PROTOCOL TITLE: Lactation at Work: A Wearable Breast Pump (Willow) Device Study - Protocol IRB # 28045

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Study Summary

Protocol Information	Description
Study Title	Lactation at Work: A Wearable Breast Pump (Willow) Device Study
Study Design	One year post market research study, providing wearable breast pumps to medical residents and fellows at IUSM to assess if providing wearable breast pumps increases the ability for working mothers to reach their goal. Individuals will be provided pumps close to delivery date, submit an intake survey, complete monthly surveys for up to 2 years and complete the postintervention survey. The study will not only assess the wearable pumps but what other methods individuals used to reach goals and how goals may have changed over time. Individuals will be allowed to keep equipment at the cessation of lactation as compensation.

	This is a Multi-institutional study. Participating institutions include: University of Michigan, Vanderbilt University, Kansas University, and Indiana University School of Medicine (IUSM)
Primary Objective	Does the wearable willow pump help working mothers reach their pumping goal
Secondary Objective(s)	Does the wearable willow pump help mothers achieve a minimum of 6 months pumping Does the wearable willow pump help mothers achieve a 2+ year goal
Research Intervention(s)/ Investigational Agent(s)	Zeina Nabhan, MD
IND/IDE #	Funding will be provided indirectly through Willow who will be providing the devices
Study Population	Residents, Fellows at Indiana University School of Medicine women of childbearing age that plan to get pregnant during study window.
Sample Size	25 + for this institution over one year
Study Duration for individual participants	Self-determined goals, recommendation is to pump a min of 6 months up to two years.
Study Specific Abbreviations/ Definitions	

Objectives

This is a post-market study to provide breast pumps to residents and fellows at IUSM as an additional layer of support in reaching lactation goals. Workers that do not have

flexible break times and/or reliable close and secure pumping space face barriers to reaching their lactation goals. Wearable pumps provide users autonomy and flexibility regarding their pumping schedules. These devices are not covered as a "free" breast pump through most insurance companies and, while discounted, are often still at a higher price point for most new parents. By providing these for free to users, we expect to see the institutions' metrics regarding duration of pumping and satisfaction with meeting goals will be higher than national metrics. In partnership with Willow, our institution will provide free pumps to individuals as part of a study including participant consent.

Among medical residents and fellows at IUSM and other participating institutions during the study window (one year providing devices and up to 2 years collecting data, tracking users through end of pumpingexperience) who have delivered a baby, does access to a wearable Willow pump improve lactation experience and meeting goals regarding duration of pumping/providing milk?

Background

The AAP, HP2030 and WHO lactation recommendations of six months exclusive breastfeeding up to two years of breastfeeding with table food, are based on decades of research regarding health outcomes for both the lactating parent and infant.[1,2,3] Research shows that for the infant, the short-term benefits of lactation (described as 3 to 6 months of exclusively consuming human milk) include building important immunities against common illness in the first year of life and reducing the risk of ear infections, stomach flu, Respiratory Syncytial Virus (RSV), Crohn's disease, eczema, diarrhea and childhood cancers.[6,7,2,8,9] Short-term benefits for the lactating parent include quicker recovery from giving birth, increased bonding with the infant, and lower risk of postpartum depression.[8,9,12,13] Long-term lactation, described as exclusively consuming human milk for six to 24+ months, provides lifetime health benefits for the infant including lower risk of asthma, diabetes, Sudden Infant Death Syndrome (SIDS), as well as, providing important nutrition (protein, calcium, vitamin a) and enhancing brain development.[6, 8, 9,10,12,14]

This evidence has also shown that infants who exclusively consume human milk for six months had higher IQs (intelligence quotient) compared to those who consumed human

milk for less than six months. Lactation can also provide emotional support for infants as a soothing tool and physical comfort during teething.[8,9] Long-term health benefits for the lactating parent include decreased risk for cancers (breast, ovary, endometrial, thyroid), type 2 diabetes, osteoporosis, cardiovascular disease, high blood pressure, and high cholesterol.[6,8,9,10,11] Successful long-term lactation for working parents includes pumping 2-3x per day to maintain milk production and creating a supply for the infant to consume when away from the providing parent.[8]

Even with this research and education during pre- and post-natal visits with the healthcare team, it can be difficult to balance lactation, returning to work, and creating a pumping schedule. A recent study showed that Hispanic (48.4%), Black (35%), Native American (37.3%), White (52.3%) or Asian (71%) mothers stop lactation by six months.[9] With more women in the workplace than ever before, returning to work after a birth is extremely common and employers must work to create welcoming environments for new parents.

Healthy People 2030 has set the goal that 42.4% of infants in the United States are provided human milk exclusively for the first six months, but as of 2020 only 25.4% of infants have reached this milestone.[2] The Center for Disease Control (CDC) data reported from the National Immunization Survey reports that nationally 58.2% of infants receive "any milk" through 6 months of life. [15] While many parents set a goal of six months, there is a wide range of individual goals that new mothers may set based on circumstances. One of the questions asked in this study is intent vs. actual pumping goal since this is another area that has not been explored. According to the CDC, 60% of mothers do not reach their lactation goal.[17] In a 2012 study conducted by the San Diego Breastfeeding Center, researchers discovered that 85% of the parents in their cohort intended to pump for 3 or more months but only 32.4% met their intended goal.[18] These data reinforce the fact that providing human milk exclusively while returning to work is a monumental task that requires resources, commitment, and support.

In general, for physicians new publications show this doesn't change much as residents leave training and enter practice. While they may have more autonomy and higher salary, they face the same challenges of time and access to private space without the protection

of training program requirements or supervisor support. “individuals, institutions, and professional organizations.”

In 1938, the U.S. Labor Department created the Fair Labor Standards Act (FLSA), which was amended in 2010 to expand protections to nursing mothers and, again, in 2022, with additional protections and clarifications regarding lactation break time and space requirements.[19] The 2022 FLSA revisions, named the Providing Urgent Maternal Protections (PUMP) Act, was revised to include more employees, who are also lactating parents at work, with protections for pump break times and harassment/mistreatment.[20] Even with these protections in place, the top three reasons that people stop pumping at work are a lack of space, a lack of support from co-workers, and a lack of flexible work schedules.[16] Educating supervisors and co-workers on what a lactating parent needs can make a difference in how long a parent chooses to pump milk.

Residents/Fellows and Physicians

This training cohort consists of women of “peak” reproductive age, as defined by the American College of Obstetrics and Gynecologists (ACOG).[21] ACOG states that in the U.S., “peak” reproductive age for women begins in late teens up to age 30 when fertility rates begin to decline.[21] By age 45, natural pregnancy is unlikely and associated with higher risks for most women.[21] While residents face the same barriers as other working mothers (e.g., inadequate space, support, and time), there are unique challenges for this group. Residents have training limitations to length of allowed parental leave outlined by their specialty boards (most boards only allow 6-8 weeks).[5,22] Longer leave may result in the following situations: (1) a delay in receiving board certification; (2) a delay in graduation, having to extend training; and (3) an impact on their career options post-training.[5,22] Since these residents are considered trainees, they are also beholden to their training program schedule, supervising faculty expectations, and team structure in the healthcare setting.

A thorough literature review shows most information focuses on exclusively consuming human milk specifically, with little to no inclusion of the value and importance of pumping at work to support lactation. Without regular human milk removal or pumping, the parent’s milk supply will slowly drop in production with both parent and infant

feeling frustrated. Research that focused on pumping milk in residency is limited, with most publications dated 2018 or later and tied to specific training programs. Examples include Pregnancy and Motherhood During Surgical Training; Availability of Lactation Accommodation Information for Urology Residency Programs by Sandozi A, Lee J, Shpeen BH, et al (2022), or more broadly on policy, Crafting an Evidence-Based, Accreditation Council of Graduate Medical Education-Compliant Lactation Policy for Residents and Fellows by Johnson HM, Walsh DS. (2020).[25,26,27] In 2018, Rangel, Smink, et al studied the implications of female residents who have children during surgical training and the future workforce challenges.[5] Sandozi A, Lee J, Shpeen BH et al evaluated if Urology residency programs that provided lactation resources for trainees on their websites as part of female resident recruitment (the majority did not).[27] Johnson HM, Walsh DS. focused on development of a lactation policy template, compliant with the ACGME requirements.[25]

At the same time, the Accreditation Council for Graduate Medical Education (ACGME) updated its Common Program Requirements to include required lactation support.[31] This expanded coverage from multiple entities only confirms the argument that supporting parents returning from leave is important to the workforce and the employer, including training programs. Infants who consume human milk have lower incidents of illness resulting in lower absenteeism among parents; also, parents who feel supported at work have higher satisfaction and retention rates.[19] Residents do not have clearly defined and protected time for pumping breaks; they rely on a faculty supervisor to approve breaks based on a clinical/operating schedule. Residents who work on a clinical team are expected to work an average of 60 hours per week, this may be exceeded in surgical specialties. The new language in the PUMP Act specifies that the employer must provide "reasonable break time" for pumping with the expectation on the employee and their supervisor to determine what that means.[20] This places the burden on the resident to communicate and justify their needs with their supervising faculty (which can change based on clinical experience).

Mothers/parents who are unable to create a reasonable pumping schedule to support their milk production and health may experience lower milk production, early infant weaning and may stop pumping altogether due to work barriers. Inability to regularly pump based

on infant need and parent preference can lead to mastitis[33] (described as inflammation and infection of the breast/chest tissue due to a blockage in the milk ducts) and early lactation cessation. Emotionally and mentally, the lactating parent may have feelings of failure, inadequacy, dissatisfaction and depression. [4,5,22,23,24]

2025 literature update review

There really aren't any interventions out there that are at the scale that we are attempting for wearable pumps. the larger systematic reviews focus on layered support including policy, training, FAQs and space. A study from University of Michigan showed that resident physicians who had access to wearable pumps reported that wearable pumps were beneficial to meeting goals and reduced barriers on meeting educational and clinical care responsibilities. *(ref. Sheffield V, Tomlinson S, McCaffery H, McCormick AD. One Pump at a Time: A Wearable Lactation Pump Pilot for Graduate Medical Education Trainees. Breastfeed Med. 2024;19(11):885-888. doi:10.1089/bfm.2024.0134*

Another study from Kansas University showed that trainees who had used a wearable pump reported statistically significant shorter lactation breaks ($p < 0.00001$) and were more likely to be able to provide breast milk to their infants for their entire intended duration ($p = 0.005$) compared to the traditional pump group. The ability to pump as often as needed while at work ($p = 0.16$) and the frequency of lactation breaks throughout the day ($p = 0.223$) were not significantly different when comparing the two groups." (ref. Colbenson GA, Hoff OC, Olson EM, Ducharme-Smith A. The Impact of Wearable Breast Pumps on Physicians' Breastfeeding Experience and Success. Breastfeed Med. 2022;17(6):537-543. doi:10.1089/bfm.2021.0266)

Study Endpoints

The Individual Participant Endpoint will be at the individuals self-determined endpoint, ideally at the cessation of pumping.

- The study end point will be at the three year anniversary of study start.
- The individuals may also determine to end study participation before they are finished pumping.

Study Intervention/Investigational Agent

Individuals will be given a free Willow device to keep at enrollment with the agreement that in exchange for usage of the device they complete an intake and outtake survey, as well as monthly. surveys, to measure goals, experience, and final metrics. Products are covered under manufacturer 1 year warranty. All participants are asked to contact Willow directly (for warranty/troubleshooting and exchange/replacement requests) https://onewillow.com/pages/faq.

Willow customer care team number to obtain live help https://onewillow.com/pages/contact will be provided to all participatns. The participants will also consent to Willow and the institution utilizing their mobile app data via their device serial number. Willow will sign the standard research agreement with the understanding that the results from the study are the property of the institution. Data can be pulled by serial number, no identifiers attached. The PIs will not need access to the application data, Willow will share data with the institution at agreed checkpoints.

Data Sharing	Willow to IUSM	IUSM to Willow
Serial Number	Via app (User profile)	Via RedCap (project participation (email address) – IUSM research team will record device as they are provided to individuals, log them in redcap with their email address, email address blinded in final data
Time (duration of pumping, total minutes) & Frequency (how freq the devices are turned on for use)	Via app	Self-reported via RedCap Survey **How many times do you use your Willow pump a day?**
Volume (fluid ounces)		Self-reported via RedCap MONTLY Survey (deaggregate)

		How many ounces to express with your Willow pump a day?
Satisfaction/Goals		Self-reported via RedCap MONTLY Survey (deaggregate) **Do you feel like you are meeting your current lactation goals?** **Which devices are you using to accomplish your lactation goals?**

Surveys will be delivered to individuals based on their serial number assignments monthly via redcap for the duration of their pumping experience, devices do not need to be returned to the institution or Willow.

This is a post-market research project targeting residents and fellows at IUSM that have recently given birth and plan to provide human milk for some duration after birth.

This study will be held over the duration of one year for device distribution and remain open for up to two years or until the last participant indicated completion by completing the endpoint survey.

PI will share results with Willow at agreed upon intervals to provide good faith study data. Results will be shared in de-identified reports with the intent to present at national academic conference in conjunction with two other medical schools that are also delivering this intervention and submission for publication in academic medical journals

Drug/Device Handling: Devices stored in GME. No special handling needed for devices, individuals responsible for cleaning and maintenance, devices covered under warranty for first year. (*Products are covered under manufacturer 1 year warranty. All Mom's are asked to contact Willow directly for warranty/troubleshooting and exchange/replacement requests)at* *https://onewillow.com/pages/faq*. *Willow customer care team number to call*

is located at the link below with days/times for live help and other avenues of communication to obtain live help. https://onewillow.com/pages/contact)

Procedures Involved

The Study design is to distribute willow pumps directly before birth of child for subjects that choose to enroll in the study, pumps will be provided prior to individual going on leave, this allows individuals to have devices at home and practice with them before returning to work.

Research procedures will include subjects to complete the consent and intake survey at initiation of pumping, completing monthly surveys through pumping and then a endpoint survey to collect final experiential data.

- Individual will be provided Willow Pumps prior to delivery and leave to allow for practice.
- Willows are single user devices per FDA regulations
- The institution will provide educational materials for users and access to Willow experts for support
- Attachments included: consent form, intake, monthly and endpoint surveys.

Data collected during survey

- INTAKE SURVEY – expectation and goals for lactation experience, demographics and knowledge of lactation from previous experiences.
- MONTLY SURVEY – changes to lactation practices, current volume, frequency and satisfaction.
- OUTTAKE SURVEY – final experience input, expectations vs reality, total length of time pumping and providing milk

No current plans for long-term follow-up

Not a Humanitarian Use Device (HUD)

Data and Specimen Banking- NA

Sharing of Results with Subjects- NA

Study Timelines

The duration of an individual subject's participation in the study will be determined by the individual. During the intake survey they will provide their expected duration and will notify the team when they have finished pumping. Individuals will indicate completion via survey response that will trigger the final survey. The monthly survey will ask users to identify if they are complete with pumping, they will then be directed to the outtake survey- branching logic to outtake survey and ask them to contact PI/administrator to remove from monthly survey queue. The duration anticipated to enroll all study subjects is a min six months and a maximum of 2 years for pumping milk.

Inclusion and Exclusion Criteria

Inclusion Criteria:

All IUSM Resident and Fellows who are expecting to deliver a child and plan on breast feeding during the study period will be eligible to participate in the study. Participant eligibility will be obtained vial self-enrollment, individuals will self-identify and notify investigators when they are going to start pumping. Some parents are proactive and plan out ahead of time their lactation needs, some pivot from original plan after returning to work and request support after initiation, intervention will accommodate both and surveys will begin at pumping initiation.

The specific population of study will be individuals of birthing age that give birth while employed or enrolled at the institution and have determined that they plan to provide human milk and pump at work post-delivery.

Vulnerable Populations-

This protocol is specifically designed for individuals to use a device already in the market designed for lactation (post pregnancy). There could be circumstances where a user becomes pregnant while also providing milk for an existing child, which is also a norm in this population.

Local Number of Subjects

The current rate of oumo users at the institution is approximately 25-30 per year, with the expansion of this offering we are anticipating that it will at most double. Willow has not indicated a limit on number of devices they will provide.

Recruitment Methods

The institution will recruit via the following methods.

- Monthly email notifications to potential subject group in Graduate Medical Education (GME)
- Monthly email to the program directors and program coordinators from the GME office to share information about the study and to ensure that they share this information with the residents and fellows at their program
- Include information about the study on the GME wellbeing toolkit webpage: https://medicine.iu.edu/gme/why-iu/wellness-toolkit

Subjects will be primarily self-identified for the university, through Graduate Medical Education there is a more focused approach by filtering notifications to just female identifying residents to remind them of the resource. Word of mouth from current users is also an important aspect to recruit participants as study grows.

Material provided during recruitment and to participants include the following:

- Existing GME lactation Policy and Procedures information
- Lactation resource page which includes education resources
- Willow product information
- Fliers distributed in lactation rooms

Users will not be paid for their participation but will be allowed to keep the devices

Investigators will promote the research project for those that may be interested but will not approach users to recruit directly

Withdrawal of Subjects-

A subject can withdraw at any time during the study without being required to return the device.

If the subject leaves to the institution (institutional email is deactivated) they will be terminated from the study unless they notify the institution of the transition to remain in the study and provide a new email.

Risks to Subjects

There is minimal risk to participants other than normally occurring risks when pumping milk. These include low supply, infection, or stressors that can lead to individual's cessation of pumping. The study team will work to provide education on the device and access to lactation education to minimize risk.

Potential Benefits to Subjects

There is substantial benefit to participants, we are anticipating that participants will experience more autonomy and success with pumping at work, ability to pump longer, improved work-life integration. There are numerous health benefits for both participant and infant as outlined in the literature study included above which increase over time providing milk. Participants gain access to equipment that is currently at a higher price point compared to the free devices covered by insurance.

Data Management and Confidentiality

Data will be stored in redcap until study concludes with monthly data reports delivered via secure email to participating sites. Data from Willow will be provided by serial number for data matching to Redcap data. Redcap is designated for research purposes at the academic medical center. Data will be quantitatively analyzed via SAS by the biostatistical partner, contracted through the institution. Willow will provide:

Individual users will be deidentified data and enrolled in the study by serial number for data matching with Willow application data.

Investigators will have access to the data for analysis and aggregate reporting purposes. Data stored on secure internal network drives. Investigators are responsible for receipt and any transfer of the data through secure network tools.

Provisions to Monitor the Data to Ensure the Safety of Subjects

Participation is fully voluntary and there will be no undue influence to pump if a participant is unhappy or unable to use the devices, individuals will need to let us know when they are done so Investigators can send them the final survey and remove them from the monthly send. Our survey will ask questions about what made them stop pumping and there is an open text box for those that would like to provide any detail about their experience.

Describe:

- Individuals will be surveyed monthly on basic data but will be asked to assess if they are satisfied with the device, and utilization, Investigators will ask users to let us know when the cease pumping so Investigators can send the outtake survey (probably link it to the monthly survey) and then Investigators will end monthly survey

- Data reviewed monthly will include number of active users in the study, volume of milk and frequency of pumping.
- Quarterly review of satisfaction with Willow devices and utilization of other resources will be reviewed in aggregate. Early cessation in the study will be reviewed for qualitative responses to determine trends in cessation.
- Project Investigators will review monthly report and provide to Willow
- Investigators will review data once a final survey has been completed and overall data quarterly including any anonymous comments, if there are concerns about safety in the comments, investigators will ask individuals to notify us immediately so Investigators can reassess.

Provisions to Protect the Privacy Interests of Subjects

Participants will be deidentified in the survey using their infant DOB and the device serial to protect anonymity.

Surveys will be completed via RedCap. Individuals that reach out to participate will be provided information on pumping with the Willows and the informed consent form at the beginning. Biographic data will be collected through the RedCap survey. And only collected at planned intervals (quarterly) to assess midpoint measurements as deidentified combined and/or aggregate data.

Compensation for Research-Related Injury- NA

Economic Burden to Subjects- Participants responsible for the purchase of any accessories or replacement parts.

Consent Process

Informed consent will be obtained at the beginning of the survey process at device handoff, individuals will complete the consent form which will trigger the survey timing.

Non-English-Speaking Subjects

It is unknown if there will be any non-English speakers enrolled in the survey, the institution hires and trains individuals that do not speak English as a primary language, but they are expected to be able to be fluent in English in order to provide patient care.

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)- **N/A**

Subjects who are not yet adults (infants, children, teenagers) **N/A**

Cognitively Impaired Adults **N/A**

Adults Unable to Consent **N/A**

Humanitarian Use Device (HUD) **N/A**

Process to Document Consent in Writing- we will be using standard university consent form for minimal risk.

Setting

Individuals will use devices in their normal settings of home and work and complete surveys based on their experience.

Investigators will promote the research project for those that may be interested but will not approach users to recruit directly.

Multi-Site Research

This is not a multi-site IRB protocol, it will be shared with other sites to adapt for their own instiution. Each site will maintain its own IRB.

References (of literature cited in preceding sections)

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