A proposed randomized clinical trial of the effectiveness ofa new breastfeeding- supportive texting program designed specifically for African-American/Black expectant women, as compared to a national maternal health texting program, on rates of exclusive breastfeeding at 2months; Short title: TOPS – Texting to Promote Breastfeeding).

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NCT06375655

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06/28/2024

IRB NUMBER: STUDY20240085
IRB APPROVAL DATE: 6/28/2024
IRB EFFECTIVE DATE: 6/28/2024
IRB EXPIRATION DATE: None

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES
(v. 04.2022)

Project Title: Texting To Promote Breastfeeding (TOPS)

Principal Investigator: Lydia Furman MD

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form. This is a research study to see if text messaging that supports breastfeeding is helpful to mothers and makes it possible for more mothers to breastfeed**.**

Why am I being invited to take part in a research study?
You are being invited to participate because you are a pregnant woman at 24-34 weeks of pregnancy, self-identify as African-American/Black, have a smartphone and are considering or committed to breastfeeding your infant. The text messaging in this research is meant to be helpful and relevant to African-American/black women and focused especially on their needs.

Things I should know about a research study
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Introduction/Purpose
The purpose of the study is to see if a program of text messages that support and promote breastfeeding for expecting and delivered African-American/Black women (called TEAM2BF), as compared to a national maternal health texting program (called Bright By Text), can result in more women being able to breastfeed their infant. Because breastfeeding is healthy for mothers and babies, and because fewer African-American/Black women decide to breastfeed and continue breastfeeding than many other racial and ethnic groups, researchers like us are trying to figure out ways to be supportive to African-American/Black mothers who might be interested in breastfeeding. We will enroll up to 80 mothers and their infants at UHCMC.

Key Study Procedures
The main study procedures are (1) using your phone to receive text messages about breastfeeding several times per week (in the early part of pregnancy) or several times per day (after you deliver your baby), and (2) then responding to surveys by text about your attitudes and knowledge about infant feeding, and how you are feeding your baby. If you join the study, you will start in your second trimester and receive up to 24 total weeks of messages from the second trimester to 10 weeks postpartum, each timed to be relevant for your due date. You will be in the study for at least a total of up to 24 weeks (from enrolling until final interview, depending on when you deliver); you can continue for an additional 9 months getting monthly messages (so up to 62

weeks) if you want. No in person visits are needed. More detailed information about the study procedures can be found under "Detailed Study Procedures".

Key Risks
The main risks of the study are inconvenience due to receiving text messages, possibly feeling anxious if the messages make you worry about breastfeeding, and a small risk of loss of confidentiality. More detailed information about the risks of this study can be found under "Detailed Risks."

Benefits
There are no direct benefits to you from joining the study. You might benefit from the information you receive about breastfeeding or about maternal health, but we cannot guarantee benefit. We hope the results will help other women in the future with their plans to breastfeed.

Alternatives to Study Participation
This study is voluntary. It is not clinical care or medical treatment. The alternative is not to join.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Detailed Study Procedures

1- At enrollment we will ask for basic information about you (age, due date, first pregnancy or not, any prior breastfeeding if other kids, partnered or not, graduated High School/have a GED or not, and phone number).

2- If you participate in this study, you will be assigned to one of two study groups by chance using a process similar to the flip of a coin. This process is called randomization. Neither you nor study staff will select the group to which you will be assigned, and both you and the study staff will know which group you are in. The possible study groups you could be assigned to are:

   a. TEAM2BF – This texting program includes 3-4 breastfeeding-supportive messages per time interval, sent weekly from 28 weeks gestation through delivery, daily through 2 weeks postpartum, weekly from 2 to 10 weeks (and then monthly to one year if you elect to continue). The messages give information and support about breastfeeding and may link to helpful resources intended specifically for African-American/Black women. Other maternal health topics are not addressed. To sign up your phone number and due date are needed.

b. Bright By Text – This national maternal child health texting program sends approximately 2-4 messages per week from the first trimester through age 8 years about a wide range of maternal and child health and development topics. There are in total 8 messages about breastfeeding. The program is intended for women of all races and ethnicities. The first 6 months after delivery are part of this research study (TOPS) and after that receiving the texts is not research. The Bright By Text Sponsor sends a survey to you about their texting program at 30 days and 6 months from your start up for their information – this is NOT information we request, collect or can obtain; like all surveys it is your choice. To sign up your phone number, due date and zip code are needed.

3- You will be asked to enter your delivery date when you deliver your baby so you can begin to receive the postpartum messages. As a backup plan, the study team will also check the medical record for your delivery date so we can reach out to you if you forget to enter your delivery date.

4- You will be asked to complete surveys at the time points below (both groups have the same surveys)

Time point	Surveys	Approximate Time Needed
Enrollment	Demographics (your name, age, family supports, WIC status, other basic info) Infant Feeding Intentions Survey (4 questions) Breastfeeding Knowledge Quiz (4 questions – answers follow) Breastfeeding Self-Efficacy Scale (14 items)	7-10 minutes
One week after delivery (PP)	Infant Feeding Information-what milk is baby drinking?	2 minutes
One month PP	Infant Feeding	2 minutes
Two months PP	Infant Feeding Breastfeeding Knowledge Quiz Breastfeeding Self-Efficacy Scale Breastfeeding Social Support Scale (16 items) Maternal Satisfaction (6 questions)	15 minutes
Three months PP	Infant Feeding	3-4 minutes

	Healthy development (1 question) Maternal Satisfaction	
Six months PP	Infant Feeding Healthy Development Maternal Satisfaction	3-4 minutes

5- If it is possible, we will take information from the systems that send out the texts to see if texts were read by you. You don't need to do anything for this to happen.
6- You can text STOP ALL or STOP SO MANY (to receive only one message per time point (by week prenatally or by day postpartum). If you do this we will ask, "Why unsubscribe?" and hope you will respond with why you decided to change or stop the messages. If you choose not to respond, or do not respond to any of the surveys, we will call you or email you (two tries only) to understand why.

7- If you forget to respond to the text surveys at the time points after enrollment, we will send one automated reminder text, and call you by phone up to 3 times.

8- We will review your medical record to see if you attended your postpartum visit with your obstetrical provider (nurse midwife or OB doctor). We will review your baby's medical record just to check that your baby attended the 2 months visit, if they got baby shots, and to see your baby's feeding information.

Please remember - when your baby is born, please text the study team (so we can switch over to the postpartum messages and surveys).

Detailed Risks

There is a small risk of emotional distress if receiving the messages makes you anxious about breastfeeding – you can unsubscribe promptly if you want to, you can get breastfeeding help from your health providers, and you can also call the 24/7 Ohio Breastfeeding Hotline for help (1-888-588-3423) with breastfeeding.
There is a risk of data overage or charge depending on what phone plan you are on so please check this for yourself. There is a small risk of fatigue due to getting many messages – you are able to unsubscribe to stop messages. There is also a small risk of breach of confidentiality, but we will protect against this by careful handling of all ingoing and outgoing messages.

Consequences of Withdrawing or Being Discontinued from the Research

There are no consequences to withdrawing from the research. If you deliver your baby prematurely (before 36 weeks of pregnancy) you will be withdrawn from the study because the breastfeeding information is meant for mothers of term and near-term infants.

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Financial Information
Depending on your phone plan you could have a charge for receiving or sending text messages. Please check on this since we cannot pay your phone bill.
You will get $25 and a gift (diapers and wipes or onesies and a blanket) at each time point that surveys are completed. You will receive your payment by a re-loadable debit card called ClinCard. At each time point you are eligible for the gifts if you are still receiving text messages (have not unsubscribed) and complete the surveys. In total, you can receive $150 and 6 either diaper+wipes packs or onesie packs. If you decide to continue to receive texts beyond 6 months postpartum (after delivery) the study thanks you but you will not be able to be paid for this.

Consent to Contact for Future Research
If you would permit us to contact you for future research, please let us know. If you check "yes" we will save your name and phone number for future contact.
Yes_____ No_____

Request to Share Study Results
If you would like us to contact you to send you a summary of the final study results, please let us know. If you check "yes" we will save your name and phone number and text a summary to you.
Yes_____ No_____

Clinical Trial Information
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. At most, the website will include a summary of the results. You can search this website at any time to find out information about the trial and basic results.

Student/Employee Rights
Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor will the results be shared with your supervisor.

Termination of Participation
We will withdraw you as noted above if you deliver prematurely before 36 weeks. We will withdraw you if you misuse the texting in any way and of course we do not expect this to happen. You will withdraw yourself if you decide to stop receiving texts.

Confidentiality
Your information will be identified by a study number and not by your name or identifying information. Only members of the study team will have access to the link between your study number and identifying information. All information will be stored in a secure password protected database on a hospital computer that is protected against hackers. Your name and

phone number will not be released to anyone outside the study team and will not be saved after the study is over unless you give permission for future contact.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Privacy of Protected Health Information (HIPAA)

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled "TOPS – Texting to Promote Breastfeeding" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Lydia Furman MD, and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: Your name, date of birth and medical record number, your baby's name, date of birth and medical record number, your due date, email address, mailing address and phone number. This is so we can send you text messages, receive your surveys for the research, review your and your baby's medical record, send gift cards and send project incentives (gifts) to you in the mail.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research:

- The Food and Drug Administration
- The Department of Health and Human Services

- Other Institutional Review Boards
- Data Safety and Monitoring Boards
- Other staff from the Principal Investigator's medical practice group that are involved in the research
- Greenphire – ClinCard,
- University Hospitals, including the Clinical Research Center and the Law Department; any UH or CWRU employee required to process information for research, finance, compliance, or hospital operation, and Government representatives or Federal agencies, when required by law.

It is possible, that in the future, additional research sites may be added. In this event, your PHI that was collected during this research project may be shared with research personnel at these additional sites.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to:

Lydia Furman MD
Department of Pediatrics, Rainbow Babies and Children's Hospital
11100 Euclid Avenue, Cleveland OH 44106

If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

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Summary of Your Rights as a Participant in a Research Study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. De-identified data from this study may be published, presented, or otherwise made publically available. If this happens, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

Disclosure of Your Study Records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. If your records are reviewed your identity could become known.

Contact Information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Lydia Furman MD can also be contacted at 216-675-6691. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Associate Chief Scientific Officer, Clinical Research Center, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

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Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X		
Signature of Participant	Date	Time
X		
Printed Name of Participant		

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

X		
Signature of person obtaining informed consent	Date	Time
X		
Printed name of person obtaining informed consent		

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Appendix A: Study Schedule

Please remember - when your baby is born, text the study team (so we can switch over to the postpartum messages and surveys).

	You get 3 breastfeeding information & support texts	You are asked to complete surveys	You get a gift card and gift
28-40 weeks pregnant	Weekly	At enrollment	$25 gift card and diaper+wipes or onesie gift for completed survey
Delivery (congratulations!)	Please text the study team to let us know you delivered!		
Day 3 until your baby is 12 days old	Daily	At one week	$25 gift card and diaper+wipes or onesie gift for completed survey
Your baby is 2, 3, 4, 5, 6, 7, 8 and 10 weeks old	Weekly	At 1 and 2 months of age	$25 gift card and diaper+wipes or onesie gift for completed surveys @ each of 1 & 2 months
Your baby is 10 weeks old	Monthly	At 3 and 6 months of age	$25 gift card and diaper+wipes or onesie gift for completed surveys @ each of 3 & 6 months

(Total possible is $150 plus the diaper gift x 6 if you enroll at 28 weeks pregnancy and complete all interviews.)