Consent, Assent, & 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

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Consent & Assent for this study
If you are 18 or older, or if you are an emancipated minor, you will use this form to give consent for you, and after your child's birth, your child's participation in this study. If you are a minor, you will use this form to provide your assent for you, and after your child's birth, your child's participation in this study. If you are a minor, your legal guardian will also use this form to provide consent for your participation in this study.

Introduction

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

Do you/your child have to participate?

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

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

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/your child - 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 are/your child is eligible to participate because you/your child are currently pregnant and because you have/your child has reported that she has 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/your child decide to participate in this study, you/your child will be one of approximately 230 women. This project is part of a multi-site study with the University of Memphis. Your/your child's 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/your child is three-months post-partum and when your

child/your child's child is one year old. After the last interview, you/your child will be invited to participate in a daily dairy study; as a part of this study, you/your child will respond to a brief questionnaire that will be sent via weblink to your phone each day for 30 days. We anticipate that the questionnaires will take between 5 and 10 minutes. 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 at the Shaw Center for Children and Families (University of Notre Dame) or the REACH Lab (University of Memphis). A separate intervention with a similar structure will also be conducted there. You/your child will only agree to participate in one part of the study at a time and if you/your child decide you/your child don't want to do one thing, it won't affect your/your child's participation in others.

COVID-19: Due to current health risks associated with in-person interactions, you may also elect to complete all study procedures online. If you/your daughter do/does so, we will work with you to identify a place in your home where you are able to maintain a private conversation. If you are concerned about a loss of your/your daughter's privacy at any point during the interview, you can end it by closing the window or by using the pre-determined "safe phrase" that you/your daughter has chosen with your/your daughter's interviewer. If you participate virtually, you should do so in a way that the audio cannot be overheard. You can do this by using the regular function of your/your daughter's phone (i.e., not speaker phone) or by using headphones. We will provide you/your daughters with headphones if you do not have them. All other study procedures will remain the same. Depending on your particular circumstances, it might be true that we are not able to do all of the components of this study virtually; if we determine that only parts of the interviews can be completed given your/your daughter's particular living situation, this will not affect your compensation. Your consent on this form will be obtained verbally and we will ask you to sign a written consent at your next in-person visit

What will your child be asked to do?

<u>Women's Individual Interviews:</u>
Your/your child's first visit will help us to learn a little bit about you/her. We would like you/her to answer a survey that asks questions about the stressful experiences you/she may have had, including the violence in her life, how you/she is coping now, and your/her thoughts on parenting her infant after birth. Any question may be skipped and you/your child will still be paid even if you withdraw early from the interview. The survey takes about 1.5-2 hours and she 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/your child's first interview and again three months post-partum and twelve months post-partum. The post-treatment survey also takes about 2 hours and you/your child will be paid $30 for your/her time. The last two interviews will take a bit longer (2.5-3 hours) and your child will be paid $50 for your time for each visit. The post-partum visits will include additional survey questions about your child's infant and her thoughts on parenting. These visits will also include developmental testing of your/your child's infant as well as video recorded interactions between the two of you/them.
After the last interview, you/your child will be invited to participate in a daily dairy study; as a part of this study, you/your child will respond to a brief questionnaire that will be sent via weblink to your phone each day for 30 days. We anticipate that the questionnaires will take between 5 and 10 minutes. You will be paid $2 for each completed daily survey, and will also earn an additional $10 for each set of 10 consecutive surveys you complete. If you complete **every daily survey on the day they are due**, your total compensation for this component would be $90. The surveys will include questions about mental health, stress, and your relationship with your baby.

The intervention will be run using a group format, meaning that you/your child 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/your child will meet with your/her 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 leader is running the sessions effectively. If you/your child do not feel comfortable answering a question, you/your child is welcome to remain silent. None of your information will be specifically linked to you/your child and when we write down things that happened in the groups, we won't use your/her name. We may use quotes or some of the information you/your child provides in our research, but we will disguise any information that could connect it to you/her in any way. You/your child will earn a small baby care item for every meeting you/she attends. If you/your child decides not to participate in the group intervention program, we will work with you/your child after your interview today to provide any community referrals or contacts you/your child 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 your child can skip any items she would like. After each interview, we will provide any referral information that might be useful to you/your child (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/she said with someone else. However, the confidentiality of your/your child's 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. Some infants may become fussy during their assessment. We will provide you/your child with opportunities to feed and soothe her infant throughout the assessment, and if your/her infant becomes distressed, we will take a break until your/your child's child feels they are ready to continue. The procedures used in this study may involve risks that are currently unforeseeable.

COVID-19: If in-person interactions are permitted by public health and safety and university officials, you/your daughter and your/her infant will be invited to come in for parts of your assessments that cannot be done virtually. Prior to these visits, both participants and personnel will complete a health screen to reduce the possibility of transmission of the virus. During these visits, both you/your daughter and all study personnel will also be asked to wear personal protective equipment. There is also one brief portion of the assessment, when you are alone in the room playing with your infant, where we will ask you to remove your mask. Other than this brief portion, you will need to remain in your personal protective equipment at all times. We will thoroughly disinfect the room and all materials between participants. These actions substantially reduce the risk of becoming infected with the virus, but your/your daughter's child will be too young to wear a mask. If you/your daughter are/is uncomfortable at any point during the assessment for any reason, despite these safety measures, we can immediately end the assessment and complete any remaining portions online. The CDC has indicated that pregnant women are at increased risk for serious illness; if you would like any modifications to the protocol due to pregnancy, or other health concerns, we are happy to accommodate you.

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. Mothers often learn more about their infants through the developmental testing and interactions as part of the study.

What are the other options?

There may be other options for your/your child's clinical care, including individual therapy services with a local psychologist, counselor or social worker. Your child's participation in this study does not prevent you from any of these additional services.

Will there be any compensation?

You/your child will receive up to $250 for completing the entire study. You/your child will also be eligible to receive up to 5 infant care items, one for each group session you/she attends.

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

All the information you/your child gives 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 her name is not attached to any of the information about her. Papers that connect your/your child's names to your/your child's 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/your child respect the privacy of other group members by not discussing the group or things that people said once you/your child 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. This research is covered by a Certificate of Confidentiality, which means that your research records will not be released without your consent unless required by federal, state, or local laws.

If you/your child choose to participate in this study, you/your child will be audio recorded during the group sessions and video recorded while interacting with your/her infant. All video and audio recordings will be stored securely and only the research team will have access to the recordings.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you/your child. At most, the Web site will include a summary of the results. You/your child can search this Web site at any time.

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 as 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 Child Services. If you/your child is a minor and living in Tennessee, we are required to report any form of intimate partner violence she has experienced to DCS. If you/your child is a minor and living in Indiana, we are required to report sexual abuse she has experienced from a partner.

If, during your/your child's 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.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal

proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

1. if there is a federal, state, or local law that requires disclosure (such as to report child abuse);
2. if you consent to the disclosure, including for your medical treatment;
3. if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
4. for the purpose of auditing or program evaluation by the government or funding agency.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Will your/your child's information be used for research in the future?

Information collected from you/your child for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed (e.g., your name, address or phone number) before any information is shared. Since identifying information will be removed, we will not ask for your/your child's additional consent.

Whom to contact with questions about the study?

Prior to, during or after your participation you/your child can contact the researcher If you have any questions or concerns about your/your child's participation, or if you/your child would like to know more about the BRAVE Lab's ongoing studies, you/your child can contact Dr. Miller-Graff at lmiller8@nd.edu or 574-631-3245. Dr. Kathryn Howell is the principal investigator at the University of Memphis. If you/your child have any questions for her, you may contact her at khhwell1@memphis.edu or 916-678-1541.

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

By providing their name below, you also agree to allow your child to participate in this study.

_____
Printed name of minor

_____
Printed name of child subject *(if applicable)*

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