Official Study Title

Improving Prenatal Care to Reduce Early Onset Preeclampsia in Low-Income Black Women in Kansas: A Randomized Trial of Centering Health, Empowerment, and Reproduction (HER)

ClinicalTrials.gov Identifier

NCT Number: _____
(»Pending.registration.at.ClinicalTrials¡gov‹)

Principal Investigator

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University of Kansas Medical Center (KUMC)

Study Sponsor

National Institutes of Health (NIH)

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Site Name

University of Kansas Medical Center
Kansas City, Kansas

RESEARCH CONSENT FORM

Improving Prenatal Care to Reduce Early Onset Preeclampsia in Low-Income Black Women in Kansas

Sharla Smith
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- We are asking you to be in a research study.
- Research is done to answer a scientific question. Research studies may or may not help the people who participate.
- Joining this study is completely voluntary. If you say yes, you can quit the study at any time.
- You can still get medical care and other services from the University of Kansas Medical Center even if you are not in the study.
- The research team will explain what happens if you decide to join the study. This conversation is called "informed consent."
- Informed consent includes a chance to get your questions answered before you make your decision. Please ask as many questions as you need to.
- This consent form explains the study. Take as much time as you need to decide.
- If you decide to be in the study, you will be asked to sign this form.

Dr. Sharla Smith is doing the study at the University of Kansas Medical Center (KUMC). About 72 people will be in the study.

Why is this study being done?
The study is being conducted to reduce needless preeclampsia and preeclampsia-related deaths among Black pregnant women by increasing access to evidence-based care. The study offers a group health care discussion to discussion prevention of pregnancy related hypertension and peer to peer support.

We are doing the study to learn more about disparities in preeclampsia and the management of pregnancy related hypertension.

How long will I be in this study?
The study will last one year and you will participate in a 7 week intervention for the 8 months. and involve 7 virtual visits on zoom and usual doula care in addition to regular

access to your OBGYN. A Doula is a trained professional who provides continuous physical, emotional, and informational support to their client before, during, and shortly after childbirth to help them achieve the healthiest, most satisfying experience possible. Usual Doula Care involves building a trusting relationship, answering questions, discussing a birth plan, and educating about the birth process. A doula will also be present at birth and act as a continuous advocate on behalf of the patient.

What will I be asked to do?

We will use REDCap software to assign 72 women in a 2:1 randomization scheme in variable block sizes to, respectively, Centering Health, Empowerment, Reproduction (HER) or usual doula care. You will have a 2 out of 3 chance to participate in the intervention.

Group assignments are random, like flipping a coin or rolling the dice.

Group 1-Non-Intervention

- You will receive usual doula care.
- You will complete a baseline survey, antepartum study survey, and postpartum survey.

Group 2- Centering HER Intervention

- Once selected for the study, you will participate in 7 virtual visits vi Zoom with two study team members: a doula and a medical professional.
- The 7 virtual meetings will be an hour and a half and led by a doula and a medical professional.
- You will receive 7 virtual visits with a group of four to six women participating in the study and at the same gestational week.
- Each telehealth/virtual visit will discuss blood pressure/hypertension, blood pressure, nutrition, weight management, exercise, and risk factors for hypertension.
- You will receive a Bluetooth blood pressure cuff and scale to take your blood pressure at home. The Blood pressure will be sent to a Bluetooth dashboard.
- You will self-report blood pressure.
- You will receive an apple watch if applicable to track exercise, movement, and sleep.
- You will complete a baseline survey, antepartum study survey, and postpartum survey to complete online.
- You will keep a medication log if applicable.

If you decide to be in the study, the researchers will ask you to do the following:

- Complete the informed consent form.
- Complete all virtual and usual care visits.
- Complete a medication log if applicable.
- Self-report blood pressure.

The primary objective of the study is to increase blood pressure monitoring and health behaviors: knowledge, activities, nutrition and social support to decrease the incidence of preeclampsia. The data collection will include birth outcomes at birth and 3 months postpartum.

If you assigned to the Non-Intervention arm
You will be given the following:

- Blood pressure cuff
- Medication Log
- Usual Doula Care Access
- Online surveys to complete

If you are assigned to the Centering HER Intervention
You will be given the following:

- Blood pressure cuff
- Apple Watch (if applicable)
- Medication Log
- Usual and Virtual Doula Care Access
- Online surveys to complete
- Doula support during labor and delivery

If you join the Centering HER program, you will take part in seven small-group sessions (about 60 minutes each, mostly virtual) during pregnancy, with an optional check-in reunion about 3 months after the last session. In the sessions, we'll talk about stress and wellness, nutrition and movement, sleep and coping, preparing for labor, postpartum planning, and long-term heart health, and you'll practice how to recognize warning signs and what to do if your blood pressure is high. You will be asked to check your blood pressure at home twice each week using the program's blood pressure cuff and log your readings and any symptoms in the MyBP app; you may also use an Apple Watch to track sleep and activity (the watch is not used to measure blood pressure). You can expect supportive group discussion, simple activities (like mindfulness check-ins and planning tools), and help building a postpartum safety plan and "warm hand-off" plan for follow-up care.

Sessions will be scheduled on a day and standing time (e.g., over the lunch hour or evening) and occur weekly for 7 weeks. You will need to use your own computer or mobile device and data plan to join the sessions. Prior to the first session, you will be provided technical assistance, a starter pack, and all needed technical devices and items with an individual practice connection.

In some instances, a family member of a participant my also join the group if needed to support and assist with their participation.

Participants will be asked to complete the following:

- **Data Collection / Questionnaires (Online)**

At **enrollment (around Session 1 / Week 12)** and again at the **end of the program (around Session 6 / Week 22)**, you will be asked to complete questionnaires either online or on paper. These surveys will ask questions about your health and wellbeing, including stress/"weathering," health behaviors, and your experience communicating with your care team.
Some check-ins may also be completed during the program (for example, brief bi-weekly stress and wellness check-ins). Each questionnaire typically takes about **15–30 minutes**. You may skip any question you do not want to answer.

- **Home Blood Pressure Monitoring & Tracking**

You will be asked to use the program's validated home blood pressure cuff and **monitor your blood pressure twice weekly**, then record your readings in the **MyBP app** (which can sync with the BP cuff). You may also be asked to track symptoms and wellness check-ins using the program booklet/logs.

- **Program Session Participation (Group Sessions + Optional Reunion)**

You will be invited to participate in **six group sessions** as part of the HOPE program. You may also be invited to an **Reunion** check-in session about **3 months after Session 6** to strengthen community connection and reinforce health behaviors.

- **Patient Experience Interview (Optional; Selected Participants)**

A subset of participants (about **6 people per group**) will be randomly selected for an interview to help researchers better understand barriers to program participation and follow-up care, experiences with provider communication, and barriers related to living in a rural community. These interviews will be conducted by video (or in person if available) and will last about **30–45 minutes**. With your permission, the interview may be audio-recorded to ensure accuracy. You may skip any question and may stop the interview at any time.

What are the risks of being in the study?
There are no physical risks involved in collecting information about you.

Questionnaire Risk. A possible risk is feeling uncomfortable when answering questions or discussing personal experiences (for example, stress, discrimination, mental health, or healthcare experiences). You may skip any question or stop at any time without penalty. There is a small risk of breach of confidentiality. For that reason, your information will be protected as described in the Privacy section below.

Text Messages. Standard text-messaging rates may apply, depending on your mobile phone plan. Because text messages depend on mobile carrier network availability, delivery may be delayed or not occur. You can stop receiving study texts at any time by replying **"STOP"** to any study message.

Participants in both study groups may also incur mobile data charges if you use a smartphone or cellular data to join **Zoom** study visits or complete online study activities. If you would like to reduce or avoid data charges, you may join using **Wi-Fi** when available (or request paper-based options, if offered).

Are there benefits to being in this study?
You will not get personal benefit from being in this study. Researchers hope this study may be helpful in improving treatments for patients with managing pregnancy related hypertension and reducing preeclampsia. You will receive 7 virtual visits with a doula and a medical professional to discuss health behaviors and receive peer to peer support to manage your hypertension and/or reduce preeclampsia.

Will I have any costs or payments for being in the study?
You will not be charged for being in the study. In appreciation of your time, you will receive $25 for each study session (n=6) and survey completion (n=2), Centering HER dollars for completion of each session, and $50 for final survey/interview. If you complete all regularly scheduled visits, you may receive up to $250. If you leave the study early, you will be paid only for the visits you completed.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will be added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money. You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year. If you do not provide a valid social security number or tax identification number, 30% of your payments will be set aside by KUMC and sent to the IRS for withholding on your behalf.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

Will the researchers get paid for doing the study?
The institution (KUMC Research Institute, Inc.) will receive payments from the sponsor, the National Institute of Health for conducting this study. Payments will be used for research purposes only.

What other choices do I have if I don't want to be in the study?
You can choose not to be in the study. You can decide to leave the study at any time. Leaving will not affect the treatment or services you get at KUMC.

How will my confidentiality and privacy be protected?
The researchers will keep your identity confidential, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any

publication or presentation about the study.

If you sign this form, the research team will collect, use and share your private health information as described below. If you decide not to sign this form, you cannot be in the research study.

Study data includes information from your study activities and from your medical record. Your health care providers may release your private health information to Dr. Sharla Smith and the research team. The team may use any and all of your information needed for the study. Your medical records may contain your name, address, phone, date of birth, social security number, or other identifiers. Others at KUMC might need to look at your research records. They include KUMC Research Institute, the Institutional Review Board or other committees and offices that review and monitor research studies.

Your participation in this study and your study information may be put into the University of Kansas Health System electronic medical record and combined with your health information from your clinical care. The health system may use and share this information for other purposes described in the Notice of Privacy Practices.

You may not be able to see your records relating to the study until after the study is over and the results are known. Any research information that is put in your medical record will be kept indefinitely.

Your permission to use and share your health information will not expire unless you cancel it. To cancel your permission, please write to Sharla Smith. The mailing address is Sharla Smith, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel your permission, you will be withdrawn from the study. They are permitted to use and share information that was gathered before they received your cancellation.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This protects the researchers from being forced to give out personal information about you for legal proceedings. This does not stop you from voluntarily releasing information about yourself or your participation in this research.

One exception to the Certificate is if you agree that we can give out research information that identifies you. Your information will be shared for the purposes listed in this consent form. Other exceptions are information we must report if we learn about child abuse or neglect or if we think you might harm yourself or others.

Information about your research participation may be included in your medical record. The Certificate of Confidentiality does not prevent releases of information in your medical record for routine purposes such as treatment or billing purposes. Any research information in your medical record might be included when copies are sent for routine purposes.

What if I decide to leave the study?
You can choose to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Sharla Smith using the contact information on the first page of this document. If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you about you unless they need information about a side effect of the study intervention. They are permitted to use and share information that was gathered before they received your cancellation.

Will I be told about research results?
You will be told about any study results that directly affect your personal medical care. At the end of the study, we will send you a letter with a summary of the results.

Who can I talk to about the study?
Sharla Smith or other members of the study team should answer all your questions before you sign this form. They will also tell you if they learn anything new that might affect your decision to stay in the study. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints. If you have questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may contact the KUMC Institutional Review Board at (913) 588-1240 or IRBhelp@kumc.edu.

CONSENT
Dr. Sharla Smith or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

In the future, the researchers may conduct additional studies about preeclampsia. If you agree, the researchers will contact you to see if you want to join future studies. You would receive a separate consent form describing the future studies.

☐ Yes, I would like to be contacted if I qualify for future studies. _____
Signature

☐ No. Please do not contact me about future studies. _____
Signature