Official Title: Systematic Monitoring and Remote Testing of Blood Pressure in Postpartum Women

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Wake Forest®
School of Medicine

Department/Section of Epidemiology and Prevention / Public Health Sciences

SYSTEMATIC MONITORING AND REMOTE TESTING OF BLOOD PRESSURE IN POSTPARTUM WOMEN (SMART-BP)

Informed Consent Form to Participate in Research
Elizabeth T. Jensen, MPH PhD, Principal Investigator

CONCISE SUMMARY

This is a research study to determine the usefulness of checking your blood pressure (BP) at home using a special Bluetooth enabled BP cuff/monitor for about 3 weeks after you have delivered your baby (or babies).

If you choose to participate, we will review information in your medical records about your health and recent pregnancy and delivery. This research is a randomized control trial, meaning you will be randomly assigned, or have a 50/50 chance, to be in one of two groups. You will not know which group you will be in until after you have given your consent to be in this study.

Group A: Will complete a brief demographic survey, will be asked to monitor their blood pressure 1-2 times a day at home using a special BP cuff/monitor for 3 weeks, and will then complete an online follow-up survey.

OR

Group B: Will only complete a brief demographic survey.

If you are assigned to be in Group A, your BP measurements will be remotely transmitted using a free smart phone app called BabyScripts that is downloaded to your personal cell phone. If your BP is too high, an Atrium Health Wake Forest Baptist provider will be notified and will call you and let you know what you should do next. If you are assigned to be in Group B, you will not be asked to do anything other than complete a brief survey.

The main risks involved in this study is a loss of confidentiality. You may or may not receive any direct benefit from being in this study. If you are interested in learning more about this study, please continue reading this consent form.

You are invited to be in this study because you live in Forsyth County, NC , have a smartphone (with Wi-Fi or a monthly data plan), have recently had a baby (or babies) and you received postpartum care at The Birth Center at Atrium Health Wake Forest Baptist. This study is a Randomized Control Trial. This means that your participation in this research will involve being selected to be in one of two different groups. You will be randomly assigned to one of these groups after you consent to participate in this study. You have a 50/50 or equal chance of being selected for either group. Neither you nor the study staff will not know which group you will assigned to until after you have reviewed and signed this consent form.

Participation in this study will involve completing either 1 or 2 short online surveys. If you are assigned to Group A, you will also need to check your blood pressure (BP) 1-2 times daily using a special Bluetooth enabled BP cuff/monitor provided to you when you are discharged from The Birth Center.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. Another choice is not participating. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Dr. Elizabeth T. Jensen. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: [redacted] or [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you live in Forsyth County, NC, recently delivered a baby (or babies) and received medical care after delivery in The Birth Center at Wake Forest Baptist Medical Center and own or have daily access to a smartphone with Wi-Fi or a monthly data plan.Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to find out the usefulness of checking a woman's blood pressure remotely (at home) for 3 weeks after being discharged from the hospital after having a baby (or babies). Some women can develop hypertension, or high BP, after delivery even if they have not had this problem before or during their pregnancy. Untreated or unknown high BP can

lead to medical complications, and if severe, can be life threatening. Monitoring, or checking, remote BP after a woman has delivered her baby (or babies) has been suggested to be a better way to monitor BPs without having to stay in the hospital for a longer time after delivery. Other researchers report that women who have checked their BP remotely after delivery found out that this was both possible and acceptable.

Typically, women that are considered to be "low risk", meaning having no history of high BP or other medical conditions that could contribute to developing high BP, do not have their BP checked until they see their doctor at their follow up appointment about 6 weeks after having their baby (or babies). Women that are considered to be "high risk", meaning having a history of high BP before or during their pregnancy, or other medical conditions that could contribute to developing high BP, may not have their BP checked until they see their doctor about 1 week after having their baby (or babies) and, then again at 6 weeks. Sometimes, doctors will ask these "high risk" women to check their BP at home, but they are not typically given a BP monitor to use or are instructed on how to use a BP monitor.

This research study will be comparing 2 groups of women who have recently delivered a baby (or babies). One group will be made up of women who have their BP checked usually only at their regular, scheduled follow-up doctor visits (either at 1 week or 6 weeks following delivery, depending on their risk level), this is known as the Standard of Care (SOC). The other group will be made up of women who will be checking their BP at home for 3 weeks after delivery in addition to going to their regular, scheduled follow-up doctor visits, or SOC.

How Many People Will Take Part in the Study?

About 2000 women living in Forsyth County that receive care in The Birth Center at Wake Forest Baptist Medical Center will take part in this study.

What Is Involved in the Study?

You will be randomized into one of the two study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in either group. Neither you or the investigators or study team members will know which group you will be in until after you have reviewed and signed this consent form and completed a brief survey of demographic information. You will be given a study identification (ID) number. A study staff member will enter your ID number into a software program that will assign you to one of the two study groups, either the remote BP monitoring group (Group A), or the SOC group (Group B). Both you and the study staff member will find out which group you will be assigned to at the same time. There is no way to know ahead of time if you will be in Group A or Group B.

If you are assigned to Group A, the remote BP monitoring group, then you will be asked to do the following:

1. Complete a brief survey which includes demographic information (race, ethnicity, education level, etc.)
2. Download the BabyScripts app on your personal smart phone with assistance from a study staff member.
3. Enter your name, email address, date of birth, mobile phone number, pre-pregnancy weight and height, and your actual or expected date of discharge from the hospital into the BabyScripts app. Your height and weight will be used to calculate your BMI. Your BMI will help us determine the correct size of blood pressure cuff you will need for this study.
4. Receive verbal and written directions on how to use both the BabyScripts app and the specialized Bluetooth enabled BP cuff/monitor that we will loan you.
5. Demonstrate that you know how to use the BabyScripts app and are able to take your own BP measurement using the BP cuff/monitor before you are discharged from the hospital.
6. Use the specialized BP cuff/monitor to check your blood pressure at home, twice a day (once in the morning and once in the evening) starting the morning after you get home from the hospital – this is Day #1 – and continuing until Day #16. The BabyScripts app will send you messages reminding you when it is time to take your BP.
7. Then starting on Day #17, you will start checking your blood pressure only once a day and continue this until Day #21. If you want to check your BP more often during this time, that is fine, but only one BP measurement will be expected.

8. If any of your BP measurements are **mildly elevated (<u>140/90 or higher</u>)**, then
    - You will receive an immediate message and an email alert from BabyScripts with a short checklist about any symptoms you may be having
    - You will be instructed to recheck your BP in 10 minutes
    - If your BP remains elevated on recheck and/or you have certain symptoms, you will receive a call from a medical provider within 5 hours.
    - The medical provider will then ask you more questions and will provide you with more instructions, such as:
        - If this is the first time you have had a mildly elevated BP measurement, and you have no symptoms, then you will be scheduled for an office visit in 1-3 days.
        - If you also have a chronic or known history of high BP, but you have no other symptoms, then continue checking your BP as usual based on the study protocol.

9. If any of your BP measurements are **critically elevated <u>(160/110 or higher)</u>**, then
    - You will receive an immediate message and email alert from BabyScripts with a short checklist about any symptoms you may be having
    - You will receive a call from a medical provider within 45 minutes
    - The medical provider will then ask you more questions and will provide you with more instructions

10. You will be emailed an online survey to complete sometime between Day #21 and Day #28. If you forget to complete this survey, we will send you a reminder email.

If you are assigned to Group B, the Standard of Care (SOC) group, then you will be asked to do the following:

1. Complete a brief survey which includes demographic information (race, ethnicity, education level, etc.)

If you are in Group A, then a report of your BP measurements and any alerts will be sent in real-time to a secure cloud-based portal. This report will be will be uploaded into your electronic medical record at Atrium Health Wake Forest Baptist when feasible. If your personal physician is not part of this network, or we are unable to upload a report into your electronic medical record, we can send copies of any elevated BP measurements to your personal physician. If any alerts are triggered, each alert and outcome will be documented in your electronic medical record. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

Do you request that we send any elevated BP measurements collected for this study to your personal physician?

[ ] Yes [ ] No _____ Initials

How Long Will I Be in the Study?

You will be in the study for about 3-4 weeks.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

We may want to contact you at a later date to request additional information about your health status.

Do you consent to being contacted at a later date?

[ ] Yes [ ] No _____ Initials

What Are the Risks of the Study?

Being in this study involves some risk to you. The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect

your confidential information. There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

The BabyScripts application is fully HIPAA compliant. BabyScripts follows industry standard efforts and has established reasonable security procedures in order to safeguard the confidentiality of your personally identifiable information. In addition, they comply with the policies and procedures recommended by Accountable HQ for the protection and online security of protected health information and with respect to HIPAA compliance when it comes to the uses and security of such information. However, "perfect security" does not exist on the Internet and/or the World Wide Web, and the loss or disclosure of your personally identifiable information and/or protected health information is possible due to causes outside of its direct control, including, general Internet or transmittal failures and the actions of third-parties, such as hackers. BabyScripts detailed Privacy Policy is located on their website (getbabyscripts.com/platform/privacy.php)

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there is a potential for a direct benefit to you. If you are randomized to Group A, the benefits of participating in this study will be receiving prompt medical advice and instructions in the event your blood pressure is mildly or critically elevated during the time you are using the remote BP monitoring device. Also, we hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

All study costs, including the use of the BabyScripts app and specialized BP cuff/monitor related directly to the study, will be paid for by the study. Costs for your regular medical care will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will not receive any payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by The Duke Endowment. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** your name, date of birth, medical record number, demographics, email, pre-pregnancy weight and height (to calculate BMI), medical diagnoses, pregnancy-related data (e.g. blood pressure, complications, and delivery complications), birth outcomes, length of stay of hospital admission and any readmissions, and billing for health care services utilized during the 6-8 weeks after delivery.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If

disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.
You can tell Dr. Elizabeth Jensen that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Elizabeth Jensen, MPH PhD
Associate Professor
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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

Clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to

individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, please contact the study investigator, Dr. Elizabeth Jensen at [redacted]. For any medical questions or in the event of a research-related injury, please call: [redacted] anytime, day or night.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of a signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm