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FLORIDA INTERNATIONAL UNIVERSITY

ADULT CONSENT AND PARENTAL PERMISSION TO PARTICIPATE IN A RESEARCH STUDY

Engaging Male Caregivers in Effective Prevention Programming

SUMMARY INFORMATION

Things you should know about this study:

- **Purpose:** The purpose of the study is to find out how different types of parenting groups help caregivers.
- **Procedures**: If you choose to participate, you will be asked to complete some forms about your child's behavior, your parenting, and how you get along with the other caregivers before, after, and 1-month following the parenting group. You and other participating parents will also be invited to attend one of three 8-week parenting groups. You will be put in one of the three groups randomly (like a lottery).
- **Duration:** This will take about four months in all – two weeks to get enrolled, two months for the group, and two weeks to complete forms after the study to tell us what you thought about it and how it worked. We'll contact you one last time around a month later to find out if anything has changed.
- **Risks**: You may dislike filling out some of the forms. You may be put in a group that was not your first choice.
- **Benefits:** The main benefit to you from this research is that you will be able to participate in 8 weeks of a group to help you and your child get along. This might improve how your family works.
- **Alternatives:** Alternatives to this study include working with your child's pediatrician, or meeting with school or community support professionals.
- **Participation:** Taking part in this research project is voluntary.

Please carefully read the entire document before agreeing to participate.

PURPOSE OF THE STUDY

The purpose of this study is to study the best approach for helping male caregivers parent young children and co-parent with female caregivers. Male caregivers have been understudied. We will explore three different ways of working with male caregivers to see if one way works best.

NUMBER OF STUDY PARTICIPANTS

If you decide to be in this study, you will be one of 144 families in this research study.

DURATION OF THE STUDY

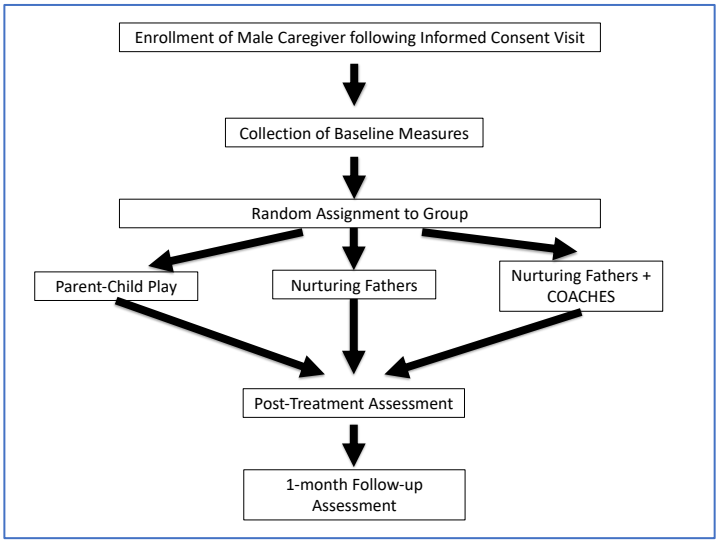
This will take about four months in all – two weeks to get enrolled, two months for the group, and two weeks to complete forms after the study to tell us what you thought about it and how it worked. We'll contact you one last time around a month later to find out if anything has changed. When in the group, it is expected that each weekly meeting will be about 1.5 hours.

During the study we will ask to complete some ratings of your behavior, your family, and how your child is behaving. We will also watch you and your child play together to see how you get along. Before the study starts, after the program you are in, and then again one month later, we will ask you to answer these questions during a meeting that will take about 45 minutes.

PROCEDURES

If you agree to be in the study, we will ask you to do the following things:

1. Meet with the study team to review the study and make sure you and your child want to volunteer to attend.
2. Complete forms about your child's behavior and your family, including your parenting.
3. Schedule a meeting where you will play with your child using Zoom. The study team member will watch you and your child during the play over Zoom and write down information on how you parent and how your child behaves.
4. Participate in the 8-week parenting program with your child. There are three groups:
    a. *Nurturing Fathers* – caregivers meet with other caregivers to learn parenting skills, and the children attend a fun activity with other children.
    b. *Nurturing Fathers +COACHES* - caregivers meet with other caregivers to learn parenting skills the children practice soccer skills. At the end of the meeting the caregivers join the children and help coach them in a soccer game.
    c. *Parent-Child Play* – caregivers and children join together for fun play activities.



5. Complete forms about your child's behavior and your family, including your parenting after the program is over.
6. After the groups are completed, schedule a meeting where you will play with your child using Zoom. The study team member will watch you and your child during the play over Zoom and write down information on how you parent and how your child behaves. We will also ask you to complete some checklists about your parenting and family.

7. One month later, schedule a meeting where you will play with your child using Zoom. The study team member will watch you and your child during the play over Zoom and write down information on how you parent and how your child behaves. We will also ask you to complete some checklists about your parenting and family.

RISKS AND/OR DISCOMFORTS

The study has the following possible risks to you: First, you may become bored when completing the forms.

A child may show some worsening of behavior when a parent tries to use new approaches to parenting. Although this worsening behavior is usually only for a short time, it can make parents frustrated and result in the need to use additional parenting strategies. Parents should discuss any concerns about the child's behavior with their group leader or the study team immediately.

You may also disagree with some of the advice in the parenting groups. You are free to take or ignore any advice, and use the advice in the best way you see fit to help your child and family.

You may also disagree with some of the other caregivers in your group. You should focus on how to help your child and family, and you do not have to agree with everyone in the group on the best way to do this.

An additional risk relates to the group format of the parenting program. Although the research team will hold all your information in strict confidence, it is possible that another caregiver attending the meeting will not do so. You are encouraged to use only your first name during the meeting, and to hold back specific details about your family (for example, your address). If there is something you would not want shared outside the group, you may wish to hold that back.

BENEFITS

The study has the following possible benefits to you: the skills taught during the group may help you with your parenting. Talking with other caregivers may help you learn new skills too, or strengthen the skills you already have. Also, you might benefit from meeting with other caregivers and learning about how they support their child's positive behavior.

ALTERNATIVES

There is help available if you need someone to talk to. There is help available if you feel unsafe or you think your child is unsafe. You can talk to the person on the phone privately if you choose. You can call any time 24 hours a day, any day of the week.

- National Domestic Violence Hotline (1-800-799-7233)
- National Child Abuse Hotline (1-800-422-4453)
- Call, text, or chat in New York at the Office for the Prevention of Domestic Violence Website (opdv.ny.gov)

Any significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

CONFIDENTIALITY

The records of this study will be kept private and will be protected to the fullest extent provided by law. In any sort of report we might publish, we will not include any information that will make it possible to identify you. Research records will be stored securely, and only the researcher team and the Centers for Disease Control and Prevention will have access to the records. However, your records may be inspected by authorized University or other agents who will also keep the information confidential.

Finally, there is a risk that the study information collected may include behaviors that could result in economic or social harm if others learned about it (for example, in family court). Our team does not want the collection of this information to be used against you, for example in a legal proceeding.

To help us protect your privacy, we have applied for a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we can't be forced by a court order or subpoena to disclose information that could identify you in any civil, criminal, administrative, legislative or other proceedings.

There are circumstances where the Certificate doesn't protect against disclosure of your personally identifiable information:

- when the US government is inspecting or evaluating federally-funded studies
- when information must be disclosed to meet FDA requirements (only required for FDA-regulated studies)
- if you give someone written permission to receive research information or you voluntarily disclose your study information
- if the researcher reports that you threatened to harm yourself or others
- in cases of child abuse reported by the researcher
- if the investigator reports cases of contagious disease to the state
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The U.S. Department of Health and Human Services (DHHS) may request to review and obtain copies of your records.

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

USE OF YOUR INFORMATION

Identifiers about you might be removed from the identifiable private information, and that, after such removal, the information could be used for future research studies or distributed to another

investigator for future research studies without additional informed consent from you or your legally authorized representative.

In this project, we plan to collect questionnaires from both maternal and paternal caregivers, including ratings of co-parenting, parenting behaviors, conflict situation tactics, and parenting alliance. Responses to study ratings will be completed individually from a direct survey link sent to each participant's email, and that results will not be shared between caregivers.

COMPENSATION & COSTS

You will receive a payment of $50 (cash or giftcard) for the time you spend completing study measures before the 8 week program. You will receive a payment of $50 (cash or giftcard) for the time you spend completing study measures after the 8 week program. You will also receive a payment of $50 (cash or giftcard) for the time you spend completing study measures at the 1-month follow-up.

There are no costs to you for participating in this study.

MEDICAL TREATMENT

Routinely, FIU, its agents, or its employees do not compensate for or provide free care for human subjects in the event that any injury results from participation in a research project. If you become ill or injured as a direct result of participating in this study, contact your regular medical provider. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be billed. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.

RIGHT TO DECLINE OR WITHDRAW

Your participation in this study is voluntary. You are free to participate in the study or withdraw your consent at any time during the study. You will not lose any benefits if you decide not to participate or if you quit the study early. The investigator reserves the right to remove you without your consent at such time that he/she feels it is in the best interest.

RESEARCHER CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues relating to this research study you may contact Greg Fabiano, Ph.D. at Center for Children and Families, 4600 Main Street, Suite 101, Amherst NY 14226, 716-359-7823, gfabiano@fiu.edu.

IRB CONTACT INFORMATION

If you would like to talk with someone about your rights of being a subject in this research study or about ethical issues with this research study, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION

If you sign this document, you give permission to the health care providers at Florida International University (FIU) Center for Children and Families and the study researchers to use or disclose (release) your health information that identifies you in this research study.

What information may be used and given to others?
The health information that may be used or given to others includes your personal and medical information. For example:

- Research records
- Records about your study visits

Who will use or receive my health information?
The health information listed above will be given to the study researchers. The information may also be given to the Institutional Review Board (IRB) that reviewed this research, authorized FIU agents, and other federal or state agencies as necessary.

Why will this information be used and/or given to others?
To do the research, to study the results, and to make sure that the research was done right.

Is my health information protected after it has been given to others?
Those persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them.

What if I decide not to give permission to use and give out my health information?
You do not have to sign this document, but if you do not, you will not be able to be in this research study. If you do not sign this document, your right to other medical treatment will not be affected.

May I withdraw or revoke (cancel) my permission?
You may change your mind and withdraw or take back your permission at any time. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others. To withdraw your permission, you must write to: Gregory A. Fabiano, Ph.D., Florida International University, Center for Children and Families, 4600 Main Street Suite 101, Amherst NY 14226.

Does my permission have an expiration date?
This permission expires at the end of the research study.

IRB CONTACT INFORMATION

If you would like to talk with someone about your rights of being a subject in this research study or about ethical issues with this research study, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

PARTICIPANT AGREEMENT

I have read the information in this consent form and agree to participate in this study. I have had a chance to ask any questions I have about this study, and they have been answered for me. I understand that I will be given a copy of this form for my records.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

PARENTAL PERMISSION

I have read the information in this consent form and agree to allow my child to participate in this study. I have had a chance to ask any questions I have about this study, and they have been answered for me. I understand that I will be given a copy of this form for my records.

_____ _____

Signature of Parent/Guardian Date

_____

Printed Name of Parent/ Guardian

_____

Printed Name of Child Participant

_____ _____

Signature of Person Obtaining Consent Date