Optimizing a Pediatric Intervention to Increase Maternal Depression Care-Seeking

NCT02938598

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Title of research study: Factorial Trial of Maternal Depression Motivation Intervention

Investigator: Erik Fernandez y Garcia, MD MPH

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are a woman between the ages of 21-65 years old who is the primary caretaker of a child between the ages of newborn and 12 years old. Furthermore, you are presenting today at either the UC Davis Pediatric Primary Care Network, the Wellspace Oak Park Health Center, or the Walton Pediatric, Medical Associates, Inc. with your child for a Well Child Check with his or her pediatrician; have the ability to speak and read English well enough to participate in a guided discussion with study staff and utilize our study materials; are willing to talk openly about emotional health and care-seeking for problems with emotional health with our study staff; are not currently under active care for depression by a medical practitioner or mental health specialist; and have not been previously enrolled in this study.

What should I know about a research study?

(Experimental Subject's Bill of Rights)

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any common or important discomforts and risks.
  - Any benefits you might expect.
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (916) 734-3201. For non-emergency issues you can call the UCDMC Hospital Operator (916-734-2011), tell the Operator you are participating in a research study and you wish to talk to Dr. Fernandez y Garcia. In the case of an emergency, dial 911 from any phone. This research has been reviewed and approved by an Institutional Review Board ("IRB"). Information to help you understand research is on-line at http://www.research.ucdavis.edu/policiescompliance/irb-admin/.You may talk to a IRB staff member at (916) 703-9151, IRBAdmin@ucdmc.ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

Maintaining good emotional health in mothers of young children is important for the mothers and their children. Many mothers visit pediatric offices with their children but don't go to their own doctor. So, pediatrician office contact provides a chance to identify mothers with emotional health needs who otherwise would not be identified. We developed a process to identify these mothers and then motivate them to seek care and support for their emotional health and we are now seeing if we can improve that process.

How long will the research last?

We expect that you will be in this research study for approximately two weeks, plus up to five additional days if required to obtain contact with you. The periods of active participation (that is, the time you will actually need to spend interacting with study staff) will be broken into three parts:

1. Screening, enrollment, and provision of study materials at the pediatrician's office (will last approximately 30 minutes);
2. A 2-7 day follow-up phone call (will last approximately 15 to 20 minutes; we will make up to six attempts at contact for this call);
3. A 2-week follow-up phone call (will last approximately 15 to 20 minutes; we will make two daily attempts at contact for a period up to one week for this call).

Therefore, the total amount of active participation from you will be approximately one hour, spread over a two-week period. We expect that it will take 18 to 24 months for all of the participants to go through the study.

How many people will be studied?

We expect about 48 people will be in this research study.

What happens if I say yes, I want to be in this research?

If you decide to participate, you will be asked to stay in the clinic after completion of your child's checkup to fill out paper questionnaires and to receive study literature and a brief talk provided by a study staff member. At that time, we will schedule a time for us to call you, at a time when you have privacy to speak, in 2-7 days to ask you follow-up questions related to the study literature and brief talk that you will receive today.

The study literature that you will review and talks that you will hear today in the office and over the telephone in 2-7 days are designed to give mothers information about and support for their emotional health. The talks will be 1 of 8 different versions that are available. All versions of the material provide the same information but may differ slightly in the following ways:

1. The way the messages are said,
2. The length of the brief talk, and
3. The length of the follow-up phone call.

The version that you get will be chosen by chance, like flipping a coin. Neither you, the study staff, nor the study doctor will choose what version you get. You will have an equal chance of

receiving each of the 8 possible versions (1 in 8) of talks. Neither the study staff, nor the study doctor will know which version you are getting ahead of time. The information you will receive does not take the place of the care that you could receive from your doctor, nor is it a diagnosis of any condition. There are no mothers in this pediatric clinic who are receiving the study literature or talks as a part of regular pediatric care outside of participation in this study.

The talk may be audio-recorded with a small digital recorder, and may be reviewed by the PI to ensure the talks are being delivered correctly. Audio-recordings will be erased immediately after they are reviewed.

You will also receive another follow-up phone call from a study staff member at 2 weeks after today to ask about what you did or did not do in response to the study literature that you receive. This call will be scheduled at the end of the 2-day follow up phone call. Some of these calls will be randomly recorded and we will listen to them to make sure that everything is being done correctly. Once we have listened to the recordings, we will destroy them. All calls will be made at a time when you feel you have the most privacy to speak.

We will also ask at that time if you will allow us to contact some of the people with whom you said that you have appointments in response to the literature you receive. We will call them with you on the line. If you agree to let us contact these people, we will be asking them if you have a current appointment scheduled or if you have kept a reported past appointment with this person.

Timeline

-Today: remain in the clinic for 20-30 minutes after your child's appointment ends to fill out a questionnaire and receive study materials;
-2-7 days from now: receive a scheduled, 15-20 minute phone call;
-2 weeks from now: receive another scheduled, 15-20 minute follow-up phone call.

What happens if I do not want to be in this research?

You may decide not to take part in the research and it will not be held against you. Any information we have collected from you up to this point will be destroyed. We may need to tell the pediatrician you just saw or your own healthcare provider the results of the mood questions if we feel that you need immediate help. The pediatrician may or may not call you to talk about your mood; that is up to him/her and not the study staff. If we do not tell the pediatrician whom you just saw the results of the mood questions (because we do not think you need immediate help) your child's pediatrician will not know either way if you decide to participate or not, so your child's care will not be impacted in any way by your decision to participate.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. Data that has been collected from you up to the point where you decide to withdraw from the study will remain as property of the research team and will be used in the research, but there will be no way to connect your personal information identifying you to that data.

Is there any way being in this study could be bad for me?

There is a slight risk of loss of confidentiality/privacy should you choose to take part in this research. Steps will be taken during every part of the study to ensure that your information is safe and that the information that you give us can not be traced back to you. Your information will be stored in a secured and locked cabinet only accessible by study staff. Any digital information will be stored on a secure, password-protected computer server only accessible by research team members.

As this research is related to emotional health and care-seeking and support for emotional health, there is also a risk that you may experience emotional distress or discomfort during the time spent participating in the study. To mitigate this risk, the Principal Investigator has ensured that all research staff have at least a college-level education relating to emotional health and have experience in a research setting interacting with people experiencing problems with their emotional health.

Due to the study requiring two follow-up phone calls as previously discussed in this consent form, there may be costs associated with you receiving and accepting these phone calls. This is subject to your personal telephone provider plan and cannot be accurately predicated by study staff. We offer thank you gift cards of $30 for hearing the tested materials here in the office and over the telephone 2 – 7 days later and $10 for the second telephone call in this study where we ask questions 2 weeks from now, in part to offset any costs you may incur due to receiving our phone calls.

If, during the time spent in the research study, you disclose suicidal plans, plans for or incidents of harming your child(ren), or report an impairment of your ability to provide adequate care for your child(ren) due to problems with your emotional health, researchers will be required to report possible endangerment of your child(ren) to Child Protective Services (CPS). You will be informed of this need to report for the sake of maintaining child well-being prior to any CPS referral. We will provide you with opportunities to seek immediate assistance for any plans for harming yourself or your children or inability to care for them.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include being identified as having feelings of depression and receiving education related to seeking care for those feelings.

What happens to the information collected for the research?

During your participation in this research, data will be collected about you. The information that you provide will be assigned a unique code number. Data analysts will not know your identity. The completed surveys and analyses will be stored on a secure server that is password-protected; hard copies will be kept in locked cabinets. The confidentiality of the data will be maintained within legal limits.

The de-identified data will become the property of the University of California. The data may be used in this research, may be used in other research, and may be shared with other organizations. The data could lead to discoveries or inventions that may be of value to the University of California or to other organizations. Under state law you do not have any right to money or other compensation stemming from products that may be developed from the data.

Efforts will be made to limit use or disclosure of your personal information, including research study participation, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB and other University of California representatives responsible for the management or oversight of this study, as well as the National Institute of Mental Health, who is sponsoring this study.

It is also possible that law enforcement agencies could subpoena your information from this study, especially in the case of reports of plans for harming your self or your child(ren) or inability to care for your child(ren) leading to contacting CPS. However, Dr. Fernandez y Garcia has received a Certificate of Confidentiality from the Federal government that will help protect the privacy of the research records. The Certificate of Confidentiality allows the Researchers to refuse to disclose identifying information on your participation in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself and your involvement in this research. If you have given your consent for an insurer or employer to obtain information about you, the Researcher may not use the Certificate of Confidentiality to withhold this information. A Certificate of Confidentiality also does not prevent a Researcher from disclosing information about you to prevent serious harm to yourself or others, such as reporting to the authorities' incidents of child abuse, elder abuse or spousal abuse.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include: reports or plans of currently harming yourself, harming your children, or inability to care for you children and/or involvement of CPS due to those factors in the course of this study. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

This research is being funded by the National Institute of Mental Health, also called the sponsor. An additional funding source has been provided by the Children's Miracle Network. Sponsors may change or be added.

UC Davis is being paid to conduct this study, but the study doctor and research staff have not received any direct income from the sponsor.

It is important that you promptly tell the person in charge of the research if you believe that you have been injured because of taking part in this study. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about compensation, you may call the IRB Administration at (916) 703-9151 or email at IRBAdmin@ucdmc.ucdavis.edu.

If you agree to take part in this research study, we will compensate you up to $40 in gift cards for your time and effort. The breakdown of compensation is as follows:

1. You will receive $30 gift card upon completion of the office-based study visit for your time here today and for your time on the phone in 2-7 days; and
2. You will receive one final $10 gift card upon completion of the 2-week follow-up phone call (the card will be sent to you via mail).

You may be asked for your social security number for payment purposes (this is a necessary step to track that cards are given only to study participants). It will not be used for any other purpose without your permission.

The results of this study may have commercial value to the sponsors, UC Davis, and/or the researchers. You will have no legal or financial interest in any commercial development resulting from the research or from the information or materials collected.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	