Official Title: EngagINg the COmmunity to Reduce Preterm Birth Via Adherence To an Individualized Prematurity Prevention Plan (INCORPorATe IP3)

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Duke University Health System

Consent to Participate in a Research Study
ADULT
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CONCISE SUMMARY

The purpose of this study is to evaluate an intervention to improve uptake and adherence to Individualized Prematurity Prevention Plans (IP3) in pregnant people with a history of preterm birth by developing a patient-centered, community–involved intervention that will include a community doula led social support group.

Joining this study involves participating in a private Facebook group where community doulas will be providing information on various topics . You will be able to interact with the doulas and other participants enrolled in the study. All participants and doulas are also Black and many have a history of a prior preterm birth. After the Facebook group discussion, you will be offered to participate in a series of up to 8 group meetings that you can join by Zoom that will include pregnancy-related topics as well as reflection topics.

Risks include a possible loss of confidentiality and possible charges for text messages based on your cell phone carrier.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you are pregnant, self-identified as Black or African American, have a history of prior preterm birth, eligible for an Individualized Prematurity Prevention Plan (IP3), and you are planning to deliver your baby at Duke University Hospital. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Sarahn Wheeler and her research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. Wheeler will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
In the United States, Black women are more likely to deliver a baby preterm (before 37 weeks gestation). We worked with a group of non-Hispanic black women (NHB) to understand some of the barriers to following prenatal care. These studies revealed that NHB women with prior preterm birth felt that stress and lack of support were key barriers to preterm birth prevention care. We have developed an intervention (presentations) based on their feedback.

The current study is being done to get additional information on how well the intervention works and participant's opinion on the interventions.

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HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 60 women will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form.

Joining this study involves participating in a private Facebook group where community doulas will be providing information on various pregnancy and support topics. You will be able to interact with the doulas and other participants enrolled in the study. The doulas may contact you to introduce themselves and encourage zoom participation. All participants and doulas are also Black and many have a history of a prior preterm birth. Prior to being invited to this group, you will be asked to review a set of guidelines for appropriate Facebook page usage and sign that you acknowledge the guidelines and understand them.

After the Facebook group discussion, you will be offered to participate in a series of up to 8 group meetings that you can join by Zoom that will include pregnancy-related topics as well as reflection topics. Each meeting could last up to 2 hours in length. Other study participants will be able to join these meetings, as well as the community doulas and other study team members such as Dr. Wheeler.

Over the course of your participation and during your pregnancy up to 12 weeks after the delivery of your baby, we will access your medical records to review information about the course of your pregnancy and hospitalization for delivery of your baby.

At the end of your participation we will conduct an exit interview over the phone to as you questions having to do with your experience with the Facebook group and Zoom meetings.

HOW LONG WILL I BE IN THIS STUDY?
You will be in the study from the time you sign this consent until 12 weeks after the birth of your baby. This is around one year. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks of the study. The main risk includes a possible loss of confidentiality.
Risks specific to mobile apps:
Information collected by mobile applications or 'apps' is subject to their terms of use, which you should read carefully. Many apps make claims that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these mobile apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your device (phone/tablet) or what information from your device may be stored outside of Duke. You are encouraged to limit personal identifiers you enter into mobile applications (particularly your name, date of birth, address, place of employment, and other details that could allow someone to identify you) only to those that you wish to voluntarily share with others.

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These apps may send/receive information with other mobile apps, including social networking apps or websites (for example, Facebook). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully.

It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (e.g., battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges. At the conclusion of the study, we will provide you instructions on how to remove the mobile apps from your device.

We are not asking you to make any health decisions based on the use of these mobile apps. You should discuss health decisions directly with your healthcare provider.

As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
The information in the presentation contains information that we believe may be helpful to you during you pregnancy. We also hope that your feedback will help us to improve the presentation for women in the future.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1. there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2. you have consented to the disclosure, including for your medical treatment; or

3. the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

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You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. 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. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

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. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT ARE THE COSTS TO YOU?
You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please

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discuss the costs of the study with Dr. Wheeler. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

WHAT ABOUT COMPENSATION?
You will receive $20 at the study intake. You will receive an additional $20 after completing the exit-interview.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Wheeler at (919) 681-5220 during regular business hours and at (919) 970-6606 (pager) after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Wheeler in writing and let her know that you are withdrawing from the study. Her mailing address is 2608 Erwin Road Suite 210, Durham, NC 27705. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Wheeler at (919) 681-5220 during regular business hours and at (919) 970-6606 (pager) after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

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FACEBOOK GUIDELINES

Below are the guidelines for using the private Facebook page, please sign after you have read the guidelines acknowledging that you agree to follow the guidelines.

1 Be Kind and Courteous

We're all in this together to create a welcoming environment. Let's treat everyone with respect. Healthy debates are natural, but kindness is required.

2 Respect Everyone's Privacy

Anything discussed in this group should be kept private and confidential. Please do not share photos or information from this group without permission.

3 Medical Information Disclaimer

While there may be medical issues discussed in this group, this group should not be a substitute for seeking medical advice from your provider when necessary.

4 No Hate Speech or Bullying

Make sure everyone feels safe. Bullying of any kind isn't allowed, and degrading comments about things like race, religion, culture, sexual orientation, gender or identity will not be tolerated.

5 No Promotions or Spam

Give more than you take to this group. Self-promotion, spam and irrelevant links aren't allowed.

_____ _____ _____
Signature of Subject Date Time