NCT Number: NCT02724969

Title: A Mobile, Semi-automated Text Message-based Intervention to Prevent Perceived Low or Insufficient Milk Supply

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STUDY PROTOCOL

Study staff will approach pregnant individuals for enrollment who are attending a prenatal appointment between 13-25 weeks gestation. Potential participants who would like time to think over their enrollment decision will be offered a consent form or handout to take home and review, and can contact the study coordinator later if interested. Confirmed eligible participants providing written informed consent will be randomized via computer-generated simple randomization to the experimental or control intervention group (MILK intervention or Text4Baby, respectively). For patients not recruited at the primary enrollment site at MWH (e.g., website; study flyer), arrangements will be made to meet to explain the study, obtain informed consent, randomize to a group, and collect baseline data.

At enrollment, study staff will collect baseline data including demographic, obstetric and breastfeeding history, anxiety, breastfeeding self-efficacy, breastfeeding attitude, breastfeeding intentionality, breastfeeding knowledge, and breastfeeding support via oral administration of paper-based or electronic questionnaire on a study iPad. Data will be inputted into and managed in REDCap (secure, password protected and backed up data management system through University of Pittsburgh). We will also collect contact information for follow-up data collection (email, telephone numbers) and, for participants in the experimental intervention (MILK) group, we will provide written and oral instructions regarding text message frequency and how to stop or reduce volume of text messages (or withdrawal from study). We will provide participants in the control intervention (Text4Baby) instructions about how to sign up for the freely available Text4Baby services. The baseline visit is expected to last an hour or less and will occur either in the prenatal exam room or private MWH space.

Participants in both groups will begin receiving automated prenatal and postpartum texts containing breastfeeding education and support at 25 weeks, and will continue to receive, on average, 3-5 texts weekly through eight weeks postpartum (some MILK texts have multiple parts and are more frequent, particularly in the first week post-birth). Participants in the control group (Text4Baby) will receive more general texts about breastfeeding and infant care, while participants receiving the MILK intervention will receive messages that focus specifically on establishing breastfeeding confidence and behaviors to prevent perceived insufficient milk (PIM). Participants in the MILK group will not be excluded from study participation if they sign up to receive Text4Baby messages. Rather, we will assess receipt of Text4Baby messages in both groups at each data collection point. At enrollment, both groups will be provided contact information for local lactation support resources for as-needed individualized breastfeeding support.

Experimental Intervention (MILK): The experimental MILK intervention is based on the Breastfeeding Self-Efficacy (Social Cognitive Theory) conceptual model that theorizes self-efficacy as a primary driving force of breastfeeding behavior, and PIM as a consequence of impaired breastfeeding self-efficacy. Prenatal texts encompass general aspects of breastfeeding management; positive reinforcement regarding the decision to breastfeed; information about breastfeeding benefits and current breastfeeding recommendations; and anticipatory guidance regarding how breastfeeding “looks” and works (e.g., interactive website links featuring real moms breastfeeding). While participants will have the option to text the study immediately about delivery of their infant(s), and thus drive the conversion to postpartum-

oriented messages, we will monitor MWH participant hospital delivery records roughly daily for this purpose. In the postpartum period, texts will continue at roughly the same frequency, but anticipatory guidance about breastfeeding will be modified based on infant's gestational age (e.g., milk expression for preterm infant) and time since delivery (e.g., feeding expectations at 24 hours versus 1 week). Texts include guidance related to milk volume, infant breastfeeding behavior, and technical aspects (positioning/latch); referrals to local and online support groups; and encouragement. Participants will be able to text a key phrase to reduce message frequency or stop messages altogether. We have also added automated personalization and interactivity, such that participants and their infants will be addressed by name and some texts attempt to engage participants by requesting responses, with follow-up texts or web links addressing concerns in greater detail. To provide the assistance needed while still maximizing sustainability, participants experiencing complex breastfeeding issues will have the option to request individualized support from study lactation consultants via the text message system (texting a keyword, which will then be followed by study lactation consultant following up with participant via the participant's preferred communication medium). We will keep a log of issues addressed in individual consults to inform future modifications to the MILK intervention. In addition, consults will be audio-recorded (if by telephone) or saved as electronic files (if via text or email) in order to later review content in detail for future interviews and assure adherence to study protocol.

Control Intervention (Text4Baby): The national, free, automated text message system, "Text4Baby," was developed by the National Healthy Moms, Healthy Babies Coalition in collaboration with the Centers for Disease Control and Prevention. The system—rigorously developed through expert review, research, and input from pregnant and postpartum women, is designed to provide perinatal health support and information to women from pregnancy up to one year after delivery. Messages are updated annually and address various aspects of maternal and infant prenatal and postpartum care, including safe sleep, infant developmental milestones, and breastfeeding. Conversion to postpartum messages is automatic, based on gestational data provided by users. Similar to participants in the MILK intervention, participants in the control group will also receive contact information for study lactation consultants to converse by telephone, email, etc. Participants will receive a total of 3-5 text messages per week during pregnancy and postpartum from a database containing more than 250 messages. There are seven total prenatal breastfeeding messages, which begin in week 25. There are 8 total postpartum breastfeeding-specific messages commencing at 2 weeks postpartum, and continuing in weeks 7, 8, 13, 18, 24, 28, and 50. Participants may continue to receive Text4Baby messages after 8 weeks, but study data collection will end at that point. Participants can text a "STOP" reply to discontinue these messages. Research personnel will not receive any data from Text4Baby. Rather, participants will self-report their use/whether they are receiving texts from this system as part of the questionnaire data. Participants assigned to Text4Baby will be provided instructions regarding how to register with the system (texting BABY to 511411 or signing up on website); when signing up, participants will be prompted to enter their phone number, zip code, an email, their age, and the due date of the baby. Text4Baby does not sell information to any third parties but may share de-identified data with Health Insurance Plans, Government Health Departments, and academic research organizations. Users have the right to request deletion of their personal identifiable information stored by Text4Baby via email. Text4Baby web servers automatically collect non-personal information such as the domain name of the Internet access provider, the Internet protocol address used to

connect the computer to the Internet, the average time spent on the website, pages viewed, information searched for, and access times. Participants can disable cookies to restrict this monitoring.

After enrollment, we will collect data from participants remotely at 34-36 weeks of pregnancy, and at 1, 2, 5, and 8 weeks postpartum and 6 months postpartum. We collect birth hospitalization and feeding data via the birth electronic medical record after birth. At 34-36 weeks of pregnancy, we will collect questionnaire data regarding breastfeeding self-efficacy, breastfeeding intentions, and maternal employment (covariate impacting breastfeeding) via an electronic REDCap survey link sent to participants via email. At 1, 2, 5, and 8 weeks postpartum, we will collect data including breastfeeding self-efficacy, anxiety, depression, breastfeeding knowledge, perceived milk supply, infant feeding status, feeding activities, breastfeeding support, and receipt of Text4Baby texts via REDCap survey (emailed link to participants). All participants will be assigned a number (chronological based on enrollment order), and this will be used on all data collection instruments (including emailed surveys), rather than participant's real name. Research staff or the PI will review survey responses within two days of completion to assess missing/non-sensical data. Research staff will attempt to contact participants by phone to resolve missing or non-sensical data upon identification of the issue. Time for participants to complete remote surveys is estimated at no more than 30 minutes. They may begin a survey and return to it. Participants will have approximately 1 week to complete surveys. A reminder email will be sent at 3 days if no survey is received. We will attempt to call participants up to three times to complete questionnaires over the phone if no electronic survey is completed after the email reminder at 3 days. Note that we will also call participants by phone without emailing a survey first if they prefer a phone call. The timepoints chosen for data collection were based on the higher prevalence of perception of insufficient milk and early breastfeeding cessation in the first 1-2 months postpartum.

At the conclusion of the main study (8 weeks), we will conduct individual telephone interviews with approximately 25% of participants in the Text4Baby control group (to be selected purposively based on mutual availability of research and participant and variability in participant characteristics known to impact breastfeeding, e.g., age, race). This individual interview will be offered to all MILK (experimental group) participants to assess intervention use, burdens and challenges, and suggested modifications. Interviews are expected to last 30-60 minutes, and will be audio-recorded and transcribed verbatim. A list of MILK text messages will be sent to participants in the intervention group ahead of the interview for reference. All interviews will be conducted and analyzed by the PI or research assistant(s)/coordinator who have or will have training in qualitative interviewing.

Breastfeeding continuation and exclusivity (i.e., supplementation behaviors) will be assessed via a follow-up telephone call at 6 months postpartum. We will place up to 3 follow-up calls to make contact with study participants.

STATISTICAL ANALYSIS PLAN

Data will first be screened for anomalies (e.g., outliers, non-normality, missing data, imbalances between groups). If anomalies are encountered, appropriate remedial strategies will be applied

(e.g., data transformation, imputation, statistical adjustment of covariates, etc.) prior to primary analyses. We will analyze efficacy outcomes using an intention-to-treat approach, but also conduct sensitivity analyses and perform comparisons based on protocol deviations (e.g., comparisons between participants who do and do not receive all texts, participants in the intervention group who receive Text4Baby). Between group (each time point) and group × time differences will be examined graphically and via generalized mixed-effects modeling for all outcome variables of interest. For our main outcome of breastfeeding exclusivity at 8 weeks and other categorical outcome variables (e.g., any breastfeeding at each follow-up), we will use chi-square test statistics and logistic regression (if statistical adjustment is needed) to determine between-group differences. For continuous-type outcome variables (e.g., perceived milk supply/confidence scores), we will assess between-group differences at postpartum follow-ups via analysis of variance procedures (e.g., ANCOVA, ANOVA) or analogous nonparametric methods.

We will descriptively analyze study participation, attrition, and intervention use (e.g., proportions with 95% CIs). We will also explore possible predictors of participation (yes, no) and intervention use (yes, no) with group comparative statistics (e.g., independent sample t-tests and chi-square test statistics or binary logistic regression for continuous and categorical variables, respectively). The PI will code interview data for major themes using Atlas TI. The interview script will be modified on a continual basis to include new perspectives broached by participants.

University of Pittsburgh

School of Nursing

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

Study Name: **MILK Trial (**A **M**obile, Semi-Automated Text Message-Based **I**ntervention to Prevent Perceived **L**ow or Insufficient Mil**k** Supply*)*

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Study Coordinator: Melissa Glasser, PhD *(412-622-4370)*
Erin Caplan, BS *(412-648-9236)*

Study Sponsor: National Institute of Nursing Research (NINR): R00NR015106 "Preventing Perceived Insufficient Milk: Development of a Text Message-Based Intervention"

Why is this research being done? The purpose of this study is to determine the feasibility and effect of a text message-based breastfeeding support system on length of time mothers breastfeed without formula and mothers' perceptions that they have enough breast milk.

Who is being asked to take part in this research study? You and your baby are being asked to be in this research study because you are a healthy first-time mother in your second trimester of pregnancy, are pregnant with a healthy baby to your knowledge, plan to breastfeed, and have an unlimited text message plan on your phone. About 250 pregnant women will take part in this study. Because breastfeeding is not advised for certain women in the U.S. (e.g., HIV-positive, T-cell lymphotrophic virus, taking street drugs), we will verbally ask you if you have these conditions. If you do, you will not be able to participate in the study.

What is involved? If you agree to take part in this study with your baby, you will be randomized to one of two different text message support systems: Text4Baby or MILK study texts. Beginning at 25 weeks of your pregnancy, you will begin receiving text messages. Text messages are designed to provide breastfeeding support alone (MILK texts) or breastfeeding support + general pregnancy and postpartum support (Text4Baby). Study texts are semi-automated—meaning they are sent automatically based on your baby's age/stage of pregnancy, but some messages will ask for your feedback and provide an opportunity to interact with a certified lactation consultant (breastfeeding specialist). Regardless of group, you will receive on average, 3-5 text messages per week throughout pregnancy and up to 8 weeks after birth. You will be able to stop receiving text messages in either group you are assigned to simply by texting

back "STOP." If you are assigned to MILK text messages, you can reduce the number of text messages received to one series per week by texting "REDUCE". You may also contact the researchers by phone or email to stop or reduce study text messages. If you change text plans during the course of the study such that that you no longer have unlimited texting, you should immediately notify researchers so that we can stop texts and avoid charges to your phone plan. The research team is not responsible for any text message charges billed to you.

We will collect information from you in-person at the time of study enrollment and via a telephone or online survey (emailed link) at 34-36 weeks of pregnancy, 1 week, 2 weeks, 5 weeks, 8 weeks, and 6 months after birth. The enrollment visit should take an hour or less; follow-up surveys should take about 30 minutes; if you complete an 8-week telephone interview, it should take 30-60 minutes and will be audio-recorded. Information collected will include demographics, information about your pregnancy, baby, breastfeeding, feeding attitude, stress, anxiety, and opinion about the study interventions. The research team will also collect information from you/your baby's medical records including medical and psychiatric conditions/problems, medications you are taking, prenatal and labor and delivery data, and information concerning your baby's feedings in the hospital. This information is needed to examine potential issues that may affect breastfeeding during your participation in the study. No information we obtain from you will be placed in you or your baby's medical records.

Regardless of your study group, you will be provided contact information for local lactation resources for breastfeeding questions or concerns. If you are assigned to the MILK group, please note that the study lactation consultant is not a substitute for seeking medical advice or assistance, and you should address any medical concerns you have with your or your baby's medical care provider. If the study team notes any potentially serious health issues during data collection or interactions with the study lactation consultant, we will contact you by phone to ensure the issue is being addressed appropriately by your and/or your baby's medical care providers.

What are the possible risks and discomforts of this study? It is possible, but unlikely, that your survey responses may be visible over the internet. To minimize this risk, we ask that you delete your emailed survey link after completing the survey and empty your computer's "trash" after deletion. Likewise, if you are a MILK group participant and interact with the study lactation consultant via email or text message, we advise deleting this correspondence once complete. It is also possible, but unlikely, that your voice may be identifiable on the audio-recorded phone call. We will code all of your research records to minimize potential breaches in confidentiality. Text messages are not encrypted or secure during their transmission, and therefore, it is possible that they may be intercepted. If you are assigned to Text4Baby, please be aware that this is not a University of Pittsburgh hosted or created website/mobile app and therefore out of the control of the University of Pittsburgh and study team. We direct you to read and understand the privacy policy and terms and conditions of use of Text4Baby at this website: https://partners.text4baby.org/index.php/privacy-policy

Will I benefit from taking part in this study? You may find the text message support helpful in managing breastfeeding or other pregnancy and postpartum concerns. Your participation may help us understand more about what types of interventions benefit first-time breastfeeding mothers.

Will anyone know that I am taking part in this study? We will make every attempt to protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University. Hard copies of forms will be stored in locked file cabinets in locked rooms at the University of Pittsburgh. The Principal Investigator has responsibility for control over this storage area. Computer text and audio files will be password-protected and user-restricted. A study number, rather than your name, will be used on all forms and files, with one exception. We will keep a single password-protected, user-restricted computer file linking your study number with your name.

You will not be identified by name in any publication or presentation of research results. The information collected in this study may be used by other investigators after any information that might link you or your baby to the study information has been removed.

In unusual cases, the investigators may be required to release identifiable information (which may include identifiable medical information) related to your/your child's participation in this research study in response to an order from a court of law. If the investigators learn that you/your child are in potential serious danger, they will need to inform the appropriate agencies, as required by Pennsylvania law.

Will I be paid for participating in this study? You will receive a University of Pittsburgh cash card, which we will reload as you complete study activities. You will receive $10 at the time of enrollment, and $15 upon completion of surveys at 2 weeks postpartum. You will receive $25 at completion of the 8-week survey. If you stop breastfeeding before 8 weeks but respond to an email/phone call regarding reasons for cessation will receive $10 for the call. You can receive up to $50 for study participation. <u>There will be no costs to you or your insurance provider for being in this study.</u>

Certificate of Confidentiality. To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities, such as those dealing with child abuse and neglect, or harm to self or others.

Is my participation in the study voluntary? Yes! Your/your baby's participation in this study is completely voluntary. You may refuse to participate or stop participating at any time, even after signing this form. Your/your baby's medical care will not be affected by study participation.

If I agree to take part in the study, can I be removed from the study without my consent? If you stop breastfeeding or decide not to begin, your participation in the study will be discontinued. You may supplement with formula and continue to participate in the study. Your participation will also be discontinued if you or your baby develop a condition that will directly interfere with breastfeeding (e.g., your baby becomes critically ill, you find out you are pregnant with more than one baby). If you lose cell phone access or change your phone plan and can no longer receive free text messages part of the study, you may remain in the study and complete questionnaires.

How do I get more information? If you have questions about your participation in this study, contact the Principal Investigator, Jill Demirci, at the phone number listed on this form. If you have any questions about your rights as a research subject, contact the Human Subject Protection Advocate, IRB Office (1-866-212-2668). You will receive a copy of this consent form.

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-888-212-2668).

By signing this form, I agree to participate and have my baby participate in this research study. I understand that, as a minor (age less than 18 years), my baby is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his/her participation in this research study. By signing this form, I also give my authorization to share my/my baby's medical records with the research team. This is necessary in order for the researchers to obtain details related to medical factors that may affect breastfeeding. This authorization is valid for an indefinite period of time, and identifiable medical record information will be made available to members of the research team for an indefinite period of time. However, I am aware that I can always withdraw my authorization to allow the research team to review my medical records by contacting the investigator listed on the first page and making the request in writing. If I withdraw authorization to access my/my baby's medical records, I am aware that I will no longer be permitted to participate in the study, and any information obtained from my/my baby's medical records up to the point of withdraw will continue to be used by the research team. A copy of this consent form will be given to me.

For study-related business (e.g., answering my questions, lactation consultant contact), I give permission for researchers contact me via: *[check all you feel comfortable with]*

☐ Telephone call (6-month follow-up is a telephone call only)
☐ Email
☐ Text message

Maternal Subject/Parent Name	Maternal Subject/Parent Signature	Date/Time

Infant Subject Name

Cell phone for text messages: _____

Email: _____

Secondary phone number: _____

Best time of day to reach you (by phone): _____

INVESTIGATOR CERTIFICATION

I certify that I have explained the nature and purpose of this research study to the above-mentioned maternal participant and I have discussed the potential benefits and possible risks of study participation. Any questions about this information have been answered. I further certify that no research component of this protocol was begun until after this consent form was signed.

Investigator Name	Investigator Signature	Date/Time