Official Study Title: Intervening during the prenatal period with women exposed to intimate partner violence to improve maternal functioning and infant adjustment

Date of Document: June 4, 2019

Parental Consent for Participation in the Pregnant Moms' Empowerment Program (PMEP) Intervention Study

Title: Intervening during the prenatal period with women exposed to intimate partner violence to improve maternal functioning and infant adjustment

Principal Investigators: Laura Miller-Graff, PhD, University of Notre Dame; Kathryn Howell, PhD, University of Memphis

Introduction

The purpose of this form is to provide you information that may affect your decision as to whether or not to participate in this intervention study. The person conducting the research and conducting this interview will answer any of your questions. Read the information below and ask any questions you might have before deciding whether or not to take part. If you decide to be involved in this study, this form will be used to record your consent.

Purpose of the Study

Each year, many women and children experience violence. For many of these people, it can be hard to find people to help with the physical and mental health problems that they might have afterward. There are a few interventions that have been shown to be helpful for women who have experienced violence. However, we know less about helpful interventions for pregnant women who have experienced violence. After meeting with women like you- those who have a history of exposure to partner violence and are currently or have recently been pregnant, we have developed an intervention program. You were eligible to participate because you are currently pregnant and because you have reported that you have experienced violence perpetrated by an intimate partner. In this study, we would like to know whether our program will be helpful in meeting the specific needs of pregnant women exposed to violence. If you decide to participate in this study, you will be one of approximately 230 women. This project is part of a multi-site study with the University of Memphis Your involvement in our study will include four interviews, lasting approximately two hours each. The first of these occurs today, another one will occur 6 weeks from today, and the final two interviews will be scheduled when you are three-months post-partum and when your child is one year old. Half of the women in this study will be randomly selected to participate in one type of group intervention program and half will participate in another type of group intervention program. Women in both programs will be asked to attend 5 meetings over the course of 5 weeks (between your first and second interviews).

The interviews and group sessions will take place at a safe community center, the BRAVE Lab, the Center for Children and Families (University of Notre Dame) or the REACH Lab (University of Memphis). You will only agree to participate in one part of the study at a time and if you decide you don't want to do one thing, it won't affect your participation in others. A separate intervention with a similar structure will also be conducted there. The principal investigator of the South Bend site is Dr. Laura Miller-Graff, an Assistant Professor in Psychology and Peace Studies at the University of Notre Dame. If you have any questions or concerns about your participation, or if you would like to know more about the BRAVE Lab's ongoing studies, you can contact her at lmiller8@nd.edu or 574-631-3245. Dr. Kathryn Howell is the principal investigator at the Memphis site. If you have any questions for her, you may contact her at khhwell1@memphis.edu or 901-678-1541.

What will you be asked to do?

Women's Individual Interviews:
Your first visit will help us to learn a little bit about you. We would like you to answer a survey that asks questions about the stressful experiences you may have had, including the violence in your life, how you are coping now, and your thoughts on parenting your infant after birth. Any question may be skipped and you will still be paid even if you withdraw early from the interview. The survey takes about 1.5-2 hours and you will be paid $30 for your time.

All women will also be invited to participate in three follow-up interviews. The first will occur 6 weeks after your first interview, the second will occur at three-months post-partum, and the third will occur one-year post-partum. The post-treatment survey takes about 2 hours and you will be paid $30 for your time. The last two interviews will take a bit longer (2.5-3 hours) and you will be paid $50 for your time at each of these interviews.

The intervention will be run using a group format, meaning that you will meet as part of a group with other pregnant women who have also experienced stressful life events. It is a five-week intervention, where you will meet with your group once a week for approximately two hours. The intervention sessions will also be audio-recorded. The purpose of this is to make sure that the group leaders are running the sessions effectively. If you do not feel comfortable answering a question, you are welcome to remain silent. None of your information will be specifically linked to you and when we write down things that happened in the groups, we won't use your name. We may use quotes or some of the information you provide in our research, but we will disguise any information that could connect it to you in any way. You will earn a small baby care item for every meeting you attend. If you are not participating in the group intervention program, we will work with you after your interview today to provide any community referrals or contacts you might need to gain access to support services.

What are the risks involved in this study?

The risks involved with participation in this study are low. Some women find some of the interview questions to be sensitive in nature; please remember that you can skip any items you would like. After each interview, we will provide any referral information that might be useful to you (e.g., mental health resources). For those women participating in the group intervention, risks may also include another participant from the group sharing what you said with someone else. However, the confidentiality of your data is protected by the study and we will also ask all group members to respect the privacy of other group members by not discussing the group or things that people said once you leave here today. The procedures used in this study may involve risks that are currently unforeseeable.

What are the possible benefits of this intervention study?

Research is designed to benefit society by gaining new knowledge. Many women also find it interesting and informative to respond to survey questions, and from past research studies on similar topics, we have found that women enjoy attending group sessions like those included here.

Do you have to participate?

No, your participation is voluntary. You may decide not to participate at all or, if you start the study, you may withdraw at any time. Withdrawal or refusing to participate will not affect your relationship with the University of Notre Dame, University of Memphis, the BRAVE Lab, or the REACH Lab in any way.

If you would like to participate, please complete the bottom portion of this form. You will receive a copy of this form.

Will there be any compensation?

You will receive up to $160 for completing the entire study. You will also be eligible to receive up to 5 infant care items, one for each group session you attend.

How will your privacy and confidentiality be protected if you participate in this research study?

All the information you give us will be kept strictly confidential and will not be shared with anyone outside of our project staff. Names will not be used so that confidentiality will be protected. Numbers will be substituted for names so that your name is not attached to any of the information about you. Paperwork that connects your name to your identification number will be kept in a locked file in the project director's office and destroyed one year after the study is done. The project will keep the information discussed in this group protected, but we also ask that you respect the privacy of other group members by not discussing the group or things that people said once you leave here today.

If it becomes necessary for the Institutional Review Board to review the study records, information that can be linked to you will be protected to the extent permitted by law. Your research records will not be released without your consent unless required by law or a court order.

If you choose to participate in this study, you will be audio-recorded. Any audio recordings will be stored securely and only the research team will have access to the recordings. Recordings will be kept for one year following the completion of the study and then erased.

If, during your participation in the study, we have reason to believe that any child is a victim of abuse or neglect, we are required to report this. Child abuse and neglect are situations where children's "physical or mental condition is seriously impaired or seriously endangered as a result of the inability, refusal, or neglect" of the child's parent/guardian to supply the child with necessary things, such as food or shelter. Child abuse and neglect also includes physical abuse, sexual abuse and parental allowance of children's participation in sexual offenses. If we become aware of PAST OR PRESENT child abuse and/or neglect, we are required by law to report this to the Indiana Department of Child Services or Tennessee Department of Children's Services, as relevant for your location.

If, during your participation in the study we learn that you are in serious danger of hurting yourself or someone else, we are also required to report this to local authorities.

Whom to contact with questions about the study?

Prior to, during or after your participation you can contact the researchers if you have any questions or concerns about your participation, or if you would like to know more about the BRAVE or REACH Lab's ongoing studies. You can contact the principal investigator at the University of Notre Dame site Dr. Laura Miller-Graff at lmiller8@nd.edu or 574-631-3245. Dr. Kathryn Howell is the principal investigator at The University of Memphis site. If you have any questions for her, you may contact her at khhwell1@memphis.edu or 901-678-1541.

This study has been reviewed and approved by The University's Institutional Review Board and the study number is 19-03-5260.

Whom to contact with questions concerning your rights as a research participant?

For questions about your rights or any dissatisfaction with any part of this study, you can contact, anonymously if you wish, the Notre Dame Research Compliance Office, at 574-631-1461 or by email at compliance@nd.edu .

Signature

You have been informed about this study's purpose, procedures, possible benefits and risks, and you have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time. You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

_____
Printed Name

_____ _____
Signature Date

As a representative of this study, I have explained the purpose, procedures, benefits, and the risks involved in this research study.

_____
Print Name of Person obtaining consent

_____ _____
Signature of Person obtaining consent Date

____Participant has received a copy of the consent