RESEARCH CONSENT FORM

Lactation at Work: A Wearable Breast Pump (Willow) Device Study
Protocol # STUDY00161527
Sponsor: One Willow, https://onewillow.com/

Investigator: **Andrea McMillin MP\H**
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University of Kansas Medical Center
913-588-7223

Key Information: You are being invited to consider a research study. Research studies are always voluntary. The first section of this form is a short summary of the study. Please also read the Detailed Information that follows this summary before you make your decision.

- We are asking you to be in a research study.
- Research is done to answer a scientific question. Research studies may or may not help the people who participate.
- Joining this study is completely voluntary. If you say yes, you can quit the study at any time.
- You can still get medical care and other services from the University of Kansas Medical Center even if you are not in the study.
- The research team will explain what happens if you decide to join the study. This conversation is called “informed consent.”
- Informed consent includes a chance to get your questions answered before you make your decision. Please ask as many questions as you need to.
- This consent form explains the study. Take as much time as you need to decide.
- If you decide to be in the study, you will be asked to sign this form.

Please review the rest of this document for details about these topics and important things you should know if you decide to join. Before you sign up for the study, please ask the study team to answer all your questions.

DETAILED INFORMATION

This research study will take place at the University of Kansas Medical Center (KUMC) with Andrea McMillin, MPH as the researcher. About 25-50 people will be in the study at KUMC. A total of about 100-200 people will be in the study at 2-4 centers across the United States,

Why is this study being done?
The goal of this study is to determine if wearable breast pumps help parents returning to work/school after the birth of a child(or children) achieve lactation goals. In addition, the study will help other institutions determine if a wearable breast pump program could work for their employees and students.

Most instiutitonsl provide very basic support for lactation, meeting the legal requirements. Parents can struggle if the aviable resources do not meet their needs regarding flexible break times and/or reliable, close, and secure pumping space.

The device for this study has been shown to help parents reach their goals, as a wearable pump that does not require a wall plug and can be worn discreetly, the Willow pumps provide to users for this study can provide users with more autonomy and flexibility regarding their pumping schedules compared to more traditional pumps.

What is being tested in this study?

Users will be able to select from 2 different willow wearble breastpump devices- the Willow Go and the Willow 360 https://onewillow.com/collections/pump-kits.

These products are already FDA approved, we are studying them because they are a novel way to accomplish lactation support. By showing that this is a sustainable model that improves the employee and student experience we are hoping that other institutions will consider creating similar interventiosn for their lactation support programs.

How long will I be in the study?

We expect your participation to last from the beginning use of your Willow device through the end of your Willow pump usage, you are welcome to continue to provide information via the study survey until cessation of lactation/providing breast milk to provide more robust data for the survey.

What will I be asked to do?

If you join the study you will be asked to complete the Intake Survey, the Monthly Survey while you are pumping breastmilk from Willow or other pumping devices and the Final Survey to collect final usage data from end users.

Users that continue to provide breast milk after pumping can continue to provide data through cesstion of providing milk.

What are the possible risks or discomforts?

Pumping milk, in general, has some risks associated with the activity regardless of device used. The American College of Obsterics and Gynecology reports that common risks include:

Engorgement, sometimes leading to infection
Nipple injury
Breast pain
Perceved or actual low milk supply
Infant lack of interest in breastmilk (early weaning)
Physical incompatibility with wearing the devices

For best results its important to research all of the available options to support lactating parents. If you are struggling with any of these symptoms consult with your lactation consultant (IBCLC) or one of the Willow lactation specialists, manufacturer help guides available through this study. Wearable devices are an effective way to sustain lactation when traditional resources may not be accessible or available. Best production results may be using traditional pumps, consult your primary care provider or a lactation consultant to ensure best results.

Participants can withdraw from the study if any of the above risks occur, consult with your primary care provided and inform the study leads if you encounter one of these health conditions.

Pregnancy Risks

There may be pregnancy risks that are not known yet. For this reason, you must tell the study contact right away if you get pregnant during the study.

Are there benefits to being in this study?

Direct benefits include –

Wearable breast pumps increase the flexibility of the parent to choose when and where they can pump milk at work or outside of work. These devices are quieter than normal pumps and do not need to be tethered to a power outlet. They also fit discreetly under clothing.

Pumping milk at work in general provides the following direct benefits, supporting breastfeeding goals, health benefits for both parent and baby, comfort and relief from engorgement from milk, provides natural and free nutrition from baby, provides parent with fulfillment for being able to work and provide nutrition to infant.

Indirect benefits include – pumping at work provides both short and long term health benefits for both parent and baby by allowing the parents to provide milk for duration than if they had switched to formula and stopped pumping. Wearable pumps allow for individual to pump milk more easily in the setting they choose.

Will it cost anything to be in the study?

Participants may chose commercially available accessories that are available to enhance the ease or fit of the devices. These accessories are paid for by the pariticpant with no expectation of reimbursement.

There will be no medical visits or billable services associated with this study.

Will I get paid for participation?

There is no payment for this study. Individuals will be able to keep the Willow device at the end of the study.

What happens if I get hurt or sick during the study?

If you have a side effect or other problem during this study, you should immediately contact your primary care provider and inform Andrea McMillin, MPH amcmillin@kumc.edu when the medical emergency is over.

How will my information be protected?

The researchers will keep your identity confidential, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Your study information will be labeled with your research ID number. The study team will keep a separate list that matches your name to the research ID number. These steps will lessen the risk that your personal identity and information will be seen by others who shouldn't have it.

If you sign this form, the research team will collect, use and share your private health information as described below. If you decide not to sign this form, you cannot be in the research study.

Study data includes information from your study activities, the three survey types and data from the Willow App regarding duration and frequency. Others at KUMC might need to look at your research records. They include KUMC Research Institute, the Institutional Review Board or other committees and offices that review and monitor research studies.

You may not be able to see your records relating to the study until after the study is over and the results are known. Any research information that is put in your medical record will be kept indefinitely.

The research team will share your study data with people outside KUMC. These groups or agencies may make copies of study data for audit purposes. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may not protect it. These groups may include:

- Federal agencies that oversee human research (if a study audit is performed)
- Study partners, internal and external to the institution
- One Willow, https://onewillow.com/
- Experts who inspect the study information to see if the study is being done correctly and if it is still safe to continue
- Other groups that help manage or provide services to support the study
- Ethics committees that review the study for other locations

Your permission to use and share your health information will not expire unless you cancel it. To cancel your permission, please write to Andrea McMillin, MPH. The mailing address is Andrea McMillin,MPH, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160 or via email amcmillin@kumc.edu. If you cancel your permission, you will be withdrawn from the study. The researchers will stop collecting any additional information about you about you unless they need information about a side effect of the Willow device. They are permitted to use and share information that was gathered before they received your cancellation.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Will I be told about research results?
Yes, if you select this option in the final survey you will be notified when and where the results are published.

You will be told about any study results that directly affect your medical care. If there is a change in the FDA approval of the device or in cases of manufacturer notification of a recall of device.

At the end of the study, you will receive notification that includes a summary of the results.

How will my research information and specimens be used in the future?

In the future, researchers at KUMC and at other locations might re-use the information and specimens from this study for other research. If that happens, information that could identify you will be removed first. You will not be asked if you agree to the future research that has identifiers removed.

The future research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other aspects of health. These studies may be done by researchers at KUMC, at other institutions, or by commercial entities.

Your data will be combined with others who participate in this study and uploaded into a RedCap database. Once uploaded, it may not be possible to remove your information.

The place where your data will be stored may not be controlled by or owned by KUMC or by the Principal Investigator for this study. The decision on how and with whom your data is shared is made by individuals who own the database.

Can I stop being in the study?
You may stop being in the study at any time. Stopping will not prevent you from getting treatment or services at KUMC.

If you decide to stop pumping breastmilk but would like to continue providing data on your breastfeeding journey you are able to continue as long as you are able to so that we can better understand how long working parents are able to provide breastmilk and work. Continuing in other parts of the study is completely optional.

Who can I talk to about the study?
Andrea McMillin, MPH amcmillin@kumc.edu or other members of the study team should answer all your questions before you sign this form. They will also tell you if they learn anything new that might affect your decision to stay in the study. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints. If you have questions about your rights as a research participant, or if you want to talk with someone who is not involved in the study, you may call the KUMC Institutional Review Board at (913) 588-1240. You may also write the Institutional Review Board at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160 or IRBhelp@kumc.edu

CONSENT
Andrea McMillin, MPH or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily agree to be in this research

study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Explaining Consent

_____ _____ _____
Signature of Person Explaining Consent Time Date