Wake Forest®
School of Medicine

Department of Pediatrics

PEDIATRIC PARENTING CONNECTIONS YOUNG MOMS PROGRAM

Informed Consent Form to Participate in Research
Anna Miller-Fitzwater, MD, MPH, Principal Investigator
Claudia Barrett, MHA, Co-Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to evaluate parenting programs for young mothers. You are invited to be in this study because you have a new baby, you live in Forsyth County and you are less than 22 years old. Your participation in this research will involve at least 6 months of post-natal and parenting support.

Participation in this study will involve one-on-one and peer group meetings with a parent educator. These may be virtual or may be in person in your home or an Imprints Cares office. All research studies involve some risks. A risk to this study that you should be aware of is that it will take your time to attend the sessions. You may/may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include obtaining the same services but not enrolling in the study or not participating in post-natal and parenting support meetings. You will not lose any services, benefits, or rights you would normally have if you chose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Anna Miller-Fitzwater, MD, MPH. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [redacted].

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific

knowledge that may help other people in the future. You are being asked to take part in this study because you are less than 22 years old, you live in Forsyth County NC, and you have recently given birth. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to compare the effects of providing parenting support through a traditional home visiting based program, Parents as Teachers, to that of a virtual hybrid Parents as Teachers program to see which is better and which families prefer.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

30 people at one research site will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in either group.

Group 1 – Traditional Parents as Teachers. This group will receive twice-a-month home visits from trained family educators. Other parts of the Parents as Teachers model include regular group connections for peer interactions and support, age-appropriate health and developmental screenings, and referrals that reflect mother and infant needs to community agencies that include the Child Development Services Agency, family services, intensive mental health services, among others. The study team will collect baseline data during the first home visit and complete monthly questionnaires during each month the mother is enrolled. An outcome assessment and participation in a focus group will be administered the last month of the study.

Group 2 – Hybrid Parents as Teachers. This group will begin with a six-week virtual evidence-based parenting class entitled What You Do Matters, which combines short parent-educator discussions followed by interactive activities and peer to peer networking. Young moms will participate in Group Connections for peer interactions and support. After completing the six-week course, participants will begin receiving once a month home visits, ongoing Group Connections, age-appropriate health and developmental screenings, and referrals that reflect mother and infant needs to other community agencies and resources, as listed above. The study team will collect baseline data prior to the beginning of the virtual What You Do Matters program and will complete monthly questionnaires during each month the mother is enrolled. An outcome assessment and participation in a focus group will be administered the last month of the study.

Both groups will receive the same quality home visitation intervention by a certified Parents as Teachers family educator. All young moms will participate together in monthly group

connections. All study participants will be encouraged to continue receiving Imprints Cares Parents as Teachers home visitation after the study is over, until their child reaches 5 years of age. The only difference is that young moms randomized for the hybrid model will participate in a 6-week virtual parenting program and receive once a month home visits vs. the traditional program that will receive two home visits a month.

How Long Will I Be in the Study?

You will be in the study for about 6 months. You can continue to receive services after the study ends until your child reaches 5 years old.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

What Are the Risks of the Study?

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

As part of this study, you will be asked questions about depression and parenting. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be: Based on pre-existing research and experience with the Parents as Teachers program, researchers believe that this will positively impact you and your child. Through Parents as Teachers children's developmental delays and health problems are detected early, parents improve their parenting knowledge and skills, and ultimately children enter kindergarten ready to learn.

What Other Choices Are There?

You do not have to be in this study to receive treatment. Instead of being in this study, you have these options:

You could choose to participate in the Parents as Teachers program even if you do not take part

in the study.

This is not a treatment study. Your other alternative is to not participate in this study or receive the Parents as Teachers program.

WHAT ARE THE COSTS?

All study costs will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your child's identity if this study falls within its jurisdiction.

If you participate in the focus groups or group meetings you do not have to use your real name during the discussions. Subjects participating in group interviews or focus groups must agree not to disclose any information talked about in the group to protect the confidentiality of all participants.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid up to $150 if you complete all the scheduled study visits. The study offers $75 for completing the first six-weeks of services and then $75 at the end of services. In addition, participants in both models will receive developmental toys and each child will receive 2 books per month.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by The Center for Translational Research at Wake Forest University School of Medicine. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from

your medical records about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** monthly questionnaires, developmental screening (Ages and Stages Questionnaire), Socio-emotional screening (Ages and Stages Questionnaire- SE), Depression Screening (PHQ9), Positive Parenting Strategies (Protective Factors Survey 2, and STIMQ-I). Health information that will be collected includes: breastfeeding rates, well child visit and immunization rates, emergency department visit rates, and referrals and linkages to community agencies including the Child Developmental Services Agency.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your de-identified health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the National Center for Advancing Translational Research.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified.

You can tell Anna Miller-Fitzwater, MD, MPH that you want to take away your permission to

use and share your Protected Health Information at any time by sending a letter to this address:

Anna Miller-Fitzwater, MD, MPH
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because new information becomes available, or because the entire study has been stopped. Information that identifies you may be removed from the data or that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Anna Miller-Fitzwater MD, MPH at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

Legally Authorized Representative Name (Print):_____

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Relationship to the Subject:_____

Legal Representative Signature: _____ Date:_____ Time:_____ am pm