A Pilot Study of the Womb Watch App: Fetal Assessment Using the Microphone of the Smartphone

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The University of Texas at Austin

Consent to Participate in Research

Basic Study Information

Title of the Project: A Pilot Study of the Womb Watch App: Fetal Assessment Using the Microphone of the Smartphone
Principal Investigator: Kenneth Moise, Jr., MD, The University of Texas at Austin, Dell Medical School

You are Invited to Join a Research Study

You are invited to join a research study. Before you choose to join, it is important for you to know why the study is happening and what you will need to do. Please take your time to read this information carefully. Please ask questions if you do not understand something in this form.

Key Points about this Research Study

Important Things to Know:

- The purpose of the study is to assess your baby's movements (fetal movements) using the Womb Watch smartphone application for the duration of your pregnancy.
- If you decide to join, you will be asked to download the Womb Watch application to your smartphone. You will be required to record fetal movements via the Womb Watch application for 15 minutes each day, preferably in the evening, until your baby is delivered or you decide to no longer participate in the study.
- Possible risks from this study include loss of confidentiality, slight discomfort from holding the smartphone on your abdomen during the recording for 15 minutes daily, and possible emotional discomfort answering survey questions about anxiety.
- Using the application could provide reassurance that your baby is doing well. In case your baby is not doing well, you will have more information to provide for your doctor when reporting it. Ultimately, the goal of the app is to provide you with a personalized profile of your baby's movements in your womb.
- Taking part in this research study is voluntary. This means that you can choose if you want to join this study. You do not have to join, and you can stop participating whenever you decide without any penalty.

You can find more detailed information later in this form.

Please take your time to read the whole form and ask any questions before you decide if you want to join this research study.

Joining this Study is Voluntary - It is Your Choice

You get to decide if you want to join this study. Joining this study is voluntary, which means that it is completely your choice. Even if you join the study now, you can change your mind and stop participating in the study whenever you want. You do not have to answer any questions you do not want to answer. If you decide not to take part, there will be no penalty or loss of benefits to which you are otherwise entitled. This means you can choose not to join or decide to stop the study without any negative effects.

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What is the study about and why are we doing it?

Healthcare providers often ask their pregnant patients to notice when their fetus (unborn baby) is moving. The timing and number of “kick counts” is a sign that the fetus is doing well. However, many people are not sure if what they’re feeling are actual fetal movements.

The purpose of this study is to determine whether or not it is helpful to use the Womb Watch smartphone app to track your unborn baby’s movements. This app is experimental and not intended or approved for medical diagnosis.

What will happen if you join this study?

If you agree to join this study, you will be asked to download the Womb Watch application to your smartphone. Participants will be required to record fetal movements via the Womb Watch application 15 minutes per day, preferably in the evening, until they deliver.

To start, participants will schedule a 15-to-30-minute screening and enrollment visit with the study coordinator at their local healthcare provider’s office. At this visit, the study coordinator will briefly review your pregnancy history, update your contact information (telephone number and email address) and discuss the consent form with you to make sure you understand the requirements. You will have the opportunity to ask questions as much as you need. If you understand and agree, you and the study coordinator will sign the consent form together within the HIPAA-compliant Dell Medical School REDCap database and you will receive a copy of the consent form for future reference.

You will then complete a General Anxiety Disorder Assessment (GAD-7) survey within the database. There are seven questions in total in this survey, and it should take about five minutes to complete. This survey is to determine your level of anxiety. The GAD-7 scoring ranges from 0-21. If your score is less than 10, you will qualify for the study. If your score is 10 or greater, you will not qualify for the study, and the study coordinator can assist with a referral to your provider to discuss your behavioral health.

You will then scan a QR code with your smartphone to download the Womb Watch application. The study coordinator will assist you with the initial setup of the app. Together, you will review the instructions for how to properly use the recording app. To record with the app, you will be asked to turn off the Bluetooth option on your smartphone and to turn on the “Airplane Mode”. You will then position your smartphone against your pregnant belly. The microphone of the smartphone should be held against your skin for the best recording position. You will be asked to hold the smartphone in place for 15 minutes per day. During the recording session, you will not be able to make or receive incoming phone calls or to use social media. We advise that you minimize conversations and record in a quiet place. You will have the option to delete any recording and re-record prior to uploading the data to the app. After the recording session, you will be asked to describe the strength of your baby’s movements using a slide indicator on one screen of the app. You will then be prompted to turn the “Airplane Mode” off and then to upload your audio recording. Within a few minutes, you will receive feedback about your baby’s movement in the app.

The expectation is to record fetal movements via the app daily. You will be contacted by a study coordinator once every two weeks to make sure that the app is running as expected. If during

the study, we find something important about your health, we will let you know, and we will arrange medical referrals, as necessary.

If you fail to record for three days in a row, an automated email will be sent to you as a reminder to record. If three more days pass without a recording, you will receive another automated email as a reminder. After seven days with no recording sessions, a study coordinator will contact you to troubleshoot, confirm possible delivery, or confirm whether you wish to continue the study.

You will complete up to four GAD-7 surveys within the UT REDCap database; once at the time of setup, and again every four weeks until you deliver. You will take your first GAD-7 survey at the time of consent and before you download the Womb Watch app. You will be sent a link to the rest of the GAD-7 surveys via email. The links to the surveys do not expire. After delivery, participants will be asked to complete a final GAD-7 survey and a Usability Survey. The GAD-7 surveys have seven questions and take about five minutes to complete. The Usability Survey has 25 questions and takes 15 minutes to complete. After the final post-delivery surveys are completed, you will be asked to remove the Womb Watch app from your smartphone.

Throughout the study your prenatal records and obstetrical ultrasounds will be reviewed by a study coordinator to determine if there are any complications developing with you or your unborn baby. After delivery, your baby's hospital records will be reviewed by the coordinator to see how your baby did at birth and during his/her hospital stay.

You will be part of this study for up to 15 weeks, depending on your gestation of pregnancy at the time of enrollment. 60 pregnant patients will be enrolled in this study.

What risks and discomforts might you experience from being in this study?

A risk is the chance that something bad might happen. There are some risks you might experience from being in this study.

Using the Womb Watch app daily and reviewing the fetal movement analysis, you might feel more anxious. To watch out for this, you will be answering up to four GAD-7 surveys while enrolled. You might feel uncomfortable while answering the GAD-7 survey questions. You do not have to answer any questions that make you feel uncomfortable or that you do not want to answer.

Joining this study might mean losing some privacy. There is a risk that someone who is not part of the study could see and misuse information about you. More information about how we will keep your information safe to reduce this risk can be found below.

It's also important for you to be aware that the audio recordings of your baby will also pick up other noises taking place around you, such as conversations or words you say. You will need to minimize conversations and be in a quiet space during the recording times.

You might find that holding a phone against your pregnant belly for 15 minutes per day to capture a recording can become slightly uncomfortable. A study coordinator will discuss positioning options with you to help with ease of comfort.

Are there any risks that we do not know about or cannot see coming?

We will let you know about any important new information we learn during the study (like additional risks) that might make you change your mind about being in this study.

If during the study, we find something important about your health, we will let you know, and we will arrange medical referrals, as necessary.

The Womb Watch smartphone app will create a movement profile for your baby. If this profile determines that your baby is moving less, we advise you to contact your healthcare provider.

You will be asked to complete the GAD-7 every four weeks. If your score is elevated (10+), we will provide you with mental health resources. Depending on the severity of your anxiety, you may be asked to withdraw from the study.

How could benefit from this study?

We cannot promise that this study will help you. However, you might find reassurance and validation of your intuition about your baby's movements, as well as empowerment to communicate with your pregnancy care provider if you learn that your baby is not moving well.

How will information about you be protected?

UT Austin has private computer systems and databases to securely store information and to help with monitoring and oversight of research. Your information will be kept in these databases but only people working on this study or given access for research-related tasks will be allowed to see the data.

Your personal information might be shared with or copied by approved people from these organizations to run, check on, or manage this study:

- People from UT Austin, Dell Medical School, UT Houston, UT Medical Branch, the Texas Advanced Computing Center, and the Institutional Review Board (IRB; a group that makes sure that people who join research are safe and treated fairly).
- People or helpers from UT Houston and UTMB are also working on this study.
- People from the Food and Drug Administration (FDA)

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. This website will include a summary of design of the study, the number of subjects to be enrolled, the inclusion and exclusion criteria and the sites where the study is being conducted. You can search this website at any time.

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What will happen to your information after this study is over?

We will keep the data we collect for at least 6 years after this study is finished. During this time, your name and other information that can directly identify you will be kept safe and stored separately from the research data that was collected for this project.

We will keep your audio recordings from the Womb Watch app secure with your other research information. Your deidentified recordings will be kept indefinitely.

In the future, we might remove the details that can identify you with the information and audio recordings you give us. After that, your information and recordings could be used for other research by our study team or other researchers without asking you for additional consent.

There are no plans to share any money or profits with you if your audio recordings lead to inventions or discoveries that can be sold.

How will your health information be used and shared during the study?

As part of this study, we will ask you to share health information that can identify you, or to let us use information from your healthcare records. We might also create new health information from the tests, tasks, visits, and/or questionnaires from this study. This type of information is called "Protected Health Information" and it is protected by federal law.

What type of health information will be used or shared with others during this research?

We might use these kinds of information for this research:

	☐ Complete health record	
☐ Information about diseases that can be spread through sexual contact	☐ Codes for diagnosing & treating illnesses	☒ Summary of your medical visits and treatments
☒ Medical history and physical tests	☐ Reports from doctors with their advice about your health issue(s)	☒ Notes about your health, such as changes
☐ Laboratory test results	☐ X-ray reports	☐ Pictures from X-rays
☐ Photographs, videotapes	☐ All of your billing information	☐ Detailed list of services you got, along with the prices
☐ Information about drug or alcohol abuse	☐ Information about Hepatitis B or C tests	☒ Information about mental health, such as how you think, feel, and act

☐ Other physical or mental health information (specify):

Where will you get my records?

For this study, we will get information from these hospitals and clinics:

- Ascension Medical Group clinics/Comprehensive Fetal Care Center / Ascension Seton Medical Center/ Dell Children's Medical Center
- UTHealth Houston prenatal clinics / Memorial Hermann Hospital
- UTMB Health prenatal clinics / John Sealy Hospital

Who will use or share protected health information about me?

The hospitals and clinics listed above must follow the law to keep your health information private. By signing this document, you give permission for them to use and/or share your health information for this research. The health information listed above can be used and/or shared with these people and groups to run, check on, or manage the research:

- Principal Investigator and their team
- Co-Investigators and their team
- Doctors, nurses, and other people at Ascension Medical Group clinics, Comprehensive Fetal Care Center, Ascension Seton Medical Center, Dell Children's Medical Center
- UTHealth Houston, UTMB Health
- Institutional Review Boards (IRBs) of UT Austin and other places or groups working with them

We will only share your information with the people and groups listed above. It is not very likely, but we cannot promise that the people who get your information will not share it with others without your permission. If this happens, your information may no longer be protected.

When will this authorization (permission) to use my protected health information expire?

Your permission will expire when the research study is closed, or when we no longer need to look at the data from this study, whichever is later.

Your Privacy Rights

You can change your mind and take back your permission to use your protected health information at any time. However, even if you take back your permission, the researchers can still use or share the health information that they have already collected about you for this study. If you take back your permission, you might not be able to be in the research study. To take back your permission, you need to write to the Principal Investigator, Kenneth Moise, Jr., MD, at 4910 Mueller Blvd, Ste. 103, Austin, Texas 78723 or email kmoise@austin.utexas.edu.

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What happens if I do not want to share my protected health information?
If you decide not to share your health information, you will not be able to join this study.

How will we pay you for being in the study?

You will get up to $200 worth of gifts cards for completing the study. A $100 electronic TANGO gift card will be provided to your email address after your first 4 weeks of app recordings and upon completion of your second GAD-7 survey. You will get your final $100 electronic TANGO gift card via email after you deliver your baby and complete the final GAD-7 and the Usability surveys.

What are the costs to you to join this study?

There will be no direct cost to you for participating in this study. However, you will need access to the internet for the smartphone app to be able to send recordings to the study team and to receive evaluations of your baby's movements.

Can you stop being in the study?

You can stop being in this research study at any time. Leaving this study will not affect your medical care. Please let us know if you are thinking about stopping or decide to stop.

If you decide to leave before this study is finished, please notify the study coordinator. You will then need to delete the app from your smartphone.

Your participation can be stopped at any time, even if you do not agree or give permission. The reasons might be:

- the researchers think it is important for your health or safety
- you do not meet the requirements for this study
- you did not follow the study instructions
- administrative or procedural reasons require your participation be stopped
- If your GAD-7 survey scores become elevated

Data that has already been collected prior to your withdrawal will remain part of the study database and will not be removed.

How to Contact the Study Team

If you have any questions about this research, you can contact:

Kenneth Moise, Jr., MD (Principal Investigator)
Phone: 713-444-7603
Email: kmoise@austin.utexas.edu

Or

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Kathy Lowry, MSN, RN (research coordinator)
Phone: 512-324-0040 ext 80649
Email: Kathy.lowry@austin.utexas.edu

Or

Emily Hutson, MSN, RN (research coordinator)
Phone: 512-324-0040 ext 80607
Email: Emily.hutson@austin.utexas.edu

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights, want more information, or have questions or concerns about this study, you can contact the following people who are not part of the research team:

The University of Texas at Austin Institutional Review Board
Phone: 512-232-1543
Email: irb@austin.utexas.edu

Your Consent

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. A copy of this consent will be entered into your medical chart as well. If you have any questions about the study after you sign this document, you can contact us by using the information above.

I understand what the study is about and my questions so far have been answered. I agree to be in this study.

_____
Printed Subject Name

_____
Signature Date

_____
Printed Name of Person Obtaining Consent

_____
Signature of Person Obtaining Consent Date