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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Objectives

Specific Aims

1. Demonstrate the feasibility and acceptability of a scaled-up program to deliver Team2BF text messages to AA/B expectant women considering breastfeeding.
2. Compare breastfeeding outcomes in the group receiving Team2BF with rates among those receiving Bright By Text.
3. Compare breastfeeding related knowledge and self-efficacy and social support as moderators of the relationship between the texting intervention and breastfeeding outcomes. (Exploratory aim)
4. Compare other key health outcomes (appointment attendance and vaccine receipt and book reading to infant) between the groups to verify that a focus on breastfeeding enhances rather than detracts from general maternal-infant health outcomes. (Exploratory aim)

Study Hypotheses

1. Participants will find the Team2BF intervention acceptable as measured by >90% continuation, by >75% top score helpfulness of messages for breastfeeding and >75% endorsement of friend and family referral.
2. Participants receiving Team2BF will have significantly higher exclusive breastfeeding rates at 2 months as compared to participants receiving Bright By Text.
3. Breastfeeding knowledge, perceived social support for exclusive breastfeeding and self-efficacy will positively moderate the relationship between texting and breastfeeding outcomes, with those in the Team2BF group demonstrating a significantly greater increase in these domains with time as compared to the Bright By Text group.
4. Participants in both groups will have >75% rates of attendance among mothers at the (2-6 weeks) postpartum obstetrical visit and >75% rates of attendance and vaccine receipt for infants at the 2 month (6-12 weeks) well care visit.

Background

Exclusive breastfeeding at 6 months is recommended by professional bodies worldwide, with profound health benefits for mothers, infants and society, yet achievement continues to be an elusive goal with profound national racial inequities persisting. [1-5] Nationally 83.9% of all mothers but just 75.5% of African American/Black (AA/B) mothers initiate breastfeeding; with respect to the HealthyPeople 2030 goal for 6 months exclusive breastfeeding of 42.4%, 24.9% of all mothers but just 19.8% of AA/B mothers are achieving this goal. [6,7] The state of Ohio faces similar racial breastfeeding inequities, in that 75,4% of all infants, but just 68.8% of AA/B infants, are breastfed at discharge from hospital (2020 data). [8] In specific counties targeted by

the Ohio Equity Institute (OEI, Ohio Department of Health, Bureau of Maternal Child and Family Health) for improvement in birth outcomes, our own Cuyahoga County reports rates of continuing breastfeeding at 8 weeks postpartum of 65.8% among AA/B mothers and 73.9% among all others. [9]

These continuing racial inequities in breastfeeding rates create opportunities for new ways of supporting and promoting breastfeeding for AA/B mothers. Smart phone technology may provide a way to reach and engage AA/B women who otherwise face barriers related to racism in accessing resources for breastfeeding. [10] Approximately 83% of AA/Bs, 76% of those with income < $30,000 and 95-96% of those ages 18-49 years own a smartphone. [11] There is evidence that mobile health (m-health) applications including telephone support, SMS text messaging and internet-based support can increase rates of postpartum exclusive breastfeeding, however the total number of studies is limited (n=15) with just one focused solely on SMS text messaging. [12] With respect to m-health apps, though, most are solely informational, few are tailored or personalized [13] and very few are designed specifically for AA/B mothers [14]. This gap in m-health products designed with AA/B women's breastfeeding concerns and needs in mind creates another racial inequity; research is needed to overcome this barrier. In prior work we elucidated topics and features that AA/B expectant women intending to or considering breastfeeding would like to see in a phone app [15], and texting/messaging was one specifically endorsed.

In this research, we follow up on prior work that assessed the feasibility and acceptability and content of a culturally-tuned Breastfeeding-supportive Text Messaging Library intended for AA/B women. That work (TEAM2BF, STUDY20221270) demonstrated that expectant and delivered AA/B women found the text messaging process and content acceptable and helpful. None stopped any or all of the messaging, and approximately 6 messages were revised as recommended by participants. In this current study we aim to obtain preliminary efficacy data by comparing this texting library aimed at promoting breastfeeding to a professionally endorsed national maternal child health texting program, Bright By Text, whose focus is not breastfeeding. By comparing the TEAM2BF texting program to Bright By Text, we can compare whether message content impacts breastfeeding initiation and exclusivity at 2 months. The study design is equitable for participants in that both programs use a similar approach (texting), both are designed to be accessible to minoritized women of low socioeconomic status, and the comparator (Bright By Text) has demonstrated benefits.[16] This study aims to address identified gaps in breastfeeding support for AA/B women that we hope can ultimately reduce racial inequities in breastfeeding rates.

Inclusion and Exclusion Criteria

	Inclusion Criteria - mothers
1.	Expectant women initiating obstetrical care <34 weeks or at any prenatal visit up to 34 weeks gestation
2.	Daily access to a mobile phone with text message capabilities,
3.	18 years or older (i.e., adult),
4.	Self-identify as African-American/Black,
5.	English speaking, and
6.	Infant feeding plan of "might or will breastfeed".
7.	Receive care at Ahuja Midtown or MAC1200

	Exclusion Criteria
1.	Minors
2.	Committed to feeding formula only to their infant
3.	No mobile phone with text capability

	Inclusion Criteria - infants
1.	Infant of maternal participant

	Exclusion Criteria -infants
1.	Not infant of maternal participant

Number of Research Participants

We will enroll up to 80 participants. Infants are a secondary population and we will enroll up to 85 infants (85 not 80 to allow for inclusion of multiples if this occurs).

Recruitment Methods

Maternal participants will be recruited via OB provider schedules at Ahuja Rainbow Center for Women and Children (ARCWC- Midtown location) and MacDonald 1200. Women will be approached in person before or after clinic visits with the permission of the OB provider. The study may be introduced in a group setting (CenteringPregnancy) but all consent procedures will be individual and private.

Setting

Expectant women will be recruited at UHCMC locations ARCWC and Mac1200. The intervention itself is virtual so following the consent process and enrollment there will not be inperson contact (except for the optional interview which can be by telephone or in person as preferred).

Consent Process

Potential participants will be recruited as above and approached in person before or after clinic visits with the permission of the OB provider. Signed consent will be obtained in person following an informed consent procedure with time for questions. The potential participant's exam room is a private place and if this is not available, we will find an unused office or conference space to have a private consent process. Potential participants who are interested will discuss the research with a study team member using the informed consent document. Family or friends may join the discussion if the potential participant chooses, and all questions will be answered. The potential participant can decide to participate and sign the informed consent or can decide to not join or can think about it further and call the study team if she decides to join.

Sharing of Results with Research Participants

☒ Results will not be shared with research participants.
Results are very preliminary and the number of participants is small so to avoid identifiability we will not provide results.
☒ Results will not be shared with research participants' doctors

Study Design

A prospective block-randomized two arm unblinded cohort study.

Study Procedures

1- Intervention – study procedures. In summary these include receiving texts, completing surveys and interviews, and permitting review of the medical record.

The study intervention is texting of health information from 28 weeks gestation or from time of enrollment (24-34 weeks) through one year postnatally. Participants will be block randomized to either Bright By Text or Team2BF. Blocks will be by CenteringPregnancy group for those in this program and in sequential blocks of the same number of participants for those in individual obstetrical care.

Those randomized to Bright By Text begin receiving texts as soon as they sign up, and those randomized to Team2BF begin receiving texts at 28 weeks or at the time of enrollment if after 28 weeks.

Bright By Text sends messages total from the first trimester through eight years postpartum, with 2-4 messages per week about a wide range of maternal and child health topics as outlined on their website; there are in total 8 messages about breastfeeding from the prenatal period to 4 months postpartum.Team2BF 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. Other maternal health topics are not addressed.

We are not able to collect user interactions with the SMS system (were texts read or not, was message link clicked or not) within the TEAM2BF REDCap/Twilio system; Bright By Text does have ability to collect user interactions but there is no plan to collect this information for the research and no ability for the study team to receive or access it. For TEAM2BF, participants can text STOP ALL or STOP SO MANY (to receive only one message per time point [by week prenatally or by day postpartum]) and for Bright By Text, participants can text STOP at any time to discontinue receiving texts. At the point of any unsubscribe, and at the 6 months postpartum time point, the participant will be invited by text to participate in a 10-15 minute interview about their experience The interview will be audio recorded and the transcript destroyed once call notes are verified against the recording.

For those who do not respond to the surveys, we will send one automated reminder text, and call up to 3 times, to make sure there are not technical difficulties. For those who STOP ALL or STOP SO MANY (to receive only one message per time point (by week prenatally or by day postpartum), we will ask, "Why unsubscribe?" If the participant does not respond, or does not respond to any of the surveys, we will call or email (two tries only) to understand why.

Mothers can continue to receive monthly messages for months 6-12 postpartum for TEAM2BF and up to 8 years postpartum for Bright By Text but this will not be incentivized.

Mothers will be asked to enter their delivery date; as a backup plan we are requesting to check both Delivery Logs (the PI receives these daily weekdays – they include all UHCMC MacDonald Women's deliveries) and the maternal EMR (electronic medical record) to make sure we do not miss this date if a mother forgets to enter her delivery date, since a different set of text messages is delivered postpartum and the postpartum surveys begin.

2- Research participants' safety and comfort will be protected by their ability to text "STOP" to end all messaging. Additionally in the informed consent we will have contact information for the study team, and the participant can call or email the study team with any concerns or questions.
3- Participants will use their own smartphones for the study. The smartphone is a device but it is not being studied. The text messages are being studied. Given the definition of software as a medical device (The term "Software as a Medical Device" (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. Reference- https://www.fda.gov/medical-devices/digitalhealth-center-excellence/software-medical-

device-samd), the text messaging does not appear to be SaMD because it is not being used to treat, diagnose or manage a condition or disease.

4- The source records for the study will be the survey data that participants provide and the electronic medical record.

Study Timeline

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 Information	2 minutes
Two months PP	Infant Feeding Information Breastfeeding Knowledge Quiz Breastfeeding Self-Efficacy Scale Breastfeeding Social Support Scale (16 items) Maternal Satisfaction (6 questions)	15 minutes
Three months PP	Infant Feeding Information Healthy Development (1 question) Maternal Satisfaction (6 questions)	3-4 minutes
Six months PP	Infant Feeding Information Healthy Development Maternal Satisfaction (6 questions) Study Thank you Survey	8-17 minutes

Data to be Collected for your study

Outcome Measures

Aim #1 - Acceptability

Receipt of messages measures acceptability because participants can easily end messaging; if at least 90% of Team2BF participants continue receipt this will indicate acceptability of the intervention. This outcome will be enhanced by asking (a) a single 4 point Likert-scaled question

about the helpfulness of the texts for breastfeeding and (b) whether the participant would or would not refer a friend or family member to Team2BF.

Aim #2 – Breastfeeding Outcomes

The main outcome will be exclusive breastfeeding at 2 months because this is a meaningful milestone toward the public health goal of 6 months exclusive breastfeeding. We will assess partial and exclusive breastfeeding at hospital discharge and at 1, 2, 3 and 6 months post delivery using the World Health Organization definitions for exclusive and partial breastfeeding. We will also assess timing of discontinuation of breastfeeding if this occurs.

Aim #3 – Moderators of Breastfeeding Outcomes (Exploratory aim)

By measuring breastfeeding knowledge at enrollment and again at 2 months we will assess for change in knowledge and for relationship to the main breastfeeding outcome. By measuring self-efficacy at enrollment and 2 months we will assess for changes in self-efficacy and relationship to the main breastfeeding outcome. We will assess perceived social support for exclusive breastfeeding at 2 months to compare those who did and did not achieve this goal.

Aim #4 – Non-breastfeeding Health Outcomes (Exploratory aim)

We will compare other key health outcomes between the groups that have been documented as relevant Bright By Text outcomes, as a direct Bright By Text outcome and a proxy to verify that a focus on breastfeeding enhances rather than detracts from general maternal-infant health outcomes. Attendance at the maternal postpartum check and attendance at the infant 2, 4 and 6 months well care appointments, including whether age-appropriate vaccines were received, will be assessed, as well as a measure of literacy (number of days per week reading books to baby).

Management of surveys – Generally participants will complete the enrollment timepoint surveys electronically, but if their phone is not able to photograph the QR codes that lead to the enrollment surveys, these will be administered on paper. The documents will be maintained on and transferred on the person of the study team member to the CCHP (Center for Child Health Policy) Office MCCO 650. The surveys will be kept in a locked cabinet with study team member access only, and after entry into REDCap will be retained until data analysis is complete.

Data Analysis Plan

Populations of each group will be compared using descriptive statistics (means and ranges, percents and frequencies). The main outcome of breastfeeding exclusively at 2 months will be compared between the two arms (texting groups) controlling for factors known to impact breastfeeding rates, as well as site of enrollment.

To calculate sample size both current and near past breastfeeding rates are relevant. At the Rainbow Pediatric Practice (RPP, IRB # 11-16-07, using a 3 month annual snapshot) data from 2016-2020 inclusive years for full term and late preterm infants not admitted to Neonatal Intensive Care Unit who have an appointment in RPP in first month of life: 89/808 infants (11%) were exclusively breastfed at 2 months. Women Infants and Children Supplemental Feeding Program (WIC) Cuyahoga County data aligns with this estimate, showing "Fully Breastfed Infants" (defined as infants of participating breastfeeding women do not receive formula from the WIC Program) for the fiscal year 2021 with 594/5188 infants (11.4%) fully breasted. An increase from 11% to 14% would be clinically meaningful, and to achieve this with 80% power, alpha 0.05 (SD of not more than 5%) we need 36 mother-infant dyads per group, which is 72; and allowing for 10% attrition we aim to enroll 40 mothers per group (80 total).

Without published data on breastfeeding from Bright By Text participants, a 5% point difference between the two arms in this outcome can be considered clinically meaningful. The timing of breastfeeding cessation is the inverse of partial or exclusive breastfeeding and will be compared between the two arms at end of study (6 months); a 1 month difference between the groups can be considered clinically meaningful.

Risks to Research Participants

There is a risk of breach of confidentiality due to ongoing text messaging but this will be protected against by careful management of the texting system by study team members and by protecting and securing the data received. There is a risk of emotional distress if a participant's anxiety about breastfeeding is increased by receiving messages about breastfeeding from either texting program – this will be mitigated by providing resources through the messages, by the ability to unsubscribe promptly, and in the informed consent by emphasizing that this is a research study and breastfeeding help can be obtained from her health providers or the Ohio Breastfeeding Hotline. There is a risk of data overage or charge depending on what plan a participant is on – we cannot mitigate this, but all participants can unsubscribe whenever they choose. All participants can text STOP to unsubscribe at any point with either study arm and withdraw themselves from the research.

Provisions to Protect the Privacy Interests of Research Participants

The privacy of participants will be protected. The consent process will occur in a private space or virtually where the potential participant can protect their own privacy. All interventions occur virtually on a personal phone, so participants are not exposed to others.

Potential Benefit to Research Participants

There are no direct benefits guaranteed to participants. Participants may benefit if the TEAM2BF messaging helps them with their breastfeeding and may benefit if Bright By Text

increases their wellness, but this cannot be guaranteed. We hope the information gained will help future women, their families and their health providers with breastfeeding and ultimately reduce racial inequities in breastfeeding.

Withdrawal of Research Participants

All participants can text STOP to unsubscribe at any point and withdraw themselves from the research and from each of the texting programs. A participant would be withdrawn is if there is any abuse of the texting system with receipt of inappropriate or profane messages. Mother participants who deliver prior to 36 weeks (35 and 6/7 weeks or before) will be exited from the study since the postnatal messaging is not tuned for prematurity.

Alternatives to Participation

The alternative to participation is simply not to participate. The research is not a substitute for clinical care.

Costs to Research Participants

There could be a cost for the texting for participants depending on their phone plan. The study team cannot be responsible for these costs.

Research Participant Compensation

At enrollment, at 1 week postpartum and at 1, 2, 3 and 6 months we will give $25 gift card and a tangible gift (diapers+wipes or onesies).

Provisions to Monitor the Data to Ensure the Safety of Research Participants

The PI and research coordinator will meet at least every other week to review for adherence to protocol, trouble shooting, and any events. We will not convene a DSMB.

Drugs or Devices

Participants will use their own smartphones for the study. The smartphone is a device but it is not being studied. The text messages are being studied. Given the definition of software as a medical device (The term “Software as a Medical Device” (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. Reference- https://www.fda.gov/medical-devices/digitalhealth-center-excellence/software-medical-device-samd), the text messaging does not appear to be SaMD because it is not being used to treat, diagnose, cure, mitigate or manage a condition or disease. There are no drugs involved in this study.

Additional Information

The program that is used for the TEAM2BF texting is currently Twilio via REDCap. Twilio, a third-party web service, allows SMS text messages to be sent via REDCap Links within the messages go to free content – most content is publicly available, and for those PDFs that are not publicly available, we have used a REDCap function called "Dashboard" that permits us to create an URL for each of the PDFs. Bright By Text (https://brightbytext.org/) is commercially available– when signing up, participants provide due date, zip code, language preference (English or Spanish) and phone number to the site. Research surveys will be sent from REDCap for all participants.

Regarding the study title: The CTSC funding submission long title, "A proposed randomized clinical trial of the effectiveness of a 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 2 months" has been added to both the Protocol and the Supplemental form. Due to the complexity and length of the formal title, we are requesting to retain the shorter title, "TOPS – Texting to Promote Breastfeeding," as the header in the informed consent. The reason for this request is that the population of interest may have low health literacy and may have negative perceptions of very academic descriptors; the study is the same and is described equally by both the short and long titles.

Community-Based Participatory Research – NA

International information – NA

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