

Cover Letter

Randomized Controlled Trial of Prenatal Coparenting Intervention

(CoparentRCT)

NCT03097991

Adult Informed Consent Form

Document Date 3.27.2020



Informed Consent to Participate in Research Information to Consider Before Taking Part in this Research Study

IRB Study # Pro00021462

Researchers at the University of South Florida (USF) study many topics. To do this, we need the help of people who agree to take part in a research study. This form tells you about this research study.

We are asking you to take part in a research study that is called: Figuring it Out for the Child (FIOC) because you and your coparent are about to have your first child together.

The person who is in charge of this research study is Dr. James McHale. This person is called the Principal Investigator. However, other research staff might be involved and can act on behalf of the person in charge.

The person explaining the research to you may be someone other than the Principal Investigator.

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 & Referral Program group, will receive access to our Resource and Referral Navigator who will help to connect you with our community partners who specialize in services for pregnant women, expectant fathers 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 meetings may be online study meetings, scheduled via the Microsoft Teams platform. This research is sponsored by the National Institutes of Health.

Purpose of the 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.

Study Procedures

There are 3 parts to the study if you are assigned to the Resource & 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 & Referral Program group. You will have an equal 50% chance 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 & 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.

Total Number of Participants

About 170 moms and 170 dads will take part in this study.

Alternatives

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

Benefits

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 in addition to connecting you with the services offered in the Resource & Referral Program. For those selected for the Resource & 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.

Risks or Discomfort

This research is considered to be minimal risk for both the FIOC Program group and the Resource & Referral Program group. That means that the risks associated with this study are the same as what you face every day. Some people report feeling a bit uncomfortable at first with videotaping or audio-taping procedures. If you have any worries about these things at any point during the study, please tell me or the project staff 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.

Compensation

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 & 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 help with transportation fare to or from the sessions, we will schedule that for you and pay the cost of the transportation.

Privacy and Confidentiality

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

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. Certain people may need to see your study records. By law, anyone who looks at your records must keep them completely confidential. 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) and the study's sponsor, the National Institutes of Health (NIH).
- 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 in which we are required to share confidential information is if staff members discovered that there was 1) physical injury to any child caused by other than accidental means, which by law must be reported to authorities as required by Florida Statute 39.201; and 2) information from a study participant that led staff to believe a person is in imminent danger of physical harm.

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.

Voluntary Participation / Withdrawal

You should only take part in this study if you want to volunteer. You should not feel any pressure to take part in the study. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study.

New information about the study

While the study is being conducted, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

You can get the answers to your questions, concerns, or complaints

If you have any questions, concerns or complaints about this study, or experience an adverse event or unanticipated problem, call James McHale at 727-873-4848.

If you have questions about your rights as a participant in this study, general questions, or have complaints, concerns or issues you want to discuss with someone outside the research, call the USF IRB at (813) 974-5638.

Consent to Take Part in this Research Study

It is up to you to decide whether you want to take part in this study. If you want to take part, please sign the form, if the following statements are true.

I freely give my consent to take part in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

Signature of Person Taking Part in Study

Date

Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent

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 informed consent form in the appropriate language. Additionally, this subject reads well enough to understand this document or, if not, this person is able to hear and understand when the form is read to him or her. This subject does not have a medical/psychological problem that would compromise comprehension and therefore makes it hard to understand what is being explained and can, therefore, give legally effective informed consent. This subject is not under any type of anesthesia or analgesic that may cloud their judgment or make it hard to understand what is being explained and, therefore, can be considered competent to give informed consent.

Signature of Person Obtaining Informed Consent / Research Authorization

Date

Printed Name of Person Obtaining Informed Consent / Research Authorization

Advocate Signature (only applicable if participant is under the age of 18 and parental consent cannot be obtained)

I confirm that the information in this consent form was accurately explained to the participant, the participant appeared to understand the information, had an opportunity to ask questions, and gave informed consent freely. I also confirm that study staff sought, but were unsuccessful in contacting or obtaining informed consent from, the above-named participant's parents.

Advocate Signature

Date