Official Study Title: Development of a Mobile Health Intervention to Improve Blood Pressure Management in Pregnancy (Moms@Home)

NCT Number : K23HL163450

Date of Document : November 7th, 2024

UMASS CHAN MEDICAL SCHOOL

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: Development of a Storytelling Mobile Health Intervention to Improve Blood Pressure Management in Pregnancy (Moms@Home)

Protocol No.: STUDY00001895

Sponsor: National Institutes of Health

Investigator: Lara Kovell, MD

55 N Lake Avenue, Worcester, MA, 01605

Daytime Phone Number: (508) 856-2772

We are asking you to join a research study. The purpose of this study is to improve the care of people with hypertension or high blood pressure in pregnancy. Someone will explain this research to you and participation in the study is voluntary.

This consent form summarizes the research study and your part in the study. Please take as much time as you need. Please ask questions at any time about anything that is unclear or there is information that you do not understand. You can decide not to take part, or you can leave the study at any time. There will be no penalty, no loss of benefits, and no changes in the quality of health care you receive if you decide to quit or not to join the study.

The goal of this study is to support blood pressure monitoring at home among people who are pregnant and diagnosed with hypertension or high blood pressure during their pregnancy. The study hopes to achieve this using a smartphone mobile app called Moms@Home. We will provide you with a blood pressure cuff and Fitbit if you participate. However, the blood pressure cuff and Fitbit must be returned to the study team once the study activities are completed.

Please see below for additional details about the study. You will get a copy of this document if you sign it or want to read it over at home before signing.

KEY INFORMATION

1. What is the study about? Hypertension (or high blood pressure) is common in pregnancy, and a common cause of serious complications among people who are pregnant. **One of the important ways to reduce the complications of high blood pressure in pregnancy is for people who are pregnant to keep track of their blood pressures at home.** This study seeks to see how effective a smartphone application (app) with support videos from others who have experienced hypertension can help pregnant women monitor their blood pressure better at home.

2. You are being invited to participate in a research study because you have high blood pressure in your current pregnancy. If you have questions or don't understand something, please ask. Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled. If you participate, you will be informed of any new information or changes in the study that could affect you.

3. The main question this study is trying to answer is whether a combination of a smartphone app adapted for people who are pregnant with hypertension and a training with a home blood pressure cuff can help them monitor their blood pressure better at home.

4. If you join this research, you will be randomly assigned to one of two groups:

- A mobile app (Moms@Home) adapted for people who are pregnant (**Group 1**) OR
- A diary for writing down your blood pressure at home (**Group 2**)

For both groups, you will be given a blood pressure monitor and a FitBit to take home and use during the study. We will train you on how to take your blood pressure and what to do if your blood pressure reading at home is too high or low.

5. As part of the study, you will be asked to:

- Fill out some surveys at your first visit, at 4 weeks, and at 8 weeks.
- Check your blood pressure every day at home.
- Record the blood pressure reading either onto the mobile phone app or in the diary depending on your group.
- For **Group 1** only:
  - Watch some short videos (about 2-3 minutes) and take a very short survey (<2 minutes) through the app every day.
  - (Optional) Participate in a focus group meeting after you complete the study.

If you agree to take part in this study, you will be involved for 8 weeks. During the study, you can receive up to $125 in gift cards. If you are in **Group 1**, you will receive $50 in gift cards for participating in an optional focus group. We may continue to collect information related to your health from your medical record for about 1 year.

6. You may not want to be in this study if you are uncomfortable with:

- Using a mobile phone application or a FitBit
- Checking your blood pressure at home and sharing the measures with our research team.
- Sharing your private information with researchers.

- Allowing the research team to review your medical records while you are in the study.
- Returning the BP monitor, FitBit and study SmartPhone at the end of the study
- Not being able to choose the group to which you are randomly assigned to.

7. The risks of this study involve sharing your health information with the research team. There is a risk that someone could access your health information and misuse it. It is our duty to protect your personal information, and we take several measures to do that. Measures taken to protect your data include de-identifying your data, coding it with a research subject ID and saving the data on a secure data network. However, there is still a risk of breach of confidentiality. There may also be risks that we do not yet know.

8. There may be direct benefit to you for participating in the study. Your participation may increase your understanding of the complications of hypertension and the value of home monitoring to improve blood pressure control. Your participation will also help us to gain knowledge that may help other people who are pregnant with hypertension to control and monitor their blood pressure better.

9. Any alternatives? Your alternative is to not take part in the research. **You do not have to be in this study to receive care from your doctors and nurses during this pregnancy.10. Conflict of Interest.** We do not have any conflicts of interest.

If you think you might like to participate in this research, please continue reading to learn more about the details of this study.

STUDY DETAILS

1. How many people will take part in this research?
About 100 people will take part here at UMass Chan Medical School/UMass Memorial Medical Center over 2-3 years.

2. How long will I be in this research?
Your first visit will take up to 60 minutes. The study team will give you more information about the study, what to do with your blood pressure monitor and results, help you download and set up the mobile phone app (**Group 1** only), and fill out a survey. The study will last for a total of 8 weeks. The daily time requirements will be about 5 minutes. After the 8 weeks, the participants in group 1 will be invited to an optional focus group discussion to discuss experience using the app.

3. What happens if I say yes, and I want to be in this research?

- You will be put into a study group by random chance (like pulling names out of a hat). About half (50 people) will be in group 1 and 50 people will be in group 2. You or your doctor cannot choose your study group.
- After signing your consent at the first visit, you will be given a group by chance and fill out some surveys. The research team will review your medical chart to get some information about your health. You will be asked to check and record your blood pressure. Blood pressure ranges will be color-coded on the app as explained below for people in group 1.
    - **Green**: Systolic blood pressure (top number) less than 140, and diastolic blood pressure (bottom number) less than 90. This is considered a good blood pressure range.

- **Yellow**: Systolic blood pressure between 140 and 159, or diastolic blood pressure between 90 and 109. This represents elevated blood pressure in the study and will warrant contacting your provider if it does not improve in 4 hours.
- **Red**: Systolic blood pressure 160 and higher, or diastolic blood pressure 110 or higher. This represents a severely elevated blood pressure and will warrant contacting your provider immediately.

- You will be asked to wear a FitBit during the study to track your daily steps, heart rate and sleep patterns.
- If you are in **Group 1**, you will also fill out a very short daily survey and watch daily short videos through the app. The research team will check your medical chart periodically throughout the study. This will be to make sure that we didn't miss anything and see if there were any results or changes related to your health conditions.
- The table below includes information about what will happen at each time point of the study

	First visit (in-person)	**Daily** (at home)	**4-weeks** (phone call)	**8-weeks** (in-person)	**After 8-weeks** (in-person or virtual)
Orientation to home monitoring	X				
Baseline/self-efficacy surveys	X				
Both groups: home blood pressure checks		X			
Group 1 only: daily videos/short surveys		X			
Both groups: Check-in/mid-point surveys (~30 minutes)			X		
Both groups: End-of study surveys (~30 minutes)				X	
Group 1 only: End of study focus group (~60 minutes)					X

4. Will you be collecting any specimens from me?
No specimen (like blood, tissue, urine) will be collected as part of this study. If your doctor orders any blood or urine tests, that will go to a laboratory to be tested, not to our research team.

5. Will it cost me any money to take part in this research?
No, you will not be charged for being in this study. If you have any medical expenses at UMMHC related to your pregnancy, delivery, or post-partum follow-up care, they will be billed to you or your insurance provider, like normal if you were not in the study.

6. Will I be given any money or other compensation for being in this study?
You will receive $25 after completing your initial survey. You will receive another $25 after completing the survey after 4 weeks and $75 when you complete the study procedures after 8 weeks (total of up to $125). You will receive another $50 if you participate in the optional focus group meeting if in **Group 1**.

In order to receive the stipend for study participation, you will need to give us information like your name, address and phone number. We will then share this information with the business offices and companies that need it to process the payment. You may need to provide your social security number and complete a W-9(tax form) if you receive $600 or more in calendar year across multiple research studies at UMass Chan. The medical School may report the payment to the IRS and send you a 1099 form for tax purposes. The business offices and companies will keep the information as part of their financial records. The research will destroy this information 6 years after study completion.

7. What happens if I am injured because I took part in this research?
If you are injured while in the study, seek treatment and contact the study doctor as soon as you are able. The UMass Chan Medical School does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. You do not give up any of your legal rights by signing this form.

8. What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible for:

- Following the directions of the study doctor and research staff.
- Contacting us if you later have any concerns or questions about this research.
- Telling your other health care providers that you are in a research study.
- Seeking emergency medical care if you experience any of the following: having a blood pressure greater than 160/110 mm Hg, vaginal bleeding, seizures, extreme pain, real contractions that are shorter than 10 minutes apart and last for more than 1 hour, and water breaking. You should call the on-call OB who takes care of you, and then go where they direct you.
- Returning the BP monitor, FitBit, and study SmartPhone at the end of the study.

9. What happens if I say yes, but I change my mind later?
If you decide to leave this research, contact the research team so that the investigator can stop collecting any further health information. Data that we have already collected will stay in the study database in order to maintain the integrity of the research. If you change your mind about participating, you have the right to revoke your authorization in writing or using the contact information at the beginning of this form. In such a case, you will not be allowed to continue to participate in the study. We may also ask you if we can collect data from your medical records and your routine medical care.

10. Can I be removed from the research without my approval?

You may be removed from the study if your doctor recommends that you should be removed from the study due to changes in your medical condition. The person in charge of this research study can remove you even if you want to continue. However, you will be notified if removed.

11. How will my information be stored and when will it/they be destroyed?
We will remove any identifying information from your information, assign a study identification number which is different from your medical records number, and keep electronic health information and research data on secure computer networks. These computer networks have many levels of protection. A separate list that links your name with your study identification number will be stored securely for future reference and communication. There is no limit on the length of time we will store your data.
It is possible that we might use the research data in other future research studies. We may also share data with researchers and companies that are not part of UMass Chan. In these cases, we will not share your name or other information that identifies you directly, and we will not come back to you to ask you for your consent.

12. Who has access to my information?
Signing this document means you allow us, the researchers in this study, and others working with us to use some protected health information for this research study.

As part of the research, UMass Memorial Medical Center or any other healthcare facility where you are treated may disclose the following information:

- Demographic and identifying information like your name, date of birth, address, telephone number, and your email address.
- Related medical information like family medical history, and current and past medications or therapies
- Information from physical examinations, such as blood pressure reading, heart rate, height/weight, and lab results.

Your health information and research records will be shared only with the study team and with individuals and organizations that conduct or watch over this research, in order to conduct the study and to make sure it is conducted as described in this form. Information and records may be shared with:

- The research sponsor (the National Institutes of Health)
- People who work with the research sponsor
- Federal and state government agencies, such as federal and state auditors
- The UMass Chan Medical School and UMass Memorial Health, including their Institutional Review Board (IRB) and research, billing and compliance offices
- Health care providers who provide services in connection with this study
- People and companies who work with UMass Chan and UMMH on activities related to the research

Monitors, auditors, the Institutional Review Boards, and regulatory authorities will be granted direct access to your original medical records for verification of clinical trial procedure and data. These individuals have been trained to protect confidentiality.

We are legally required to disclose information about child abuse, abuse of the elderly or disabled, or you potentially harming yourself or others.

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

Because the National Institutes of Health (NIH) funds this research, this study has a Certificate of Confidentiality. The Certificate keeps us from sharing your identifiable sensitive information collected for the research unless you allow us to do so. It also keeps us from being forced to release information that may identify you as part of a court legislative, administrative, or other proceeding. Identifiable sensitive information includes specimens gathered during the research if there is a small risk of being able to identify you from these specimens, if they are combined with other information.

There are times when the Certificate cannot be used. For example, we cannot refuse to give information to government agencies that oversee or fund research, such as the NIH or Food and Drug Administration (FDA). The Certificate also does not stop us from giving information to local government agencies, law enforcement personnel, or others if we suspect you or someone else is in danger or if we are required to do so by law.

The Certificate does not stop you from giving out information about yourself or your participation in the research. If you give an insurer, employer, or someone else your permission for us to release information, we will do so

We will protect your identifiable information from disclosure to others to the extent required by law, but we cannot promise complete secrecy. Any disclosure carries the potential for re-disclosure. Once your protected health information is disclosed, it may no longer be protected by federal privacy laws.

Your medical record will contain a copy of this form. Other doctors, nurses, and third parties (like insurance companies) may be able to see this entire document as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

Your authorization does not have an expiration date. If you change your mind, you have the right to revoke your authorization in writing or using the contact information at the beginning of this form. In such a case, you will not be allowed to continue to participate in the study. We will not collect any new information and may only use the information already collected for this research study. Your information may still be used and disclosed if you have an adverse event.

You do not have to sign this consent. If you choose not to sign, it will not affect your treatment, payment, or enrollment in any health plans, or affect your eligibility for benefits.

13. What information will be shared/accessed for this study?

As part of the research, UMass Memorial Health Care or any other healthcare facility where you are treated may disclose the following information:

1. Demographic and identifying information like your name and date of birth

2. Related medical information like family, social, and personal medical history (including history of anxiety or depression), and current and past medications or therapies
3. Prior pregnancies and any prior pregnancy complications
4. Information from physical examinations, such as blood pressure reading, heart rate, height/weight, lab results, pathology and imaging reports
5. All tests and procedures that will be done during your pregnancy or in the post-partum period, as ordered by your obstetrician, primary care provider, and/or cardiologist

14. Will you share any results with me?
Your blood pressure readings will be shared with you. A brief end-of-study flyer with the main study findings will be sent to all interested participants when the study is complete in a few years. There is a spot for your preferred contact method below your signature on page 7.

15. Who can I talk to?
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, please talk to the research team at the phone number listed on the first page.
This research is being overseen by an Institutional Review Board (IRB). An IRB is a group of people who perform independent review of research studies to make sure researchers are conducting safe and ethical studies. You may talk to them at (508) 856-4261 or irb@umassmed.edu for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

16. Future Research studies
Would you be willing to let the research team contact you for future research studies?
☐ Yes
☐ No

SIGNATURES

Your signature documents your consent to take part in this research, titled "Development of a Storytelling Mobile Health Intervention to Improve Blood Pressure Management in Pregnancy."

Signature of participant	Date

Printed name of participant

(**Optional**) Preferred method of contact for end-of-study results

Signature of person obtaining consent	Date

Printed name of person obtaining consent

Printed name of interpreter (if used), Language

☐ Check if impartial witness required for consent

An impartial witness is required if short form consent documentation and an interpreter are used, or research participants are unable to read.
My signature below documents that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the research participant, and that consent was freely given by the research participant.

Signature of witness to consent process Date

☐ Check if an impartial witness is not required.