Matthew Haemer MD MPH
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Study Title: Family Inclusive Childhood Obesity Treatment Designed for Low Income and Hispanic Families

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You 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 effective a family group program, the Healthy Living Program/La Vida Saludable (HeLP), is compared to a protocol of motivational interviewing (MI) delivered by primary care providers to treat childhood obesity. To better understand the effectiveness of HeLP vs. primary care MI, this portion of the study will focus on the adoption and implementation of the MI intervention by providers at participating clinics.

You are being asked to be in this research study because you are a pediatric primary care provider.

Up to 100 providers will participate in the study.

What happens if I join this study?

If you join the study, you will complete four 1-hour Continuing Medical Education trainings (certified 4.0 AMA CME) about Motivational Interviewing (MI) and treatment of childhood obesity in primary care. You will refer eligible patients with overweight or obesity to attend HeLP. Your patients will be randomized to attend HeLP immediately or to attend primary care MI visits at least every 3 months, and then will be offered to attend HeLP after 18 months of treatment in primary care.

You will complete a survey at the beginning in which you will be asked for basic demographic information and characteristics of your practice. At the 12 and 36-month timepoints, we will contact a subset of participating providers to complete 30-minute recorded interviews about their experience implementing the MI intervention and making referrals to HeLP (immediate vs delayed).

You will learn motivational interviewing techniques and healthy lifestyle counseling skills and have the opportunity to practice these during the trainings. During the course of your participation in this study, you may be asked to have up to 3 visits with patients

audio recorded to measure fidelity to the intervention protocol. The study team may also observe the time you spend delivering care to patients with obesity at up to 3 separate visits.

Recordings will be stored on a secure server at the University of Colorado Anschutz Medical Campus; transcripts will be kept under lock and key. The study team will not be in the room with you and your patients during visits that are audio-recorded or when they are tracking your time delivering care. If you do not consent to be audio recorded, you may still participate in the survey and MI and enhanced primary care training.

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

Your participation will last up to 5 years

What are the possible discomforts or risks?

Discomforts you may experience while in this study include you may not feel comfortable responding to all of the questions. If you feel uncomfortable, please feel free to ask the interviewer to clarify the question or you may choose not to answer. Another possible discomfort may be your time spent during training. The time you spend in training, instead of direct patient care, will be reimbursed to your practice at your typical hourly billing rate. You also may feel discomfort discussing your usual medical practice or attempts to change that practice, but we will make every effort to maintain a non-judgmental tone to our discussions. Otherwise, we do not expect your risks or discomforts to be more than those you already experience in everyday life.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about the efficacy of HeLP vs. primary care MI counseling to treat childhood obesity. The possible benefits of the study for primary care providers will be to receive AMA certified Continuing Medical Education credits for training to improve MI counseling skills and to gain an increased understanding of potentially effective childhood obesity treatment in primary care.

Who is paying for this study?

- This research is being paid for by the National Institutes of Health (NIH).

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

You will receive up to 4.0 AMA certified Continuing Medical Education credits for participating in the four 1-hour trainings. The value of each CME credit hour is $100. For participating in the semi-structured key informant interviews, you will receive a $50 gift card for your time.

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.

Who do I call if I have questions?

The researcher carrying out this study is Matthew Haemer MD MPH. You may ask any questions you have now. If you have questions later, you may call Dr. Matthew Haemer at 720-777-7474 or Professional Research Assistant 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). You can call them 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?

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

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

- Federal agencies that monitor human subject research
- Human Subject Research Committee
- The group doing the study
- The group paying for the study
- Regulatory officials from the institution where the research is being conducted who want to make sure the research is safe

The data we collect will be used for this study but may also be important for future research. Your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data.

The results from the research may be shared at a meeting. The results from the research may be in published articles. Your name will be kept private when information is presented.

Demographic and MI training Surveys:

These surveys will be collected using the confidential REDCap survey system. If a paper form is filled out, the research team will bring it to the University of Colorado Anschutz Medical Campus and it will be stored in a locked cabinet in a locked office.

Audio Recordings:

Three enhanced primary care visits with patients will be recorded on a digital recorder that will be provided to you. The key informant interviews will also be recorded. This information will be downloaded onto a secure server at the University of Colorado Anschutz Medical Campus. This information will be protected by being on a password-protected secure University of Colorado computer. This information will be kept for 3 years and then erased.

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 know that being in this study is voluntary. I choose to be in this study: I will get a copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____