Pregnancy-Related Hypertension: Adherence to a New Type of Monitoring (PHANTOM)

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NCT: not yet assigned

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Pregnancy-Related Hypertension: A New Type of Monitoring (PHANTOM)

Study to be Conducted at: Greenville Memorial Hospital
701 Grove Rd.
Greenville, SC 29605

OB/GYN Center
1120 Grove Rd.
Greenville, SC 29605

Medical University of South Carolina
171 Ashley Ave.
Charleston, SC 29425

Sponsor Name: South Carolina Telehealth Alliance

Principal Investigator: Renata Sawyer, MD, Prisma Health (864-455-1600)
Matt Finneran, MD and David Soper, MD, Medical University of South Carolina (843-792-4500)

KEY INFORMATION

You are being asked to participate in a research study. Participation in a research study is voluntary. The information in this consent form is meant to better inform you so you may decide whether or not to participate in this research study. Please ask the study staff to explain anything you do not understand.

The goal of this study is to improve blood pressure monitoring choices after delivery for women diagnosed with high blood pressure during their pregnancy, during labor, or after delivery. The standard recommendation is to check blood pressure 72 hours after delivery if necessary and then definitely again 7-10 days after delivery. This is accomplished by coming to the OB clinic. By participating in this study, you would be randomized to either one of two study groups. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor your doctor will choose what group you will be in. You will have an equal chance of being placed in either group. The first group would have their blood pressure checked 72 hours after delivery if your Dr. or midwife thinks that is necessary - and then again 7-10 days after delivery. The second group would be provided with supplies and devices to monitor your blood pressures at home at no cost to you. This involves communication by cell phone with calls and texts. If you are randomized to monitor your blood pressures at home, this may benefit you by being more convenient than having to come to clinic and we may pick up high blood pressures that would otherwise not be noticed. Participation in this study is completely voluntary, and declining to participate will not negatively impact your care. If you decline to participate, we still recommend that you come back to clinic for scheduled blood pressure checks.

The Institutional Review Board of the Prisma Health–Upstate has reviewed this study for the protection of the rights of human participants in research studies, in accordance with federal and state regulations.

_____
Participant's Initials

PURPOSE

You are being asked to participate in this study because you have delivered and have been diagnosed at some point with high blood pressure during your pregnancy, during labor, or after delivery.

The purpose of this study is to improve monitoring of blood pressures for women like you once they have delivered. This is because high blood pressures can continue even though you have delivered, and very high blood pressures can be dangerous, leading to stroke or possible death. The latest recommendation from the American College of Obstetricians and Gynecologists recommends checking a patient's blood pressure 72 hours after delivery if necessary and 7-10 days after delivery to ensure we catch continued elevations in blood pressure after delivery and treat them appropriately.

Having high blood pressure during pregnancy is quite common. It is estimated that for pregnant women between ages 20 and 44, 1 in 12 to 1 in 17 of them will experience high blood pressure during their pregnancy. Therefore, many women are affected by high blood pressure and how we manage it. We are looking to enroll 200 women total (100 women at Greenville Memorial Hospital, 100 women at MUSC, the Medical University of South Carolina) for this study. Half of the participants at each site will be randomized to standard care, which is blood pressure checks as recommended in the above paragraph. The other half will be randomized to check their blood pressures at home using a device and cell phone app provided by BabyScripts, a telehealth company, at no cost to you. We will be comparing how well women follow guidelines to check blood pressure between the two groups as well as observing for additional outcomes.

This research study is being done because we want to improve the way in which we monitor blood pressures after delivery. Our goal is to make blood pressure monitoring more convenient and to also prevent more bad outcomes as a result of potentially dangerous high blood pressures. We also want to find out if checking blood pressures more often by a home monitor will allow us to see high blood pressures sooner and treat them before they get too high.

Your participation will last for 4 weeks.

HOW THE STUDY WORKS

The standard way we monitor blood pressures after delivery is to have patients diagnosed with pregnancy-related hypertension have their blood pressures checked 72 hours after delivery – if the provider thinks it is necessary and again 7-10 days after delivery for all. This requires clinic appointments. Our plan is to investigate home blood pressure monitoring through BabyScripts, a telehealth company, as an alternative method.

The two study groups are:

1. Standard in-office monitoring at 7-10 days after delivery
2. At home blood pressure monitoring 2 times a day for 16 days

In order to participate, you must have unlimited texting and be able to receive phone calls, as these contact methods will be required if you are in the home-monitoring group. You must also be able to read and speak English.

If you are randomized to the in-office monitoring group, you will have blood pressure check appointments scheduled for you when you are discharged from the hospital after delivery and receive standard care at these appointments.

If you are randomized to the at-home monitoring group, you will receive a blood pressure monitoring device as well as a phone app and be instructed on how to use them. You will be required to check your blood pressure 2 times daily for 16 days. These blood pressure checks will be done during the daytime hours between approximately 7am and 5pm. You will follow the instruction below depending on what your blood pressure reading is:

1. If your blood pressure is <140/90, you will be instructed to continue with your scheduled monitoring.
2. If your blood pressure is ≥140/90 to <160/100, you will be called by a physician and asked about any symptoms you may be having. If you report having certain symptoms, you will be instructed to either go to the clinic or to triage at the hospital (depending on time of day) for further evaluation. If you do not have any symptoms, it will be recommended that you start on a blood pressure medicine if your blood pressure is ≥150/100. How well you do on blood pressure medicine will be seen by your blood pressure readings. Your doctor will be able to increase the dose your medication one time. If you require another increase, you be instructed to schedule a visit with a provider.
3. If your blood pressure is ≥160/100, you will be instructed to repeat your blood pressure within 15 minutes. If it is still ≥160/100, you will be instructed to go to either the clinic or hospital triage. If the repeat blood pressure is ≥150/100, you will receive a call from a physician to assess symptoms (like in the above paragraph) and will be recommended to start a blood pressure medication even if you don't have any symptoms. If your repeat blood pressure is <150/100, you will continue with scheduled monitoring.

About 4 weeks after you have delivered your baby, participants in both groups will be asked to complete a questionnaire. .

Any blood pressure medicine that may be started during this study is Food and Drug Administration (FDA) approved for lowering blood pressure and is commonly prescribed by your doctors.

This study will be done in partnership with the Medical University of South Carolina so we can enroll women across the state in this study. All study information from both institutions will be combined for final evaluation.

POSSIBLE RISKS

For this study, the greatest risk is the possible release of your personal health information. Your study records are considered confidential, but absolute confidentiality cannot be guaranteed. This study may result in presentations and publications, but steps will be taken to make sure you are not identified by name.

Some of the questions in the survey are personal and may be upsetting to some participants. The study doctor or staff will be available to discuss these questions should you have a concern or problem. You do not have to answer any questions that you do not want to answer.

POSSIBLE BENEFITS

It is not possible to know whether or not you may benefit from participating in this study. It is possible that high blood pressure will be recognized earlier and this would be a benefit. The treatment or procedures you receive may even be harmful. The information gained from this study may be useful and may help others.

ALTERNATIVE (OTHER) TREATMENTS

The decision to participate in this study is entirely up to you. The alternative to participating in this study is simply not to participate. If you decide not to participate in the study, you will not be penalized in any way.

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Participant's Initials

NEW INFORMATION
Your doctor will tell you about new information that may affect your willingness to participate in this research study. Alternatives, or other choices, concerning your care will be discussed at that time.

There are no plans to share individual research results with you.

COST TO YOU FOR PARTICIPATING IN THIS STUDY
Study funds will pay for all study-related items and services required by the research, this includes the app on your phone and the blood pressure cuff to take your blood pressure. We will bill you or your health insurer for items and services that are not part of the research and are part of your routine care. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. You will be responsible for the cost of any care not covered by insurance or study funds.

If you have any questions or are unsure about costs from taking part in the research, please speak with the study doctor or staff.

PAYMENT FOR PARTICIPATION
To You:
You will not be paid for participating in this study.

To Institution: Prisma Health–Upstate and MUSC's participation in this study is being funded by the sponsor for staff and administrative costs associated with conducting this study.

CONFLICT OF INTEREST DISCLOSURE
Dr. Demosthenes, Co-Investigator on this study, serves as the Senior Medical Director on the Babyscripts Advisory Board has been compensated for speaking on behalf of Babyscripts.

COMPENSATION FOR INJURY AS A RESULT OF STUDY PARTICIPATION
Prisma Health–Upstate will provide you the care needed to treat any injury, or illness, that directly results from taking part in this research study.

Injuries sometimes happen in research even when no one is at fault. The study sponsor, Prisma Health–Upstate, or the investigators as part of this study have no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the 'Contact for Questions' section of this consent.

VOLUNTARY PARTICIPATION
Participation in this research study is voluntary. You may refuse to participate or withdraw from the study at any time. If you refuse to participate or withdraw from the study, you will not be penalized or lose any benefits and your decision will not affect your relationship with your doctor or hospital.

However, if you decide to stop study participation, you are encouraged to talk with your doctor regarding safe removal from the study. Further treatment would be discussed.

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Participant's Initials

If your participation in this research study is stopped, your study doctor will discuss any tests or procedures that might be needed for your health and safety, but you may refuse any or all of these tests or procedures. Following this discussion with your study doctor, you still have the right to refuse any or all of these tests or procedures.

AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, the study doctor and his/her research team will keep records of your participation in this study. These study records may be kept on a computer and will include all information collected during the research study, and any health information in your medical records that is related to the research study. The study doctor and his/her research team will use and disclose (release) your health information to conduct this study. This study may result in scientific presentations and publications, but steps will be taken to make sure you are not identified.

Some of the organizations/entities that may receive your information are:

- The study sponsor and any company supporting the study (the sponsor's authorized representatives)
- The Institutional Review Board, which is a group of people who review research with the goal of protecting the people who take part in the study

Under federal privacy laws, your study records cannot be used or released for research purposes unless you agree. If you sign this consent form, you are agreeing to the use and release of your health information. If you do not agree to this use, you will not be able to participate in this study. Once your health information has been released, federal privacy laws may no longer protect it from further release and use.

The right to use your health information for research purposes does not expire unless you withdraw your agreement. You have the right to withdraw your agreement at any time. You can do this by giving written notice to the study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

If you have any questions about the privacy of your health information, please ask the study doctor.

Outside of the use of the Babyscripts application or the Babyscripts website, Babyscripts does not collect any additional personal information or usage data from your personal device. Please see Babyscripts Privacy Policy for more details.

CONTACT FOR QUESTIONS

For more information concerning this study and research-related risks or injuries, or to give comments or express concerns or complaints, you may contact the principal investigator, whose information is included below.

You may also contact a representative of the Office of Human Research Protection of Prisma Health–Upstate for information regarding your rights as a participant involved in a research study or to give comments or express concerns, complaints or offer input. You may obtain the name and number of this person by calling (864) 455-8997

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Participant's Initials

Principal Investigator Name: Renata Saywer, MD

Telephone Number: 864-455-1600

Participant's Initials

CONSENT TO PARTICIPATE

The study staff, _____, has explained the nature and purpose of this study to me. I have been given the time and place to read and review this consent form and I choose to participate in this study. I have been given the opportunity to ask questions about this study and my questions have been answered to my satisfaction. I have been given the opportunity to review my study doctor's Notice of Privacy Practices. I agree that my health information may be used and disclosed (released) as described in this consent form. After I sign this consent form, I will receive a copy of it for my own records. I do not give up any of my legal rights by signing this consent form.

_____

Printed Name of Participant

_____ _____ _____

Signature of Participant Date Time

INVESTIGATOR STATEMENT

I have carefully explained to the participant the nature and purpose of the above study. The participant signing this consent form has (1) been given the time and place to read and review this consent form; (2) been given an opportunity to ask questions regarding the nature, risks and benefits of participation in this research study; and (3) appears to understand the nature and purpose of the study and the demands required of participation. The participant has signed this consent form prior to having any study-related procedures performed.

_____ _____ _____

Signature of Investigator Date Time

Principal Investigator		Phone
	Renata Sawyer, MD	864-455-1600
Co-Investigators		Phone
	Lauren Demosthenes, MD	864-455-1600
	Brittany Arkerson, MD	864-455-1600
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	Maja Grzejdziak	864-455-1600

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Participant's Initials