# 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
Co-Investigators: Jerrie Refuerzo, M.D., UTHealth Houston and Corey Clifford, D.O., UTMB Galveston

## 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 asked 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.
- There is no direct benefit to you in this study. However, in the future, pregnant people with access to smartphones could potentially benefit from our app that provides reassurance that their baby is moving normally. In cases where their baby is not moving normally, they could let their doctor know.
- 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.

This is a multi-site study. Participants will be enrolled at UT Austin, UT Health Houston and UTMB Galveston.

## 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. It has been developed by the UT Texas Advanced Computing Center in Austin. We are using an artificial intelligence computer program model called deep learning/machine learning to determine if this app would be useful for doctors and pregnant patients. The Womb Watch app listens to sounds from your belly and uses the computer program to identify patterns that may suggest when your baby is moving, breathing, or hiccupping. In addition to the audio file, your smartphone also tracks when your phone moves, tilts or vibrates, such as when a baby kicks or moves in the womb. These files will also be analyzed by the computer program. The more recordings that are analyzed, the better the model can accurately detect fetal movements. We want to learn how well the app works in everyday use, how participants experience using it, and how the app may be improved.

This app is experimental. This means it is still being tested, and we do not yet know how accurate it is. The app is not approved for medical diagnosis and should not replace your regular prenatal care. The app has been developed by the Texas Advanced Computing Center at UT Austin.

## 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. You will be asked to record fetal movements via the Womb Watch application 15 minutes per day, preferably in the evening, until you deliver.

To start, you will schedule a 15-to-30-minute screening and enrollment visit with the study coordinator at your 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 on an iPad. You will receive a paper copy of the consent form for future reference.

You will then complete a General Anxiety Disorder Assessment (GAD-7) survey within the Dell Medical School REDCap database, also on the iPad. 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. If your score is too high, you will not qualify for the study, and the study coordinator can assist with a referral to your provider to discuss your behavioral health.

If you are eligible, 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. You will be asked to view an Instructional Video on the iPad while it downloads. Together, you will review the instructions for how to properly use the recording app. Before you record within the app, you will be asked to turn off the Bluetooth and Wifi options on your smartphone settings and to turn on the “Airplane Mode”. When it’s time to record, you will position your smartphone against your pregnant belly. The microphone of the smartphone should be held against your skin for the best recording position, either just above your belly button, or to the right of your belly button. You will be asked to hold the smartphone in place for 15 minutes per day to make recordings. 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 is complete, you will be asked to describe the strength of your baby’s movements using a slide indicator on the screen of the app. You will then be prompted to turn the Bluetooth and Wifi back on, and “Airplane Mode” off to upload your audio recording. Within 5-10minutes, you will receive feedback about your baby’s movement in the app. You can view the analysis in the Trends section of the app. It will include information about how much your baby may have moved, if your baby may have had any practice breathing, and if your baby may have had any hiccups. You will need to keep in mind that this analysis is experimental and not accurate for diagnosis of a health condition.

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.

The Womb Watch app will be dynamic during the course of the study. This means that changes will be made based on patient input regarding the usability of the app. In addition, the machine learning portion of the app will be adaptive which means it will continue to learn to interpret the audio recordings as new ones, and other patient data, are obtained. All participating patients will get updates to the app pushed to their smartphone as they are developed.

You will be asked to complete up to four GAD-7 surveys within the UT REDCap database over the course of your study participation; 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, you 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.

The study team will review information from your medical record, including your prenatal records and obstetrical ultrasounds, during and after your pregnancy to collect information about your pregnancy and birth outcomes.

You will be part of this study for up to 15 weeks, depending on your gestation of pregnancy at the time of enrollment. Seventy-five 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.

The Womb Watch smartphone app will create a movement profile for your baby. It will include how many movements the baby might be having, how much breathing the baby might be having and if the baby may be having hiccups. Data provided by the app should not be used to make decisions about your health or pregnancy. The detection of fetal movements with the app may not always reflect the true nature of your baby's movements. If the graphic display of the app indicates a change in your baby's movements, you should contact your healthcare provider. Also, if you feel there is something wrong with your baby's movements, you should contact your healthcare provider. If you are unable to contact this person, the PI or co-I or other members of the study team can be contacted. The contact numbers for the PI and co-I's are located under the "FAQ" portion of the app and in the "Contact" menu located at the top left portion of the app screen.

Using the Womb Watch app daily and reviewing the fetal experimental 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. If there is too much noise during the recording, the recording will "fail" and need to be repeated in a quieter location.

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 (such as additional risks) that might make you change your mind about being in this study.

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

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

## How could you benefit from this study?

We cannot promise that this study will help you. The information we learn may help researchers understand how well the Womb Watch app works and how easy it is for pregnant people to use. What we learn may help improve the app in the future.

## 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 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.

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

We will keep your recordings from the Womb Watch app secure with your other research information. Your deidentified recordings will be kept indefinitely. Your data recordings will continually refine the deep learning/machine learning model to make it more accurate for future app users.

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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. The University of Texas at Austin Board of Regents have filed several U.S. and European patents regarding the use of audio recordings with a smartphone to determine fetal movements. Kenneth Moise, Jr. M.D and Kelly Gaither, Ph.D., the co-inventors of this application, share in these patents.

## 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. If you do not complete the full study (record daily and complete the requested surveys every 4 weeks and after delivery) you will not receive the full $200 compensation.

## What are the costs to you to join this study?

You may need to pay for transportation and parking to and from your enrollment visit. Additionally, you will need access to the internet for the smartphone app to be able to send recordings to the study team and to receive experimental 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 be required 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:

- 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.

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## 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

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

The University of Texas at Austin

## 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