Cover Letter

Randomized Controlled Trial of Prenatal Coparenting Intervention (CoparentRCT)

NCT03097991

Informed Assent Form

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UNIVERSITY OF SOUTH FLORIDA

Assent to Participate in Research
Information for Persons under the Age of 18 Who Are Being Asked To Take Part in Research

IRB Study # Pro00021462

Title of study: **Figuring It Out for the Child**

Why am I being asked to take part in this research?
Hi, my name is _____. I am talking with teenagers who are expecting a baby.

Who is doing this study?
I work for the University of South Florida.

What is the purpose of this study?
In our project, we are trying to learn if meetings for moms and dads expecting their first baby with one another can help them work together as parents after their baby is born. Not all moms and dads decide to get married or stay in a romantic relationship. But they can still team together to coparent the baby and help the baby develop in a healthy and positive way. The goal of the study is to find out if you and other parents think the meetings are helpful, and to see if the meetings help you to work better as a team after your baby comes.

Where is the study going to take place and how long will it last?
For this study, we'll first meet with you today for some interviews. After today's interviews, you will receive a call within 48 hours telling you whether you have been selected to participate in the study or not. If you are selected to participate, you will be randomly assigned to one of the two groups. One group, the Resource and Referral Program group, will receive access to our Resource and Referral Navigator which will help to connect you with our community partners who specialize in services for pregnant women and their families. The other group, the FIOC Program group, will receive access to our Resource and Referral program and an opportunity to participate in a set of 7 meetings to discuss and help prepare for coparenting. Assignment to a group is random which means you have equal chance of being placed in either group. Neither you nor the study team members you meet can choose what group you will be in.

Most families selected to go on in the study after today will also be invited to complete questionnaires, to take part in family discussions, and to play together with the baby twice more after the baby comes, no matter which group they are in. Those visits will take place 3 and 12 months after the baby is born. Finally, even if you are selected to participate after today, it is possible that you may be discontinued from study participation at any point during the study. All of the study meetings will be held at one or more of the following locations, depending on which is most convenient for you: USF St. Petersburg, Johns Hopkins All Children's Hospital, or Next STEPP Life Center. Alternatively, some study sessions

may be offered via the Microsoft Team platform. This research is sponsored by the National Institutes of Health.

What will you be asked to do?

There are 3 parts to the study if you are assigned to the Resource and Referral Program group and 5 parts to the study if you are assigned to the FIOC Program group. Each time we see you we will have some different things for you to do.

Today we have a one-on-one interview with you. Another member of the project team will be interviewing your baby's other parent one-on-one. I will ask permission to audiotape this session. After your baby's other parent finishes their one-on-one interview, the two of you will spend time talking together about parenting ideas. I will ask your permission to videotape this session. Please provide your initials below indicating agreement to allow us to videotape or not.

Yes_____ No_____

After today, you and your baby's other parent will receive a call within 48 hours. This call will tell you whether you have been selected to participate in the study or not. If you are selected to participate, you will learn on the call whether you will be in the FIOC Program group or in the Resource and Referral Program group. You will have an equal 50% chance, like the flip of a coin, of being placed in either group. Families will not be able to choose what group they will be in, or to switch from one group to the other.

The second part -- **for those assigned to the FIOC Program group only –** will involve meeting individually with your Mentors for 1 or 2 "get-to-know-you" sessions, followed by six meetings at one of the designated community locations. The "get-to-know you sessions will be one-on-one with your Mentor, while the six meetings will involve both you and your baby's other parent. Those 6 sessions will focus on working to build good teamwork between the mother and father as parents. It usually takes about 10 weeks to finish the get-to-know you sessions and the 6 meetings, but we can sometimes finish this second part of the study in less time if that is helpful to the parents. We will ask permission to audiotape these sessions. Please provide your initials below saying whether you agree to let us audiotape or not if you are chosen for the FIOC Program group.

Yes_____ No_____

The third part- **for the FIOC Program group Only**, takes place after the 6 meetings end. We will interview you to ask you how you thought the meetings went.

Next, **for BOTH groups, the FIOC Program group and the Resource and Referral Program group,** you will bring your baby in three months after he or she is born and again when your baby is 12 months old and take part in some interviews and discussions just like the ones we'll do today. There will also be a play session involving you, the other parent, and the baby. I ask that we be permitted to videotape the family interactions during this meeting. Please provide your initials below indicating agreement to allow us to videotape or not.

Yes_____ No_____

Ongoing Contact during the Study

Episodically throughout the project, if you choose to provide your cell phone as contact information for scheduling of visits, you will receive reminder texts in advance of upcoming appointments.

How many parents will participate in the study?

About 170 moms and 170 dads will take part in this project

What things might happen if you participate?

As far as I know, nothing bad will happen because of us talking together. Some parents say they feel a bit uncomfortable at first with videotaping or audio-taping. If you have any worries about these things at any point during the study, please tell me or the project team member who is working with you.
Though every attempt is made to minimize all risks and discomfort, additional risks or discomfort associated with this research study may include:

1. possible violation of confidentiality,
2. possible discomfort due to assessment procedures,
3. possible embarrassment in disclosing sensitive personal information,
4. possible disclosure of information about intended physical harm to victims or abuse/neglect of children that would need to be reported to the child welfare agency and an investigation of the allegations(s) and further action, as indicated, that could ensue,
5. possible disclosure of homicidal or suicidal thoughts, threats, ideation, attempts, or plans, requiring mandatory reporting if participants are at imminent risk of endangering themselves or others.
6. possible dissatisfaction with the assessment/intervention procedures.

It is unlikely you will experience any of these situations but in the event that you do, project staff will be with you to address your concerns, discomfort and to assist you in getting additional services if needed. You may also discontinue your participation at any time during the study without adverse consequences to you.

Is there benefit to me for participating?

For those selected to participate in the FIOC Program group we hope the project will benefit you by giving you an opportunity to learn how to team together better with your baby's other parent. When parents work well together as a team, babies show stronger development and adjustment. For those selected for the Resource and Referral Program group, we will help ensure that you are aware of and have access to the multitude of services available to prenatal and postnatal families in Pinellas County.

What other choices do I have if I do not participate?

You can choose not to participate in this project if you don't want to.

Do I have to take part in this study?

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. If you do not want to talk to me, nothing else will happen. It will be okay. You can ask the adults in your family or anyone else about talking with me if you have questions.

Will I receive any compensation for taking part in this study?

We will compensate you a total of $150 in gift cards for the time volunteered in the study if you participate and complete all assessments. If you are randomly selected to participate in the FIOC Program group you will receive an additional $50 in gift cards if you complete the entire intervention.
For both the FIOC Program group and the Resource and Referral Program group: You will receive $25.00 after you complete the initial research interview session. You will receive $50 after the second research interview session 3 months after the baby is born. And you will receive $75 after the third interview session 12 months after the baby is born.
For FIOC Program group ONLY:

- If you are randomly selected to participate in the FIOC Program group and attend all 6 of the FIOC meetings, you will also receive a $50.00 gift card.

Cost

There will be no cost for you to participate in this study. If you need assistance with travel to and from interventions let us know, and we can help with transportation fare.

Who will see the information about me?

For all data and information collected after you sign the informed consent, whether you are selected to participate in the study or not:

I will keep what we talk about private. We will keep your study records private and confidential. Your personally identifiable information is not used on any records other than contact form, program agreement and consent documents. All other documents are labeled with a unique identifying number that is used in place of identifying information such as name, address or other information about you. All documents are stored confidentially in locked cabinets and secure computer servers at USFSP. The only people who will be allowed to see these records are:

- The research team, including the Principal Investigator, study coordinator, and all other research staff**.**
- Certain government and university people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.
- Any agency of the federal, state, or local government that regulates this research. This includes the Florida Department of Health, and the Department of Health and Human Services (DHHS) and the Office for Human Research Protection (OHRP)
- The USF Institutional Review Board (IRB) and its related staff, who have oversight responsibilities for this study, staff in the USF Office of Research and Innovation, USF Division of Research Integrity and Compliance, and other USF offices who oversee this research.
- The designated peer review committees such as the project's Data and Safety Monitoring Board who monitor the data and safety of the study.

We have obtained a Certificate of Confidentiality for this study. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project.

The only other situation people with our project are required to share your confidential information is if somebody on the project found out that there was 1) physical injury to any child that was not because of an accident, which the law says we must report to authorities, or 2) information that led us to believe that physical harm was about to happen.

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

Can I change my mind and quit?

If at any time you want to stop taking part in the study, it's okay to tell us you want to stop.

What if I have questions?

You can ask questions any time. You may also call the study's Principal Investigator. He is in charge of the study. His name is Dr. James McHale and he works at the USPSP Family Study Center. His phone number is 727-873-4848.

Assent to Participate

I understand what the person conducting this study is asking me to do. I have thought about this and agree to take part in this study.

_____ _____

Name of person agreeing to take part in the study Date

_____

Signature of person agreeing to take part in the study

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I hereby certify that when this person signs this form, to the best of my knowledge, he/she understands:

- What the study is about;
- What the potential benefits might be; and
- What the known risks might be.

I can confirm that this research subject speaks the language that was used to explain this research and is receiving an assent form in the appropriate language. Additionally, this person reads well enough to understand this document or, if not, is able to hear and understand when the form is read.

_____ _____

Name of person providing information (assent) to subject Date