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

ClinicalTrials.gov Identifier
NCT Number: *Pending registration at ClinicalTrials.gov*

Principal Investigator
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Study Sponsor
National Institutes of Health (NIH)

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Site Name: University of Kansas Medical Center
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University of Kansas Medical Center
RESEARCH PROTOCOL INVOLVING HUMAN SUBJECTS
TEMPLATE WITH GUIDANCE

Version date: 02.09.2026

Principal Investigator: Sharla Smith

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1. Protocol Synopsis

Study Design

Prospective, two-arm randomized controlled trial; parallel assignment; open-label (behavioral/telehealth intervention).
Randomization: 2:1 allocation using REDCap with variable block sizes.
Framework: Practical, Robust Implementation, and Sustainability Model (PRISM) to guide implementation, adoption, effectiveness, maintenance, and pragmatism evaluation.

Population

Pregnant participants, age ≥18 years.
English or Spanish speaking.
Less than 13 weeks gestation at enrollment.
Moderate or high risk for preeclampsia per USPSTF criteria.
Intervention (Arm 2)
Centering HER (HGPC-T): routine prenatal care plus 7 doula-led virtual group sessions (90 minutes each) with OB/GYN fellow oversight.
Participants receive Bluetooth BP cuff and (if applicable) Apple Watch; self-monitor and self-report blood pressure and weight; complete surveys and medication log (if applicable).
Comparator (Arm 1)
Usual doula prenatal care and routine prenatal care visits with OB/GYN; completes study surveys.

Primary/Key Outcomes (as stated in source protocol)

Blood pressure rates; hypertension monitoring and aspirin compliance (# of women monitoring BP and aspirin compliance).
Feasibility, acceptability, and contextual factors required for implementation.

Duration

Enrollment at <13 weeks gestation through postpartum survey completion (baseline, antepartum, and postpartum surveys).

Data Sources

REDCap surveys (baseline, antepartum, postpartum).
Self-reported BP/weight (device-supported); medication log (if applicable).
Electronic health record abstraction (clinical outcomes) as described in the source protocol.

I. Purpose, Background and Rationale

A. Aim and Hypotheses

1. The study will use the Practical, Robust Implementation, and Sustainability Model (PRISM) to implement **Hypertension group prenatal care**- telehealth (HGPC-T) also known as Centering HER-health, empowerment, reproduction to reduce preeclampsia in pregnancy (centering GPC, screening, monitoring, and aspirin) in community clinics.[18]

Based on PRISM, we will assess HGPC-T intervention development (e.g., organizational, providers, and patients' perceptions); adoption (e.g. HGPC-T intervention adoption); the effectiveness (e.g., # of women monitoring hypertension and aspirin compliance); maintenance (e.g. intention to continue the HGPC-T); and pragmatism (e.g., adaptability of HGPC-T in other settings).[18] The central hypothesis is that HGPC-T will lead to continuous monitoring of chronic hypertension, reduce early-onset preeclampsia, and reduce barriers to prenatal care.

2. Aim 1. To determine the feasibility, acceptability, and contextual factors required for the implementation of the virtual GPC-T to reduce preeclampsia among low-income, predominantly Black women. Aim 2. To pilot the virtual GPC-T and determine whether virtual HGPC-T reduces preeclampsia among low-income, predominantly Black women. Aim 3. To determine the effectiveness of virtual GPC to reduce preeclampsia among low-income, predominantly Black women.

B. Background and Significance

1. Study Significance: This research has the potential to reduce preeclampsia disparities by considering system change in the delivery of maternal care, continuous monitoring of blood pressure, reducing barriers in transportation and time off from work, improving patient hypertension education, and improving social support and peer-to-peer learning.
2. First, the study will allow us to determine the feasibility, acceptability, and contextual factors required for the implementation of the HGPC-T to reduce disparities in EOP, which to our knowledge, has not yet been done. Second, diverging from the status quo of individual prenatal care treatment to reduce EOP, implementation of 81 mg of aspirin[6] between 16 and 20 weeks, this study will pilot the virtual HGPC-T enhancement with a hypertension intervention known to improve medication adherence and decrease hypertension to reduce preeclampsia.
3. Literature Review: (see Reference List)
4. **Importance of preeclampsia in the U.S.** Preeclampsia, a potentially fatal pregnancy condition characterized by high blood pressure, is estimated to complicate 3 percent to 6 percent of all pregnancies[1-2]. The rate of preeclampsia in the U.S. has increased 25 percent in the past two decades[22]. Preeclampsia is a leading cause of maternal and infant illness and death[1;4-5;8]. Non-Hispanic Black women carry a 3- to 4 fold greater risk of dying from pregnancy-related preeclampsia[3;12;20]. For example, preeclampsia is associated with 20-30% preterm births and 15% low birth weight[1;5]. Moreover, a significant number of women who get preeclampsia are at increased risk for cardiovascular disease after pregnancy and throughout their lives.[1;8;23]

C. Rationale

1. We posit that the implementation of HGPC-T for continuous high blood pressure monitoring is a critical step in closing disparities in preeclampsia. This research has the potential to reduce preeclampsia disparities by considering system change in the delivery of maternal care, continuous monitoring of blood pressure, reducing barriers in transportation and time off from work, improving patient hypertension education, and improving social support and peer-to-peer learning.
2. This research has the potential to reduce preeclampsia disparities by considering system change in the delivery of maternal care continuous monitoring of blood pressure, reducing barriers in transportation and time off from work, improving patient hypertension education, and improving social support and peer-to-peer learning.

3. The study may reduce preeclampsia and improve management of pregnancy-related hypertension.

II. Research Plan and Design

A. Study Objectives: The objective is to enhance the Centering GPC intervention with telehealth and take care of your blood pressure (TCYB) intervention for hypertension monitoring.

B. Study Type and Design: 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."

i. Group 1-Non-Intervention
   1. Receive usual doula prenatal care including regular prenatal care visits.
   2. Participants will complete a baseline survey, antepartum study survey, and for postpartum survey

ii. Group 2- Centering HER intervention
   1. Once selected for the study, you will participate in usual prenatal care visits with an OBGYN, 7 doula led virtual intervention sessions visits with an OBGYN fellow oversight.
   2. The 7 virtual meeting will be an hour and a half and led by a doula. A research staff member will be present to help with the coordination of the virtual intervention.
   3. You will receive 7 virtual visits with a group of women participating in the study
   4. Each telehealth/virtual visit will discuss blood pressure/hypertension, blood pressure, nutrition, weight management, exercise, and risk factors for hypertension.
   5. Participants will receive a Bluetooth blood pressure cuff, apple watch (if applicable), and doula tailored care to take your blood pressure and weight at home.
   6. Self-report blood pressure and weight
   7. Participants will complete a baseline survey, antepartum study survey, and for postpartum survey.
   8. Keep a medication log if applicable

Intervention Table

Feature	Group 1: Non-Intervention (Usual Doula Care)	Group 2: Centering HER Intervention
Prenatal Care	Standard doula support + routine prenatal care with OB/GYN	Routine prenatal care + 7 virtual doula-led intervention sessions with OB/GYN fellow oversight

Feature	Group 1: Non-Intervention (Usual Doula Care)	Group 2: Centering HER Intervention
Doula Involvement	Yes – access to traditional doula support during prenatal visits	Yes – virtual group doula-led health education and coaching
Group Sessions	None	7 virtual group sessions (90 min each) with other pregnant participants
Session Topics	Not applicable	Hypertension, blood pressure, nutrition, exercise, risk factors
Technology Provided	None	Bluetooth BP cuff, Apple Watch (if applicable)
Self-Monitoring	No	Participants self-monitor and report blood pressure and weight
Survey Completion	Baseline, antepartum, and postpartum surveys	Baseline, antepartum, and postpartum surveys
Medication Tracking	No	Keep medication log (if applicable)
Research Staff Involvement	Minimal such as surveys, reported blood pressure	Yes – staff assist with coordinating virtual sessions

Timeline

Month	Activities	Milestones / Notes
Month 0-December	Study Launch + IRB Finalization– Finalize recruitment materials– Train staff + doulas– Set up data tracking and virtual platforms	IRB approval confirmed; staff orientation completed
Month 1-February	Recruitment Begins– Begin enrolling both groups (target ~5 per group)– Distribute flyers, contact clinics, etc.	First 10 participants enrolled (5 intervention, 5 control)
Month 2-3	Continue Recruitment + Begin Intervention– Enroll next 10 participants– Begin Group 1 surveys– Intervention Group 1 starts Session 1	~50% enrollment milestone reached
Month 4	Recruit Final Cohort– Enroll remaining 36 participants– Distribute Apple Watches and BP cuffs– Start Sessions 1–2 for final intervention groups	72 participants fully enrolled (36 per group)
Month 5	Midpoint Engagement– Intervention: Sessions 3–4 (Blood Pressure, Nutrition)– Track self-monitoring data– Group 1 completes mid-surveys	Monitor adherence and troubleshoot any tech issues
Month 6	Continue Sessions + Surveys– Sessions 5–6: Physical activity, medication awareness– Group 2 logs vitals– Group 1 continues routine care + surveys	Most intervention participants complete 75% of sessions
Month 7	Final Session + Postpartum Planning– Session 7: Doula support, preparing for delivery– Collect	Sessions concluded for intervention group

Month	Activities	Milestones / Notes
	antepartum surveys– Encourage postpartum follow-up prep	
Month 8	Final Data Collection + Postpartum Surveys– Collect postpartum survey from both groups– Finalize weight/BP logs– Export and clean dataset	Study concludes; prepare for analysis and reporting

C. Sample size, statistical methods, and power calculation

1. Data will be checked for errors, inconsistencies, and missing values. Descriptive statistics (e.g., mean and standard deviation for continuous variables and number and percent for categorical variables) will be presented for all demographic variables, predictors of interest, and outcomes. Chi-square and 2-sample t-tests will be used to compare the outcomes among demographic groups and between different treatments.
2. The participants will receive education on nutrition and exercise, will be asked to monitor their blood pressure daily using blood pressure cuffs, and will receive the standard of care of 81mg of aspirin per day (if applicable).
3. This is a pilot project, so there is no power calculation for the project. The total number of participants is 72.

D. Subject Criteria (See Vulnerable Populations appendix, if applicable):

1. Inclusion criteria: English or Spanish speaking, <13 weeks gestations, >18 years old, moderate or high risk for preeclampsia according to the United States Preventative Services Task Force (USPSTF): **High Risk:** History of preeclampsia (especially with an adverse outcome): Multifetal gestation; Chronic hypertension; Pregestational type 1 or type 2 diabetes; Kidney disease; Autoimmune disease (e.g., systemic lupus erythematosus, antiphospholipid syndrome) **Moderate Risk:** Nulliparity (first pregnancy); Obesity (pre-pregnancy BMI > 30); Family history of preeclampsia (mother or sister); Black persons (due to social, not biological, factors); Lower income; Age ≥ 35 years; Personal history factors (e.g., low birth weight or small for gestational age, previous adverse pregnancy outcome, >10-year pregnancy interval); In vitro conception (IVF)
2. Exclusion criteria: <18 and not receiving prenatal care or eligible for doula care
3. Withdrawal/Termination criteria: N/A
4. N/A

E. Specific methods and techniques used throughout the study

1. Laboratory tests: **N/A**
2. **Study Procedures:** The control group will receive usual care from OBGYN and usual doula counselling and complete surveys. The study's intervention will be conducted as 7 usual care visits with OBGYN and 7 virtual group visits, including a group of women in the study. Each participant will also have access to usual doula counselling. Each virtual visit will discuss nutrition, high blood pressure/hypertension, exercise, weight

management, and risk factors for hypertension. Each participant will receive a blood pressure cuff and scale to take their blood pressure and weight at home.

3. Each participant will be expected to complete a consent, attend virtual group sessions, complete the medication log if applicable and complete the surveys.

4. **N/A**
5. Timeline: **N/A**

F. Risk/benefit assessment:

1. Foreseeable Risks
   - Privacy and confidentiality: risk of unintended disclosure of pregnancy/health information through study records or virtual sessions.
   - Group-session confidentiality limits: other participants may share information outside the group despite agreements.
   - Psychological or emotional discomfort: discussing pregnancy, health behaviors, barriers to care, or social stressors may be upsetting.
   - Device-related risks: minor discomfort with cuff use; anxiety related to elevated readings; potential for inaccurate readings.
   - Time and inconvenience: time required for surveys, virtual sessions, and daily BP/weight monitoring.

2. Risk Mitigation
   - Use REDCap and secure institutional storage (p:protecteddata drive) with role-based access; store identifiers separately from analytic datasets.
   - Use virtual-session ground rules and confidentiality agreements; allow participants to use first name or preferred name in group.
   - Provide clear instructions that participants should not change medications based on home readings without contacting their clinician; provide escalation guidance for severe readings.
   - Offer option to skip any survey question and request private follow-up for sensitive concerns

3. Potential Benefits
   - Consistent with the source protocol, potential benefits include improved ability to monitor blood pressure, increased hypertension education, and peer-to-peer social support; benefits are not guaranteed.

G. Location where study will be performed: University of Kansas Medical Center

H. Collaboration (with another institution, if applicable): N/A

I. Single IRB Review for a Multi-site study (if applicable):

1. For which sites will KUMC serve as the IRB of record? N/A
2. Indicate which study activities will occur at each site. If all study procedures will be identical across study sites, state this. N/A
3. Describe how you will assess the capacity of each site to perform the research (e.g., expertise, staffing, space, equipment, etc.) If applicable, include site evaluation tools in your IRB submission. N/A
4. Describe how the lead investigators will ensure that all participating sites use the IRB-approved version of the protocol, consent, recruitment materials and other study documents. N/A

5. Describe how the lead investigators will communicate with and disseminate new information to other sites (e.g., training meetings, regularly scheduled conference calls, notifications, etc.) N/A
6. Describe how the lead investigator will assess protocol compliance, unanticipated problems and adverse events at other sites. N/A
7. Name the member of the KUMC study team who will be the point of contact to coordinate oversight and communication with the sites. N/A

J. Community-Based Participatory Research (if applicable)

1. Participants and the nature of their involvement: N/A
2. Cultural issues: N/A
3. Origin of the research question: N/A
4. Risks and Benefits: N/A
5. Study Description and Process: N/A
6. Return of results: N/A
7. Sustainability: N/A

K. Personnel who will conduct the study, including:

1. Indicate, by title, who will be present during study procedure(s): Sharla Smith, Sapphire Garcia, Noria McCarther, Oluoma Obi, Shea Kampsen, and Claire Metcalf.
2. Primary responsibility for the following activities, for example:
    a. Determining eligibility: Sharla Smith, Sapphire Garcia, Noria McCarther, and Oluoma Obi
    b. Obtaining informed consent: Sharla Smith, Sapphire Garcia, Noria McCarther, Shea Kampsen, Claire Metcalf, and Oluoma Obi
    c. Providing on-going information to the study sponsor and the IRB: Sharla Smith, Sapphire Garcia, Noria McCarther, and Oluoma Obi
    d. Maintaining participant's research records: Sharla Smith, Sapphire Garcia, Noria McCarther, Shea Kampsen, Claire Metcalf and Oluoma Obi
    e. Completing physical examination: N/A
    f. Taking vital signs, height, weight: Doula (Sapphire Garcia)
    g. Drawing / collecting laboratory specimens: N/A
    h. Performing / conducting tests, procedures, interventions, questionnaires: N/A
    i. Completing study data forms: Sharla Smith, Noria McCarther, Sapphire Garcia, Oluoma Obi, and Shea Kampsen
    j. Managing study database: Sharla Smith, Noria McCarther, Sapphire Garcia, Oluoma Obi, and Shea Kampsen

L. Assessment of Subject Safety and Development of a Data and Safety Monitoring Plan

1. Elements of the plan include:
    a. Persons/groups who will review the data (study team; independent safety monitor, data monitoring committee or formal DSMB) Sharla Smith
    b. Data/events that will be reviewed
    c. Frequency of review Quarterly
    d. Types of analyses to be performed Descriptive
    e. Safety-related triggers that would cause the PI to stop or alter the study N/A
3. Describe how adverse events and unanticipated problems will be ascertained and handled. Explain exactly which type of problems will be considered serious and reported to the IRB. The reporting timeframe should also be detailed. N/A
   Explain exactly what will happen if a patient experiences an adverse event or other problem (for example, will discontinue study participation). N/A

III. Subject Participation

A. Recruitment:

1. University of Kansas Medical Center Utilizing community recruitment without a designated institution.
2. Target emails and text to patients enrolled in the doula network and sacred care.
3. KBEN stakeholder organizations (n=90) will distribute flyers. Community Health Workers will distribute flyers in Sedgwick and Wyandotte Counties
4. Flyers online via social media and with local community organizations.

B. Screening Interview/questionnaire: Inclusion Criteria

Yes

C. Informed consent process and timing of obtaining of consent

1 Sharla Smith, Oluoma Obi, and Shea Kampsen
2 Participants will be given an opportunity to review the consent, and consent will be read to participants, and time will be allocated for questions and concerns, participants will be informed that participation is voluntary.
3 Consent will only be completed by individuals participating.

D. Alternatives to Participation: Usual Prenatal Care and provision of doula care

E. Costs to Subjects: N/A

F. How new information will be conveyed to the study subject and how it will be documented: New information will be provided as written communication at an eighth-grade level.

G. Payment, including a prorated plan for payment: Participants will be compensated for their time as follows: $25 per intervention session, $25 after completing baseline surveys, $25 after completing the antepartum study visit surveys at the last visit before delivery, and $50 after completing the postpartum surveys.

H. Payment for a research-related injury: N/A

IV. Data Collection and Protection

A. Data Management and Security: Data collected in blood pressure.

1. Data will be stored on the p:protecteddata drive
2. No, coded numbers will be used
3. Sharla Smith
4. codes
5. p:protecteddata drive
6. N/A
7. N/A

B. Sample / Specimen Collection: N/A

C. Tissue Banking Considerations: N/A

D. Procedures to protect subject confidentiality:

A. General Approach

Participant confidentiality will be protected through data minimization, coding/de-identification, secure storage, and role-based access. Only the minimum necessary identifiable information will be collected to conduct study procedures and link survey/device/EHR data.

B. Study IDs and Linkage File

- Each participant will be assigned a unique Study ID at enrollment.
- Identifiers (e.g., name, DOB, phone, email, medical record number) will be stored in a separate linkage file ("master key") that links identifiers to Study IDs.
- The linkage file will be stored in a restricted-access, encrypted institutional location (e.g., secure server drive) separate from research datasets.
- Research datasets used for analysis will contain Study IDs only whenever feasible.

C. Data Collection Platforms (REDCap / Surveys)

- Surveys will be collected using REDCap (or equivalent HIPAA-aligned institutional system) with:
  - Role-based permissions (least-privilege access)
  - Unique user logins
  - Audit trails enabled to track data access and changes
- Surveys will avoid collecting unnecessary identifiers. When contact data is needed for follow-up, it will be stored in a contact module separate from outcomes data.

D. Electronic Health Record (EHR) Data

- EHR data abstraction will be limited to minimum necessary fields (e.g., BP values, visit dates, delivery outcomes, diagnoses relevant to preeclampsia risk).
- EHR extracts will be stored using Study IDs, with MRNs retained only in the separate linkage file (unless institutional policy requires temporary MRN storage for abstraction).
- Only authorized study staff with institutional training and access will conduct EHR review.

E. Device/App Data (e.g., Bluetooth BP cuff / wearable)

- Participants will be instructed not to transmit identifiable medical details through free-text fields.
- Device measurements will be linked to Study IDs in REDCap (or secured data repository).
- If vendor platforms are used, only necessary data will be collected and exported to the secure institutional environment as soon as feasible.

- Any exports will be stored as coded data with Study IDs; raw exports with identifiers (if unavoidable) will be stored separately with restricted access.

F. Virtual and Group Session Confidentiality (if applicable)

Because group sessions involve multiple participants, confidentiality protections include:

- Participants will sign a Group Confidentiality Agreement stating they will not share information discussed in the group outside the group.
- At the start of each session, facilitators will review ground rules:
  - Share only what you are comfortable sharing
  - Do not record the session
  - Use headphones and join from a private space when possible
  - Respect privacy and avoid using others' full names
- Sessions will not be recorded unless explicitly approved by the IRB and included in the consent form.
- Facilitators will discourage disclosure of highly identifying details during group sessions and offer a pathway for private follow-up for sensitive concerns.

G. Staff Training and Confidentiality Obligations

- All study personnel will complete required training (e.g., human subjects protection, HIPAA/privacy, data security).
- Study team members will sign confidentiality agreements as required by institutional policy.
- Access to identifiable information will be limited to staff who require it for recruitment, scheduling, or clinical escalation.

H. Data Storage, Encryption, and Access Controls

- All electronic study data will be stored on encrypted, access-controlled institutional servers or approved secure cloud environments.
- Portable devices (laptops, external drives) will not store identifiable data unless encrypted and institutionally approved.
- Email/text communications will use minimum necessary information. Identifiers will not be shared in unsecured messages beyond what is necessary for scheduling.
- Paper documents (if any) will be stored in a locked cabinet in a locked office; access limited to authorized staff.

I. Data Sharing, Reporting, and Publication

- Results will be reported in aggregate form only.
- No individual participant will be identifiable in publications or presentations.
- Any sharing of de-identified datasets with collaborators will use a data use agreement as required, and only de-identified/coded data will be shared unless IRB approval and HIPAA authorization permit otherwise.

J. Data Retention and Destruction

- Study records will be retained for [X years] after study completion in accordance with institutional and sponsor requirements.
- After the retention period, identifiable files (including linkage files) will be securely destroyed per institutional policy.

K. Privacy Limits and Mandatory Reporting

Participants will be informed that confidentiality may be limited in cases of:

- Immediate risk of harm to self or others
- Suspected child abuse/neglect or other mandatory reporting obligations

In the event of a suspected privacy breach:

- The PI will be notified immediately.
- Institutional privacy/security offices will be contacted per policy.
- The IRB will be notified according to institutional reporting timelines.
- Participants will be notified if required by policy/law.

E. Quality Assurance / Monitoring

1. Data will be collected via electronic health record abstraction, instruments administered to patients, and self-report of blood pressure and medication adherence. All data will be collected on standardized forms (on which nearly all responses will be pre-coded) in REDCap.
2. N/A

V. Data Analysis and Reporting

A. Statistical and Data Analysis: Data will be checked for errors, inconsistencies, and missing values. Descriptive statistics (e.g., mean and standard deviation for continuous variables and number and percent for categorical variables) will be presented for all demographic variables, predictors of interest, and outcomes. Chi-square and 2-sample t-tests will be used to compare the outcomes among demographic groups and between different treatments.

B. Outcome: Blood pressure rates

i. Hypertensive-range BP is defined as SBP ≥140 and/or DBP ≥90 mm Hg; severe-range BP is SBP ≥160 and/or DBP ≥110 mm Hg.
ii. Severe-range hypertension (obstetric emergency threshold): SBP ≥160 or DBP ≥110

C. Study results to participants: N/A

D. Publication Plan: Three publications will be done: Implementation of the study, analysis of study results, and health behaviors of participants.

E. Bibliography / References / Literature Cited

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APPENDIX I: VULNERABLE POPULATIONS

I. Pregnant women ages 18-35, pregnant women data will be protected on the p:drive for surveys, no medical data will be provided during group discussions, participants will be asked to use their first names during group or a name they would like to use.

II. Cognitively or decisionally impaired individuals: N/A

III. Children: N/A

IV. Pregnant women: Yes

V. Prisoners: N/A

VI. Students and/or Employees:

A. N/A

B. N/A

C. N/A

17. Attachments List (IRB Submission Packet)
Attachment 1: Informed Consent Form template (Appendix A).
Attachment 2: Recruitment materials and scripts (Appendix B).
Attachment 3: Virtual Group Confidentiality Agreement (Appendix C).
Attachment 4: Safety workflows (Appendix D): Severe BP escalation; Acute distress/suicidality response (as applicable).
Attachment 5: Measures/Instrument packet (Appendix E): baseline/antepartum/postpartum surveys; BP/weight log; medication log (if applicable).
Attachment 6: Schedule of Events and Timeline tables (Sections 4.1 and 5).
Attachment 7: Data and Safety Monitoring Plan details (Section 10).

Appendix A. Informed Consent Form (Template)
Study Title: Improving Prenatal Care to Reduce Early Onset Preeclampsia in Low-Income Black Women in Kansas
Principal Investigator: Sharla Smith (contact: [insert email/phone])

Invitation to Participate
You are being invited to take part in a research study because you are pregnant and may be eligible based on your pregnancy stage and risk factors for preeclampsia. Participation is voluntary.
Purpose
The purpose of this study is to test two ways of supporting prenatal care to help reduce early-onset preeclampsia by improving blood pressure monitoring, aspirin adherence, and reducing barriers to prenatal care.
Procedures

If you join, you will complete surveys at baseline, later in pregnancy (antepartum), and after delivery (postpartum).
You will be assigned by chance (like flipping a coin) to one of two groups: usual doula care or Centering HER (virtual group sessions).
If assigned to Centering HER, you will participate in 7 doula-led virtual group sessions (about 90 minutes each) and will be provided a Bluetooth blood pressure cuff and, if applicable, an Apple Watch to support home monitoring.
You may be asked to keep a medication log if applicable and self-report blood pressure and weight as instructed.
Randomization
Group assignment is random and neither you nor the study team can choose your group.
Risks
Some questions may feel personal. You can skip any question.
Because some sessions are done in a group, the study team cannot guarantee other participants will keep information private. We will ask everyone to sign a confidentiality agreement.
Using a blood pressure cuff may cause minor discomfort. Seeing high blood pressure readings may be stressful. You will receive instructions on when to contact your care team or seek urgent care.
Benefits
You may learn skills and receive support to monitor your blood pressure and support healthy pregnancy behaviors, but benefits are not guaranteed.
Confidentiality
Study data will be stored securely. We will use a study ID number when possible. Group confidentiality has limits because other participants are not study staff.
Compensation
Participants will be compensated: $25 for each intervention session; $25 after completing baseline surveys, $25 after completing antepartum surveys, and $50 after completing postpartum surveys.
Voluntary Participation
You may refuse or stop at any time without affecting your care or benefits.
Questions
If you have questions about the study, contact the study team at [insert]. For questions about your rights, contact the KUMC IRB at [insert].

Participant Name (print): _____
Participant Signature: _____ Date: _____
Person Obtaining Consent: _____ Date: _____

Appendix B. Recruitment Materials and Scripts (Templates)
B1. In-clinic Intro (Clinic Staff)/Doula
Hi, our clinic is partnering with the University of Kansas Medical Center on a study testing ways to support prenatal care and blood pressure monitoring to reduce preeclampsia. Would you like to hear more from the research team? Participation is voluntary and will not affect your care.

B2. Research Staff Phone/Private Screening Script
Confirm the person is in a private place to talk.
Explain the study compares usual doula care versus a Centering HER virtual group prenatal support program.

Explain random assignment and what participation involves (surveys; possible virtual group sessions; home BP monitoring).
Explain voluntary nature; answer questions; schedule consent visit.

B3. Text/Portal Message Template
Your clinic is partnering on a prenatal research study to reduce preeclampsia by improving blood pressure monitoring and support. If you are interested in learning more, reply to this message or call [phone]. Participation is voluntary.

Appendix C. Virtual Group Confidentiality Agreement
I understand virtual group prenatal sessions involve discussion with other participants.
I agree to respect others' privacy and not share personal stories or names outside the group.
I understand the research team cannot guarantee confidentiality because other participants are not staff.
I may choose what to share and may request private follow-up with the doula or study staff.
I understand staff may need to break confidentiality to address immediate safety concerns or mandatory reporting obligations.

Participant Name (print): _____
Participant Signature: _____ Date: _____

Appendix D. Safety Workflows (SOP)
D1. Severe Blood Pressure Escalation Workflow
Trigger: Any home blood pressure reading in the severe range (e.g., systolic ≥160 and/or diastolic ≥110), or symptoms suggestive of hypertensive emergency (e.g., severe headache, vision changes, chest pain, shortness of breath, RUQ pain).
If severe BP or severe symptoms: instruct participant to seek emergency care immediately (call 911 or go to the nearest emergency department).
If elevated but not severe: instruct participant to repeat measurement after 5–10 minutes of rest and contact their prenatal care team the same day for guidance.
Document the report (date/time, reading, symptoms, actions taken) in REDCap safety log.
Notify PI or designee within 24 hours of any severe-range report.

Appendix E. Measures and Instruments Packet (Inventory)

Instrument / Data Source	Purpose	Timepoints	Notes / Storage
Baseline Survey (REDCap)	Demographics, baseline health behaviors/knowledge, baseline outcomes per study measures table	Baseline (<13 weeks)	Store in REDCap; authorized versions in regulatory binder
Antepartum Survey (REDCap)	Follow-up outcomes and process measures	Late pregnancy / last prenatal visit before delivery	Store in REDCap
Postpartum Survey (REDCap)	Postpartum outcomes and acceptability	Postpartum	Store in REDCap
Home BP and Weight Log (device-supported)	Daily/regular monitoring	Throughout participation	Self-report; Bluetooth cuff/Apple Watch (if applicable)
Medication Log (if applicable)	Aspirin and/or antihypertensive adherence tracking	Throughout participation	Self-report; may be verified by doula if built into workflow
EHR Abstraction	Clinical outcomes including blood pressure, prenatal care utilization, delivery outcomes (as defined)	Ongoing / postpartum	Minimum necessary data; stored on p:protecteddata drive