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ARTICLE

Leveraging mHealth and a milk expression frequency biomarker during postpartum to prolong lactation among parents of critically ill infants: a pilot study

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OBJECTIVE: To assess the feasibility and potential benefits of personalized biomarker-based text messages in prolonging lactation among parents of critically ill infants.

STUDY DESIGN: Thirty-six participants were randomized to receive either daily texts with Mother's Own Milk (MOM) sodium levels or standard care. Surveys at months 1 and 3 assessed whether infants were receiving exclusive MOM feeding, any MOM feeding, and whether the parent was still lactating. Kaplan-Meier and log-rank tests were used for time-to-event analysis within and between intervention and control groups.

RESULTS: Participants were predominantly on Medicaid (72%), delivered infants <1500 g, and by c-section (56%). Kaplan-Meier probabilities at month 3 suggest prolonged MOM feeding (63% [0.95CI, 0.43–0.91] vs. 41% [0.95CI, 0.21–0.67]) and lactation (63% [0.95CI, 0.42–0.95] vs. 37% [0.95CI, 0.18–0.76]) in the enhanced group compared to the control group.

CONCLUSION: Personalized biomarker-based text messages are feasible and may prolong lactation and MOM feeding among parents of critically ill infants.

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INTRODUCTION

U.S. initiatives to meet the recently concluded Healthy People 2020 goals have made strides in improving breastfeeding rates and reducing supplementation of formula [1]. Yet while only 58% of U.S. infants receive some amount of mother's own milk (MOM) at 6 months of age [1], just 50% of very low birth weight (VLBW) infants receive MOM at discharge–a mean duration of 2 months [2]. This rate is starkly lower (34.4%) for Black infants compared to non-Hispanic white infants (56%) [2].

As infants in the NICU are often too ill or premature to breastfeed, their parents must often use a breast pump to obtain milk for tube feeding. This population of lactating parents is at high risk of delayed secretory activation (SA) (the sudden transition from small amounts of colostrum to copious milk volume), not coming to volume (CTV) (producing at least 500 mL milk per day), and shorter lactation duration [3–5]. Milk production relies on a positive neuro-endocrine feedback loop that requires frequent milk removal (8–12 sessions per day) [6]. Recent research suggests that a predominant reason for suboptimal lactation outcomes in mothers of critically ill and preterm infants is milk expression frequency (less than 5-6 sessions per day) that is inadequate to sustain the positive feedback loop and reach optimal milk volume [7, 8].

When milk expression is infrequent during the first two weeks, SA is often delayed [9]. During this early postnatal period, tight junctions between the milk-producing mammary epithelial cells open or close daily depending on milk expression frequency [6, 10]. With infrequent milk expression, these permeable junctions open, allowing sodium to bypass the cell and travel more readily to the mammary lumen and increasing milk sodium levels [11, 12]. With optimal expression frequency, tight junctions close and sodium must instead cross the mammary cell to reach the mammary lumen [12]. Thus, mothers who express milk more frequently have lower milk sodium levels during the first two postpartum weeks [12]. These daily fluctuations in milk sodium level during the first 2 weeks have been found to be predictable and reliable changes that allow for sodium to serve as a biomarker of expression frequency [6, 10–12].

Few studies exist in the U.S. using an "mHealth" text message intervention to support lactation among pump-dependent parents of critically ill infants. Two known studies have found breastfeeding support via text messaging to be feasible, but both only assessed lactation at 8 weeks, and participants were mothers of healthy, breastfeeding infants [13, 14]. It is unknown whether delivering a biomarker-based text message intervention to pump-dependent parents of critically ill infants is feasible, and whether

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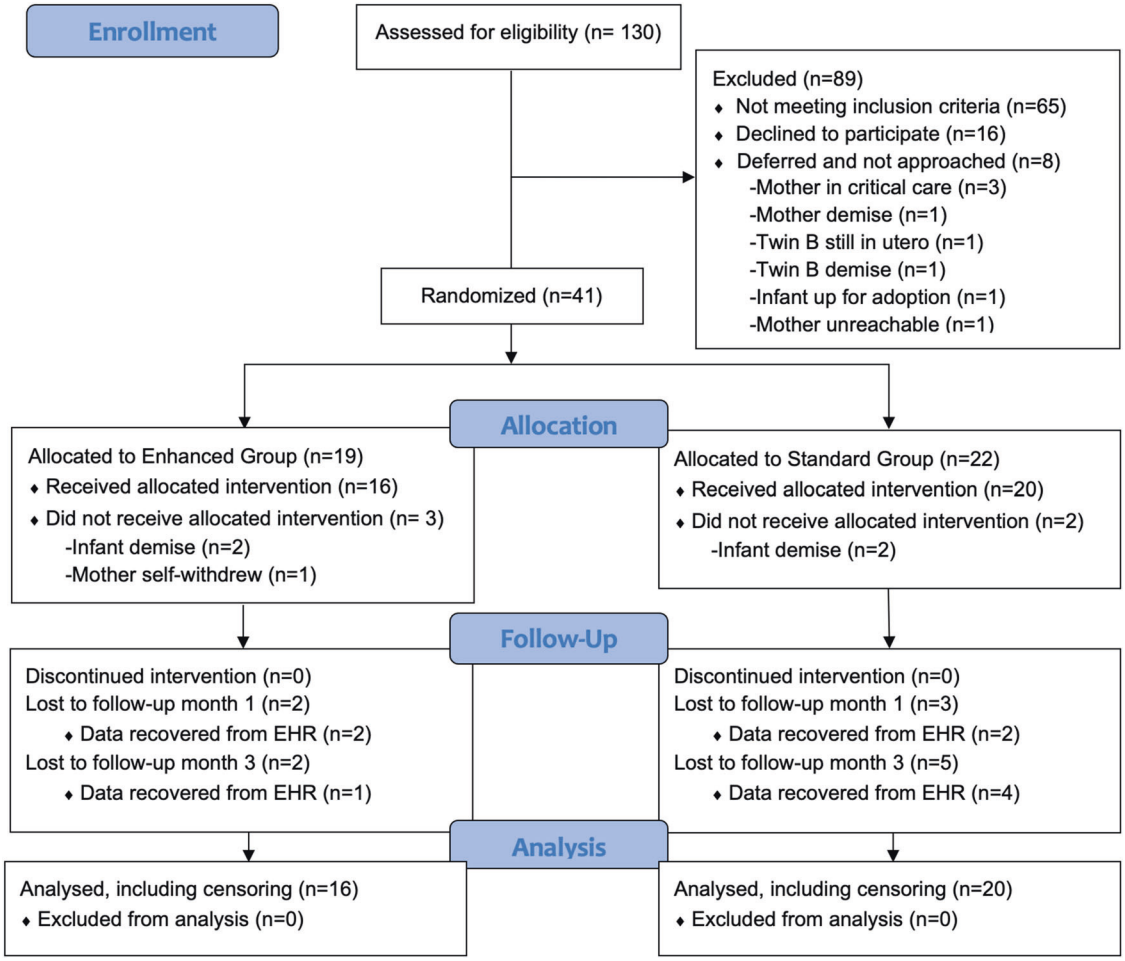

Fig. 1 CONSORT flow diagram. Diagram of enrollment, allocation, follow-up, and analysis.

communicating MOM sodium levels with personalized lactation support via text message to pump-dependent parents of critically ill infants prolongs lactation and MOM feeding.

The purpose of this randomized controlled pilot study is to examine the feasibility and potential benefits of using personalized text messages of MOM sodium levels on long-term lactation duration in parents of critically ill infants. Our first aim was to examine feasibility of conducting an mHealth study using biomarker-based text messages to prolong lactation among parents of critically ill infants. Our second aim was to assess for potential benefits of this intervention by assessing patterns in infant feeding and lactation at months 1 and 3 postpartum. We hypothesize that participants who are informed about their milk sodium levels via text message will have higher probabilities of lactating and consuming MOM at months 1 and 3 than participants in the control group.

METHODS

Sample and setting

The setting of this study was the obstetrical unit and 72-bed level IV NICU in a university-affiliated hospital in northcentral Florida, United States. The sample consisted of parent-infant dyads: birthing parents who delivered a critically ill infant and their infants who were admitted to the NICU. The serving community is largely rural, and the institution is a major referral base for northcentral Florida, the Florida Panhandle, and neighboring regions in Georgia. The facility is a Baby Friendly-designated hospital where standard care during postpartum includes consultations from Internationally Board Certified Lactation Consultants (IBCLC).

Patients 18 years of age or older who intended to provide MOM to their infant, owned a phone with text message capability, were English-speaking, and whose infants were admitted to the NICU were eligible to participate. Infants must not have been expected to bottle or breastfeed for at least the first two weeks after birth. Excluded were infants who were not expected to survive beyond one week and birthing parents who were COVID-positive, had breast surgery, had a known history of illicit drug use during pregnancy, were unable to deliver milk to the NICU at least 4 times per week, or were HIV positive.

As the aim of this pilot study was to determine feasibility and estimate distributions for our outcome measures rather than assess for intervention efficacy, statistical power was not relevant. Our sample size was instead based on recommendations for pilot studies to inform the protocol and power analysis in a larger RCT [15]. This study was approved by the University of Florida Institutional Review Board.

Enrollment and randomization

Within the first 48 h postpartum, potentially eligible parents were approached for recruitment by a member of the research team. Those consented and enrolled ($n = 41$) were randomized to one of two groups: (1) enhanced intervention ($n = 19$) or (2) standard care ($n = 22$) using random length permuted blocks of sizes 5, 6, or 8 to balance intervention group sizes (Fig. 1).

Intervention

Qualtrics, a HIPAA-compliant online platform for survey development and distribution, was used to send text messages to participants in both groups during the first two weeks postpartum. Participants in the enhanced group received messages on four days of each week–one in the morning and one in the afternoon. The morning messages contained general education on

expressing milk and the benefits of MOM. The afternoon messages contained their most recent sodium levels and were personalized by IBCLCs based upon their milk sodium levels and expression frequency, including to encourage maintenance if levels were <20 mM and provide recommendations if their level was ≥20 mM. An example messages is: *"On [date] your milk sodium went up to [value > 20 mM]. Pumping and emptying your breasts closer to 8x a day will help the sodium level to come back down."* The standard group received the same general educational information as the enhanced group in the morning to ensure that outcomes reflected the personalized biomarker component.

Participants in both groups received standard care to support lactation goals including education and printed materials from IBCLCs on how to use a breast pump and the importance of frequent milk expression to optimize milk volume. The enhanced intervention group also received education on how MOM sodium levels fluctuate daily depending on frequency of expressing MOM.

Sodium levels

It is standard practice for parents of infants at this NICU to have access to a Medela Symphony, hospital grade, double electric breast pump while visiting the unit, to be provided sterile milk storage supplies for both hospital and home use, and to routinely deliver their milk to the unit for storage and preparation. Participants in this study were also provided a Medela Symphony breast pump (McHenry, IL, USA) for home use until their infant was discharged. Participants were instructed to label each vial of milk with the date and exact time the milk was expressed, emphasizing that a new vial should be used at each pumping session rather than "batching" milk from multiple sessions as per standard NICU protocol. For this study, participants were requested to bring in all expressed milk (fresh or frozen) at least 4 times per week for sodium analysis [16].

The NICU at this hospital has a designated Milk Room operating 24 h a day where trained milk technicians weigh, document, and store all milk expressed by parents of infants, and prepare milk for each infant as prescribed. As this study's population of infants usually consumes <5 mL/day during the first few days of life, milk technicians verified that participants were producing at least 5 mL per day before extracting 0.4 mL daily samples in a 2 mL polypropylene syringe for sodium testing. All samples were stored in a designated and labeled storage container and refrigerated at <4 °C.

A trained research study team member blinded to intervention groups measured MOM sodium levels in the Milk Room using an ion-selective electrode analyzer (ISEA) (Horiba, Japan). This method of measurement has been tested and confirmed to be a valid and reliable measurement of sodium in MOM [17]. The ISEA was calibrated according to manufacturer's instructions prior to use each day. Research staff gently swirled each sample before testing to ensure a homogenous sample and injected the sample onto the electrode sensor. Samples were stabilized for 2–3 s to allow for reading. After documenting the given value, each milk sample was discarded.

Demographics. Medical history and demographic information on participants were extracted from the Electronic Health Records (EHR). Demographics extracted were age, health insurance, employment, race, and ethnicity. Importantly, race and ethnicity were analyzed as proxies for lived experiences of structural inequities as opposed to biological markers. Maternal and infant health factors extracted were parity, mode of delivery, birthweight, gestational age, multiple births, antenatal steroids, smoking history, and diabetes. Further, all participants were screened at enrollment on whether they had previous experience breastfeeding or expressing milk and their planned lactation duration.

Survey development. A survey was developed by the research team to collect information at months 1 and 3 regarding lactation duration and infant feeding (MOM and formula). Survey development began with a search of existing literature and instruments for longitudinal data collection of lactation among parents of critically ill infants. However, existing instruments were limited to healthy term and late preterm infants. The Centers for Disease Control and Prevention (CDC) Infant Feeding Practices Study (IFPS) II questionnaire [18] was therefore used to inform the survey. The IFPS II is a longitudinal survey developed by the CDC and Food and Drug Administration to better understand infant feeding practices in the United States. The survey has been extensively tested for validity, reliability, and responsiveness [18], but included items beyond the scope of this pilot study. The IFPS II survey was significantly shortened to capture only lactation duration and MOM feeding practices and indicators. Questions were adapted or added to reflect pump dependency of lactating NICU parents.

The survey was designed using branching questions that depended on participants' responses. Participants whose infants remained hospitalized in the NICU at the time of data collection did not receive questions regarding feeding type or lactation duration, as this data was collected from EHR. Questions were also added to the survey to assess social and environmental structures, including addressing those related to the COVID-19 pandemic. For instance, participants who self-reported to be employed full-time or part-time received further branching questions including a categorical item on whether the participant was working from home, and an item to assess for access to paid maternal leave. The full survey can be found in supplementary materials Figure S-1.

This version of the survey was independently evaluated by an expert panel of three IBCLCs, a neonatal Registered Nurse, and a Neonatal Nurse Practitioner. Three cycles of revisions were made following independent evaluation and group discussion. Reading level was adjusted to a 5th-grade level using the Flesch Kincaid Reading Grade Level formula [19]. A near-final version was developed on the Qualtrics platform and distributed to a convenience sample of three lactating women in the community for pilot testing. Suggestions and revisions were incorporated into the final survey (Figure S-1, supplementary materials).

Study outcomes

Follow up at months 1 and 3. Qualtrics was used for follow-up data collection by distributing 1 and 3-month follow-up surveys via text message-embedded links. This platform allows the distributor to view when each message has been received and opened, and when the survey for each contact has been completed. Participants had the option to skip questions they did not wish to answer. The survey could only be completed once from each IP address. Each participant's responsiveness was monitored, and text reminders were sent throughout the week to non-responders. If participants did not respond within the first week, a phone call was made to inquire about completing the survey via phone. Participants who indicated that they were no longer lactating were not contacted further. If participants responded that they had not completely stopped expressing milk or breastfeeding, a second contact was made at 3 months postpartum.

Lactation and MOM feeding. Among mothers of healthy infants, lactation is often measured dichotomously as any or exclusive breastfeeding. Lactating parents of infants in the NICU often do not breastfeed for many weeks, and infant feeding often varies depending on stability and care plan. Our outcome was therefore captured in three ways: (1) total days lactating, (2) exclusive MOM feeding at months 1 and 3, and (3) any MOM feeding at months 1 and 3. Lactation and infant feeding data on discharged infants whose parents did not respond to the follow-up survey were extracted from EHR when available. Among dyads whose infants remained in the NICU during follow-up, infant feeding and lactation data were also extracted from EHR. As it is standard practice at this facility for milk technicians and nurses to maintain detailed records on dates, frequencies, and volume of milk delivered and fed to the infant, EHR data was used if maternal report differed from documented health records.

Feasibility. Feasibility was evaluated by assessing enrollment rate out of those screened and recruited, acceptability, attrition at follow-up, and censoring. All participants were assessed at the end of the 2-week intervention on their acceptability of the intervention. Acceptability measures allowed us to assess whether censoring may have been related to the intervention. Acceptability was operationalized by a 6-question survey with dichotomous items asking participants if the text messages were convenient, a nuisance, easy to understand, time-consuming, provided important information, and whether the number of text messages were too many, not enough, or just right. Participants in the enhanced group received three further questions on whether the personalized messages were helpful (Likert scale), the sodium information was easy to understand (Likert scale), and the accompanying information on pumping frequency was helpful (dichotomous).

As very few studies have reported on lactation and infant feeding beyond hospitalization among infants admitted to the NICU, censoring rates were detailed. Censoring was evaluated for dyads who stopped lactating or receiving milk at an unknown time during the study (interval-censored), were still receiving milk or lactating at the end of the study period were (right censored), and were lost to follow-up–including unequal withdrawals between intervention groups.

Statistical analysis

Statistical analysis was performed using the survminer package in R version 4.1.0 (code available upon request). Descriptive statistics (median, interquartile range, and percentages) were evaluated as appropriate for participant demographics, social and environmental structures reported at follow-up, feasibility outcomes, and infant feeding and lactation outcomes. Confounders of lactation outcomes commonly cited in the literature were compared between intervention groups.

Probabilities and trends in infant feeding and lactation duration were assessed by Kaplan-Meier time-to-event analysis. This method assumes that outcome probabilities were the same for censored and uncensored participants as well as for those enrolled at different times, and that the probability of censoring was the same between intervention groups. All censored observations were included in the time-to-event analysis as time-to-censored data. For some infants, clinical circumstances arose where the infant was receiving only intravenous nutrition without any form of nutrition by mouth (NPO) on the date of follow-up. These participants were coded as missing data for univariate summary statistics. To address these circumstances in the time-to-event analysis, infant feeding immediately following NPO was used to code for any or exclusive MOM feeding. While statistical significance was not anticipated due to the pilot trial sample size, log-rank tests with an alpha level of .05 were used to compare differences in Kaplan-Meier time-to-event curves between intervention groups.

Table 1. Characteristics by group.

	Enhanced ($n = 16$) *n* (%) or median (IQR)	Standard ($n = 20$) *n* (%) or median (IQR)
Maternal age (years)	24.5 (5)	25 (7)
Race		
Black	7 (44%)	11 (55%)
White	8 (50%)	8 (40%)
Other	1 (6%)	1 (5%)
Hispanic/Latina	1 (6%)	0
Mode of delivery		
Cesarean	6 (38%)	14 (70%)
Vaginal	10 (63%)	6 (30%)
Primipara	4 (25%)	12 (60%)
Insurance		
Private	3 (19%)	7 (35%)
Medicaid	13 (81%)	13 (65%)
Employed	8 (50%)	12 (60%)
Paid Maternal Leave	1 (6%)	4 (20%)
Diabetes (Type I, II, gestational)	0	0
Smoking	2 (13%)	3 (15%)
Multiple births	2 (13%)	2 (10%)
Antenatal steroids	15 (94%)	17 (85%)
Birthweight (grams)	1470 (600)	1160 (595)
Gestational age (weeks)	31.35 (4)	29.65 (5)
Length of stay (days)	59	
Receiving formula at discharge		
Previous experience with milk expression		
Yes	8 (50%)	4 (20%)
No	8 (50 %)	16 (80%)
Previous experience breastfeeding		
Yes	5 (31%)	8 (40%)
No	11 (69%)	12 (60%)
Duration of planned lactation		
As long as possible	14 (88%)	16 (80%)
3–6 months	1 (6%)	2 (10%)
1–3 months	1 (6%)	2 (10%)

RESULTS

One hundred thirty dyads were screened for eligibility between July 2020 and February 2021, during which there was a three-month hiatus due to the COVID-19 pandemic. Sixty-five did not meet the criteria for participation, and another eight were deferred and not approached as the birth parent or infant died, a twin remained in utero, the parent was unreachable, or the infant was placed for adoption. Thus, 57 dyads were deemed eligible, of which 41 (32% of those screened) were enrolled. No patients were deemed ineligible due to not having a phone with text message capability. Before receiving the intervention, four infants died and one parent self-withdrew from the study (Fig. 1). This pilot study was comprised of 36 parent-infant dyads–20 and 16 in the standard and enhanced groups, respectively.

Descriptive analysis

Overall, more than half of infants were delivered via cesarean section ($n = 20$, 56%) with a mean gestational age of 30.6 weeks and a mean birthweight of 1386 g. Black race was overrepresented as compared to the community at 50% ($n = 18$) and the majority (72%) of study participants were on Medicaid. Characteristics cited in the literature to be associated with breastfeeding outcomes are compared between groups in Table 1.

Lactation and MOM feeding

Overall, most infants received MOM at month 1 (86%, $n = 30$), and two-thirds received exclusive MOM (66%, $n = 23$) (Table 2). Less than half (45%, $n = 15$) of infants received any MOM at month 3, including 27% who remained on an exclusive MOM diet. However, a greater proportion of infants in the enhanced group were receiving any MOM and exclusive MOM, with differences between groups widening from month 1 to month 3 (Fig. 2). A larger difference was evident for any MOM feeding than for exclusive

Table 2. Lactation and MOM feeding by group.

	Enhanced ($n = 16$) *n* (%)	Standard ($n = 20$) *n* (%)	Total ($n = 36$) *N* (%)
Exclusive MOM Intake			
Month 1	11 (69%)	12 (63%); $n = 19$	23 (66%); $n = 35$
Month 3	5 (31%)	4 (24%); $n = 17$	9 (27%); $n = 33$
Any MOM Intake			
Month 1	15 (94%)	15 (79%); $n = 19$	30 (86%); $n = 35$
Month 3	9 (60%); $n = 15$	6 (33%); $n = 18$	15 (45%); $n = 33$
Breastfeeding or Expressing Milk			
Month 1	13 (87%); $n = 15$	17 (89%); $n = 19$	30 (88%); $n = 34$
Month 3	8 (50%)	4 (21%); $n = 19$	12 (34%); $n = 35$

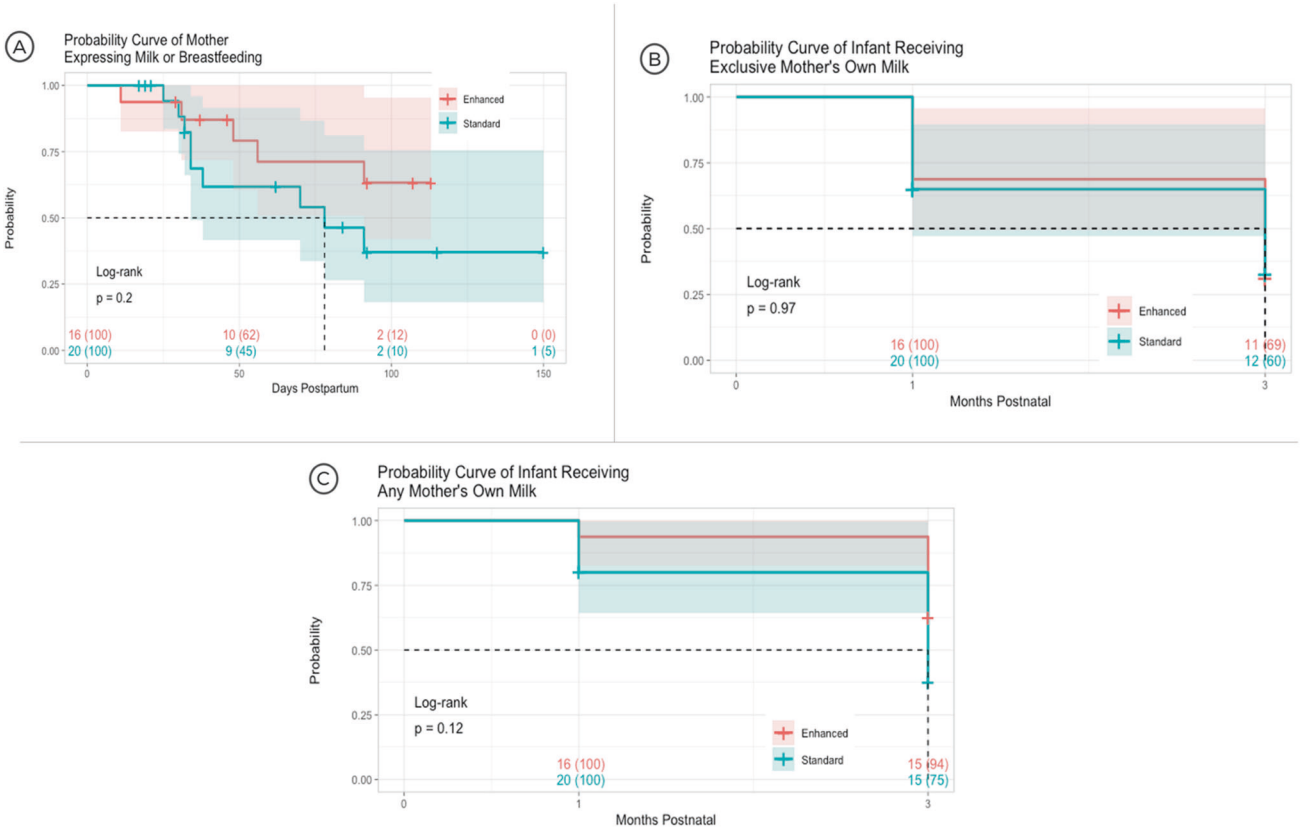

Fig. 2 Kaplan-Meier and log-rank analyses of expressing milk or breastfeeding, receiving exclusive MOM, and receiving any MOM. Numbers in red and blue represent number and percentage of participants remaining at a given time.

MOM feeding. While the average duration in each group was not measurable due to right censoring, 21% of the standard group was still breastfeeding and expressing milk at month 3 compared to 50% of the enhanced group.

Time-to-event analyses using Kaplan-Meier models were used to visualize trends in MOM feeding and lactation duration within each group. Time (days or months postnatal) at which infants were no longer receiving exclusive MOM, receiving any MOM, and at which participants were no longer lactating are "time-to-event" outcomes captured in Fig. 2. The Kaplan-Meier model for duration breastfeeding and expressing milk (illustrated in panel A, Fig. 2) depicts a narrow difference in probabilities for the standard and enhanced group at 32 days postnatal (82 vs. 87%) that widens by 92 days (37 vs. 63%). Similarly, the probability of an infant in the standard group receiving any MOM from age one month through three months decreased more rapidly than in the enhanced group (80 to 41% vs. 94 to 63%; panel C, Fig. 2). However, this trend was not found for exclusive MOM feeding (panel B). Log-rank tests were used to compare time-to-event distributions between groups for the three outcomes. As anticipated for a pilot study underpowered to avoid a type two error, log-rank tests revealed no statistically significant differences (Fig. 2).

Social and environmental factors

A post hoc analysis of social and environmental factors revealed that only 31% of employed participants had access to paid maternal leave and 69% felt they did not have all the legally required accommodations for them to express milk at their workplace. The majority (89%) of employed participants were not working from home during the pandemic and 14% stated they changed their infant feeding decision from formula to MOM because of COVID-19. Additional social and environmental factors are outlined in Table 3.

Feasibility

Our relatively high enrollment rate suggests interest in this study within our target population. After accounting for withdrawals, this study estimates a rate of 28% from screening to participation for a large RCT. In general, participants were more difficult to reach at month 3 than month 1, and this is reflected in the nearly doubled attrition rate at month 3 (14 vs. 26%). Notably, attrition in the standard group was twice as high as the enhanced group (11 vs. 22%), although infant feeding data for all but three records were recovered from EHR (Fig. 1). Overall, censoring was determined to be unrelated to the intervention due to good acceptability in both groups (Table S-5).

DISCUSSION

To the authors' knowledge, this is the first study assessing an intervention in a NICU providing lactating parents a personalized biomarker with tailored corresponding education to prolong lactation and MOM feeding. Overall, the enhanced intervention group outperformed the standard intervention group at both months 1 and 3 in probability of the participant breastfeeding or expressing MOM and in probability of the infant receiving any MOM.

There are few published studies investigating MOM feeding beyond discharge from the NICU with which to directly compare our results. One recent study of 49 mothers of preterm infants in Western Australia found that those who were supplementing with formula at discharge were more likely to stop feeding MOM before 12 weeks corrected gestational age [20]. However, no demographic description was provided, and the contextual challenges for lactation may vary within and outside of the U.S. Our exclusive MOM feeding rate in this study was 24–31% at month 3, compared to their rate of 47% at month 4 and the U.S.

Table 3. Resource and environmental factors.

Variable	*n* (%)
Pump Used	
Electric	28 (78%)
Manual	2 (6%)
Combination	1 (3%)
COVID-19 changed feeding decision	
Yes, changed to formula.	0
Yes, changed to breast milk.	5 (14%)
No	26 (72%)
Employed	
Yes	20 (56%)
No	16 (44%)
Working from home, month 1 [employed] ($n = 19$)	
Most days	2 (11%)
No	17 (89%)
Maternal Leave [employed full time] ($n = 16$)	
Yes, paid	5 (31%)
Yes, unpaid	8 (50%)
No	1 (6%)
Unsure	2 (13%)
Workplace Support [employed; multiple select] ($n = 16$)	
I feel supported to take 30 min to pump, apart from my meal break.	9 (56%)
I have a clean, private place to pump milk.	6 (38%)
I have a refrigerated place to store my breast milk.	7 (44%)
All the above	5 (31%)
None of the above	4 (25%)
Supportive Persons [multiple select]	
The baby's father	26 (72%)
The baby's grandmother	24 (67%)
Another family member	20 (56%)
A healthcare provider	19 (53%)
Hospital staff	27 (75%)
Employer or supervisor [employed]	8 (40%)
Reasons for Decision to Stop Breastfeeding and Pumping [multiple select] ($n = 10$)	
I wasn't making enough milk; milk 'dried up'.	8 (80%)
My nipples were sore, cracked, or bleeding.	1 (10%)
I didn't have enough time.	2 (20%)
Breastfeeding was too tiring.	2 (20%)
Breastfeeding was too inconvenient.	1 (10%)
Breast milk alone did not satisfy my baby.	3 (30%)
My baby wasn't gaining enough weight.	1 (10%)
My baby had trouble sucking or latching.	1 (10%)
I was sick or had to take medicine.	1 (10%)
My baby was old enough that the different between breast milk and formula did not matter.	1 (10%)
Other: "I didn't have a pump and couldn't keep up with supply by her latching only"	1 (10%)

rate of 25.6% at month 6 [1]. These discrepancies emphasize the urgent need for strategies to support parents of critically ill infants to prolong lactation. It is also possible that this intervention supported participants in the enhanced group to produce more milk by month 3 for partial, but not exclusive, MOM feeding. However, the finding that 57% of infants in the enhanced group were receiving any MOM at month 3 is encouraging, as the national average for VLBW infants at discharge–with an average length of stay of just over 2 months–is 50% [2].

This study is feasible to replicate in a large RCT with minor alterations and considerations. The use of text messages for content delivery was largely accepted within each group, and the intervention protocol was streamlined by standard practice at this institution of milk technicians logging all milk delivered to the NICU. However, while 70% of contacted participants responded at month 3, one-third of the sample was lost to follow-up at either month 1 or month 3. As attrition in the standard group was twice as high as the enhanced group, it is possible that the enhanced intervention promoted continued participation. Few breastfeeding and lactation text message interventions have been published among our population of interest, although our study's attrition rate is consistent with one text message intervention in the U.S. among mostly white and college-educated mothers of healthy infants [13]. This study included intention to exclusively breastfeed for at least 2 months as an inclusion criterion and reported a 22% attrition at postpartum month 2 [13]. Including incentives in a large RCT would likely strengthen follow-up rates, as one intervention among WIC recipients reported a 92.4% follow-up rate at 2 weeks postpartum with a monetary completion incentive [14].

Similar to many studies, [7, 8, 20, 21] the reason for weaning to formula among our sample was largely attributed to low milk supply. This sample may also have experienced greater contextual challenges to meeting their lactation goals as prevalence of MOM feeding at discharge among pump-dependent parents of critically ill infants is known to be lowest among Medicaid recipients, infants residing in the South, and non-Hispanic Black parents [2]. Adjusting for confounders in a powered RCT may inform complementary strategies by allowing for estimations of relative risk of abridged lactation based on factors such as workplace environment and support. Interventions that target barriers at multiple levels of influence such as community and policy are known to be most effective [22], but few studies examine multi-level barriers to breastfeeding and expressing milk among parents of infants in the NICU. This urgent knowledge gap includes contextual factors contributing to structural racism and enabling the widely cited breastfeeding disparities among Black parents. [21, 23] Further, federal law in the United States mandates that all employers covered under the Fair Labor Standards Act (FLSA) provide workplace accommodations for lactating parents for at least one year postpartum. The finding that less than one-third of employed parents had access to paid leave and just as few felt supported to take a break for expressing milk, had access to a clean, private location to express milk, and had access to a refrigerator at their workplace warrants investigation into how social, political, and environmental structures may enable disadvantages for parents to meet their lactation goals and provide their infants the benefits of MOM.

This study is limited by censoring of participants during and at the end of the study. Censoring due to loss to follow-up reduces the quantity and quality of data for analysis. Although much data on infant feeding from participants lost to follow-up was recovered from outpatient EHRs, data was not recovered from participants who received care at a different facility or who did not attend scheduled appointments. Similarly, more detailed data was available on participants whose infants had frequent visits to the emergency room. It is possible that these circumstances or their underlying causes are related to lactation and infant feeding outcomes. Further, it is possible that the parents who had the least availability or resources to express milk were less likely to participate or follow through in the study.

It is possible that the outcomes in this study are skewed by confounders that were uncontrolled for, such as cesarean delivery,

primiparity, and inexperience with milk expression–known risk factors for short lactation duration which were more heavily represented in the standard group. However, participants in the enhanced group were more likely to be enrolled in Medicaid and less likely to have access to paid leave, potentially minimizing differences in risk between groups [24]. A larger RCT may test for the effect of these variables on infant feeding and lactation time-to-event curves to determine an estimate of the difference between groups.

Future research includes expanding this study to an appropriately powered RCT to evaluate for intervention efficacy in prolonging lactation and MOM feeding. An appropriately powered study is needed to control for covariates, specifically common confounders such as infant acuity, education, mode of delivery, employment, maternal leave, and Medicaid or private insurance [21, 23]. An analysis of clinical significance is warranted, as meaningful clinical outcomes may not be captured in statistical significance, particularly for this vulnerable population where MOM is known to have dose-response benefits [25]. Further, infants previously hospitalized in the NICU have been minimally studied post-discharge, and future research on clinical outcomes such as ER visits, hospitalizations, and illness may identify minimal clinically important differences with which to measure lactation intervention success.

CONCLUSION

This intervention may be an opportunity to prolong lactation and MOM feeding among pump-dependent parents of critically ill infants. While imprecise estimates warrant caution with interpreting model results, a trend can be observed favoring the enhanced intervention group. An appropriately powered RCT to assess efficacy of a biomarker-based text messaging intervention to prolong lactation and MOM feeding among parents and infants in the NICU is feasible and warranted.

DATA AVAILABILITY

Data is available upon request.

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AUTHOR CONTRIBUTIONS

MM was responsible for conceptualizing the study, designing the methodology, collecting and analyzing data, interpreting results, and preparing the original manuscript. LAP was MM's primary mentor and involved in conceptualization, design, interpretation of results, and editing the manuscript. DSV contributed to designing the protocol and editing the manuscript. NC and SS provided clinical expertise and feedback on the manuscript. AHH supervised the analytical plan, programming on R, and interpretation of results, and edited the manuscript.

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COMPETING INTERESTS

The authors declare no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by the University of Florida Institutional Review Board (201902053) and performed in accordance with the Declaration of Helsinki. All participants were enrolled following informed consent.

ADDITIONAL INFORMATION

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