ClinicalTrials.gov Cover Letter

Official Title: Family Empowerment for Enhanced Development

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Welcome to Project FEED

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Family Empowerment for Enhanced Development (Project FEED)

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What is the purpose of Project FEED?

The goal of this research is to look at the effects of a community-based parenting intervention to promote healthy nutrition for families with young children (ages 2-5). Nutrition related problems (such as obesity and malnutrition) are a big problem in our society. We know that children growing up in low-income homes have increased risk for these problems. We want to understand the benefits of enhancing child meal routines to improve healthy eating habits among young children.

Who is being asked to take part in this research study?

You and your child are being invited to participate in this research because you have at least one young child (aged 2-5) and meet the current Women, Infants, and Children (WIC) Income Guidelines. We are interested in building healthy habits among young children, because food preferences established during this critical period track into adulthood.

What is involved in participating in Project FEED?

All assessment and intervention sessions will occur at your home or within your community.

Baseline Assessments: If you decide to join the study, you will complete baseline assessments today. These assessments will take approximately 60-90 minutes, and we will ask you questions about your child's eating patterns, mealtime behaviors, and routines. We will measure your child's height and weight as part of this assessment. We will also ask you questions about your health, stress level, and anxiety. We will also provide you with a form home to log all the foods your child eats on 3 separate days. We will provide a self-addressed, stamped envelope for you to return this form, or you can give it to a member of our team at your first intervention session.

Intervention: You will participate in six, weekly intervention sessions with an occupational therapy professional in your home or, upon your request, at an alternate community location. You will receive the Promoting Routines of Exploration and Play (Mealtime PREP) program and each session will last approximately one hour. During these sessions you will learn how to build child mealtime routines that support healthy eating habits. During each session, you will learn new skills and have the opportunity to practice these skills and receive feedback from an occupational therapist. You will receive recommendations for healthy, child-friendly

snacks, and a gift card to purchase some of these options to try in your home. We will also build a plan to practice new skills at home.

During intervention sessions, we will be video recording the intervention so that we can rate the therapist's ability to lead each session as planned. This data is being collected to improve our process as we plan for future programs and studies.

Post-Intervention Assessments: After the intervention sessions are finished, a member of our research team will set up another individual appointment with you to complete post-intervention assessments. This will include the same series of assessments that you completed at baseline. This appointment will also last approximately 60-90 minutes and you will answer the same questions about your child's mealtime routine and eating behaviors and about your health. We will again provide a form to log all the foods your child eats on 3 separate days. We will provide a self-addressed, stamped envelope to send this form back to us.

Follow-up Assessments: Approximately 3 and 6 months after your initial baseline assessment appointment, a member of our research team will set up two final appointments to complete follow-up assessments. These appointments will last approximately 60-90 minutes and you will complete the same assessments that you completed during previous assessment appointments. We will also ask for general feedback about your experience in Project FEED.

Will I feel comfortable during the study participation?

Our procedures are designed to create a comfortable experience for you and your child. You will complete assessments on an iPad or we will provide the materials needed to complete with paper and pencil. Trained research assistants will be able to help you complete these assessments and answer any questions that come up. You do not have to answer any question that makes you uncomfortable. You do not have to give any reason for not wishing to respond to the question. You can feel free to ask questions now or later. Intervention sessions will take place in your home or in a comfortable community setting, and we will provide all materials and supplies that you need. We will expect you to have groceries available that you typically serve your child during mealtimes. You will not be asked to share information that you are uncomfortable disclosing.

Can my or my child's data be used for medical purposes?

No. Data from intervention and assessment sessions are collected for research purposes only. This data will not be used clinically.

What are the possible risks of participating in Project FEED?

The are no medical risks for participation in this study. However, we are asking you to share personal information with us regarding yourself and your child. While breaking confidentiality is

a risk in any research study, every effort will be made to protect your family's confidentiality, including information obtained on video.

There is a small risk of choking if your child should try a new food. This risk is no greater than any time that your child tries a new food. If your child has difficulty chewing, eating, or swallowing any foods, please do not offer that food again. We can help connect you with clinicians that can evaluate your child's eating skills if this problem happens repeatedly.

What are the possible benefits of taking part in this study?

Your participation will help us design future community-based programs to promote healthy routines for young children and their families. You may benefit from learning new skills to organize and manage mealtime routines within your own home. Also, your child may demonstrate improved mealtime behavior as you implement positive mealtime routines.

Will I be paid to participate in this research study?

Yes. You will receive $50 for completion of baseline assessments, $100 for completion of post-intervention assessments, $150 for completion of a 3-month follow-up and $200 for completion of a 6-month follow-up assessment. You will also receive mealtime equipment to support healthy routines during the intervention period. If you would like to withdraw from the study, you will receive compensation for the assessments that you have already completed.

Who will know about my or my child's participation in Project FEED?

Participation in the study is confidential. Your identities on records will be indicated by a number instead of a name. The code linking numbers to names will be kept separate from research records on an encrypted flash-drive in a locked private office. Only the researchers working on this study will have access to data. It is possible that we will share deidentified data with research colleagues here or at other universities. You will never be identified by name in any publication of the results.

Your information obtained during this research study, may be shared with other groups, possibly including authorized officials from the Food and Drug Administration and the University of Pittsburgh Research Conduct and Compliance Office, for the purpose of monitoring the study. You are permitted to withdraw participation in this study at any time. Any information obtained up to that point will continue to be used by the research team.

All research records must be maintained, per University of Pittsburgh policy, for 7 years after study participation ends. In unusual cases, your research records may be released in response to an order from a court of law. Also, if the investigators learn that you, your child, or someone with whom you/your child are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.

Because you will need to complete follow-up assessments, we would like to contact you again 3 months and 6 months after study enrollment. We will ask you for your email address as well as a phone number for this purpose. By signing this form, you will be stating your permission for us to contact you for follow-up assessments.

If I agree to take part in Project FEED, can I later decide that I don't want to participate? Can I be removed from the study without my consent?

Your participation in the study is completely voluntary. You can, at any time withdraw from this research study. This means that you and your child will also be withdrawn from further participation in this research study. Any identifiable research or medical information obtained as part of this study prior to the date that you withdrew your consent will continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw from this research study, you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Your decision to withdraw from this study will have no effect on your or your child's current or future relationship with the University of Pittsburgh.

Your decision to withdraw your consent for participation in this research study will have no effect on your or your child's current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If you are unable to follow the rules for participating in intervention sessions, we may dismiss you from this study. Any information collected up to that point may continue to be used.

Are there other programs available?

Yes. Local Family Support Centers and WIC Programs offers many programs to support parents of young children. Please reach out to your local center or contact our team to help you learn more about these opportunities.

Disclosures

None of the researchers in this study have anything to disclose and no researcher in this study will benefit or profit from your participation in this study.

Please feel free to contact us at any time:

Dr. Angela Caldwell (Principal Investigator), phone: 412-383-7231, email: arl78@pitt.edu

Voluntary Consent for Parent and Child Participation

All of the above has been explained to us and all of our current questions have been answered. We understand that we are encouraged to ask questions about any aspect of this research at any time. Any questions we have about my/my child's rights, as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668). By signing this form, I agree to participate in this research study, which includes participating in 6 intervention sessions in my home/community. I understand that, as a minor (less than 18 years), the below named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his/her participation in the study.

_____
Child's name (print)

_____ _____
Parent's name (print) Relationship to child

_____ _____
Parent's signature Date

OPTIONAL CONSENT:

- ☐ I provide my permission for the identifiable video-recordings of intervention sessions to be used for educational (in addition to research) purposes.
- ☐ I would like to be contacted about future research related to the building healthy routines.

_____ _____
Name (Print) Date

_____
Signature

_____

Person Obtaining Consent

CERTIFICATION of INFORMED CONSENT:

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

_____	_____
Name of Person Obtaining Consent (Print)	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date