

FINAL COMPREHENSIVE REPORT

R40 MC 00252-03

Enhancing Breastfeeding Duration in Premature Infants

Project period: 09/01/2001 to 08/31/04

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A. Executive Summary

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Enhancing Breastfeeding Duration in Premature Infants

Statement of the Problem

The health benefits associated with human milk are particularly critical in premature infants, but breastfeeding rates are below average in this vulnerable population, and significant obstacles exist for women of low socioeconomic status when breastfeeding premature infants. Peer counseling programs are relatively inexpensive, easy to replicate, and have been shown to increase breastfeeding rates among mothers of term infants who do not traditionally breastfeed.

Research Objectives

This study tested the hypothesis that breastfeeding peer counselors in the Neonatal Intensive Care Unit (NICU) would increase breastfeeding duration among mothers of premature infants. Specifically, our objectives were to test whether peer counselors:

1. Increased breastfeeding duration rates among premature infants in the Neonatal Intensive Care Unit (NICU)
2. Increased overall amounts of breast milk received
3. Increased rates of exclusive breastfeeding.

Study Design and Methods

This was a randomized controlled trial conducted between February 2002 and August 2004 in the NICU at Boston Medical Center (BMC). BMC serves a low income, primarily minority population, and is the only Baby-Friendly hospital in Massachusetts. Baby-Friendly status is awarded by the WHO and UNICEF to hospitals that meet certain standards of breastfeeding promotion and support. The study was approved by the Boston University Medical Center Institutional Review Board.

The intervention group received breastfeeding support from a trained peer counselor within 72 hours of birth, and thereafter weekly for six weeks; the control group received standard of care treatment. Feeding status at 2, 4, 8, and 12 weeks postpartum was the main outcome measure, and was assessed by a research assistant (RA) unaware of the mother's group assignment. Data were obtained from the medical record while the infant was hospitalized, and by maternal recall by telephone after discharge.

Findings

Groups were equivalent on all measured socio-demographic factors, including birthweight, gestational age, length of hospital stay and maternal ethnicity, educational status, age, parity, and breastfeeding history. At each outcome point, intervention group (IG) mothers were significantly more likely to give any amount of breast milk (e.g. at 4

weeks IG 98% vs control group (CG) 79% ($p=0.005$); at 8 weeks IG 83% vs CG 57% ($p=0.007$); at 12 weeks IG 73% vs CG 49% ($p = 0.026$)). Proportional hazards survival analysis reflecting all observation points indicated a significant positive overall relationship between IG and any breast milk ($p<0.001$).

Separate survival models showed no significant relationship between IG and exclusive breastfeeding, but did show a significant positive relationship between IG and mother feeding mostly (more than 50%) breast milk ($p= 0.002$).

Recommendations

Breastfeeding peer counseling is an effective and inexpensive method of increasing the amount of breast milk received by premature infants of low income and African American mothers in the NICU.

These results add to the literature already describing the effectiveness of peer counseling programs at increasing breastfeeding rates.^{12,14,15,17,18,25} Not all peer programs have equal success, and comparisons are difficult because peer counseling programs vary tremendously in their methodology. We believe that the effectiveness of this particular program was due to a design which included the elements shown to be most successful in previously published peer counseling studies. Face to face contact, and a specific checklist of goals for the peer at the critical first meeting, as well as close supervision of, and support for, the peers were critical. Peers had immediate daily access to the lactation consultant working on the unit, and to the project managers; at the same time the lactation consultant and the project managers' in-person presence helped to ensure peer consistency, accuracy of knowledge, and reliability. In light of current investment at the national level in breastfeeding peer counseling as part of the WIC program, we would strongly advocate that peer programs be established with consistent frameworks, and adhere to models which have been shown to demonstrate success.

List of Products

Please note: the final paper on this project has been submitted for publication. A draft of that paper is attached.

Merewood, A; Philipp, BL. *Peer counselors for breastfeeding women in the hospital setting: Trials, training, tributes, and tribulations*. J Hum Lact, 2003; 19(1):72-76

Merewood A, Philipp BL, Chamberlain LB, Malone K, Cook JT, Bauchner H. *Using peer support to improve breastfeeding rates among premature infants: An RCT*. Platform presentation accepted for the Pediatric Academic Societies' annual meeting, Washington, DC, May 14-17 2005.

Merewood, A. *Effect of NICU-based peer counselors on breastfeeding duration among premature infants, Implications for Practice*. Conference session, International Lactation Consultant Association 19th Annual Conference. Chicago, IL. July 2005

Merewood A, Philipp BL, Cook J, Chamberlain LB, Bauchner, HC. *Effect of peer counselors on breastfeeding duration among premature infants in a US Newborn Intensive Care Unit*. Poster presentation, 132nd annual meeting of the American Public Health Association, Nov 6-10, 2004, Washington, DC.

Philipp BL, Merewood A, Malone KL, Chamberlain LB, Cook JT, Bauchner H. *Effect of NICU-based Peer Counselors on Breastfeeding Duration Among Premature Infants*. Platform presentation 9th International Meeting of the Academy of Breastfeeding Medicine. Orlando, FL, October 2004

Philipp BL, Merewood A, Cook J, Chamberlain LB, Bauchner H. *Effect of NICU-based peer counselors on breastfeeding duration among premature infants*. Poster symposium, Pediatric Academic Societies' Annual Meeting. San Francisco, CA. May 1-4, 2004

B. Comprehensive Report

1. Introduction

A. Nature of the Research Problem

National data for breastfeeding rates among premature infants are not available, but regional data suggest these rates are low. In Massachusetts, breastfeeding initiation rates among term infants in 2002 were 76%, while initiation rates among premature infants were 68%.¹ Moreover, infants with the lowest gestational ages had the lowest breastfeeding rates (56% initiation among infants born between 24 and 27 weeks, compared to 69% among infants born at 36 weeks gestational age).¹ Nationally, breastfeeding rates are lowest,^{2,3} and rates of prematurity highest, among African Americans, suggesting that breastfeeding rates in African-American premature infants will be below average.

Given that risks associated with formula feeding for premature infants are particularly high, and have been associated with adverse health outcomes such as increased necrotizing enterocolitis,⁴ delayed brain stem maturation⁵, decreased scoring on cognitive and developmental tests,⁶⁻⁹ and decreased visual development,^{10 11} human milk feeding of prematures is highly desirable. Strategies to increase breastfeeding rates in the NICU are urgently needed, especially among African Americans and women of low socioeconomic status, who experience additional and significant obstacles around breastfeeding premature infants. Peer counseling programs are relatively inexpensive, easy to replicate, and have been shown to increase breastfeeding rates among mothers of term infants who do not traditionally breastfeed.¹²⁻¹⁸

B. Purpose, Scope, and Methods of the Investigation

The objective of this study was to determine whether breastfeeding peer counselors impacted breastfeeding duration rates among premature infants in the Neonatal Intensive Care Unit (NICU). Secondary objectives were to determine whether peers increased overall amounts of breast milk received, and whether peers increased rates of exclusive breastfeeding. The study was approved by the Boston University Medical Center Institutional Review Board.

This was a randomized controlled trial conducted between February 2002 and August 2004. The trial was conducted in Boston Medical Center's, Level III, Neonatal Intensive Care Unit. Boston Medical Center (BMC) is an inner-city teaching hospital with 2000 births per year, and the only Baby-Friendly hospital in Massachusetts. Baby-Friendly status is granted by the World Health Organization and UNICEF to institutions that meet specific standards for breastfeeding promotion and support.

101 mother-infant pairs were enrolled, 48 in the intervention group and 53 in the control group. The groups were equivalent on all measured sociodemographic factors, including birthweight, gestational age, length of hospital stay and maternal ethnicity, educational

status, age, parity, and breastfeeding history. The average gestational age of the infants was 32 weeks (range 26.3 – 37) with a mean birthweight of 1875 grams (median 1845; range 682 – 3005g).

The intervention group received breastfeeding support from a trained peer counselor within 72 hours of birth, and thereafter weekly for six weeks; the control group received standard of care treatment. Feeding status at 2, 4, 8, and 12 weeks postpartum was the main outcome measure, and was assessed by a research assistant (RA) unaware of the mother's group assignment. Data were obtained from the medical record while the infant was hospitalized, and by maternal recall by telephone after discharge.

C. Nature of the Findings

At each observation point, IG mothers were significantly more likely to give any amount of breastmilk (e.g. at 4 weeks IG 98% vs CG 79%, $p=0.005$; at 8 weeks IG 83% vs CG 57%, $p=0.007$; at 12 weeks IG 73% vs CG 49% ($p=0.026$)). A proportional hazards survival model reflecting all observation points indicated a significant positive relationship between IG and any breastmilk ($p<0.001$). Separate survival models showed no significant relationship between IG and exclusive breastfeeding, but did show a significant positive relationship between IG and mother feeding mostly (more than 50%) breast milk ($p=0.002$).

II Review of the Literature

Given that the risks of formula feeding for premature infants are particularly high, and have been associated with adverse health outcomes such as increased necrotizing enterocolitis,¹ delayed brain stem maturation,² decreased scoring on cognitive and developmental tests,³⁻⁶ and decreased visual development,^{7,8} human milk feeding of prematures is highly desirable. However, breastfeeding rates are below average in this vulnerable population, and significant obstacles exist for women of low socioeconomic status attempting to breastfeed premature infants. In Massachusetts, breastfeeding initiation rates among term infants in 2002 were 76%, while initiation rates among premature infants were 68%. Moreover, infants with the lowest gestational ages also had the lowest breastfeeding rates (56% initiation among infants born between 24 and 27 weeks, compared to 69% among infants born at 36 weeks gestational age).⁹ Nationally, breastfeeding rates are lowest,^{10,11} and rates of prematurity are highest, among African American mothers, which also suggests that breastfeeding rates nationally in premature infants will be below average.

Methods to increase breastfeeding rates among premature infants are urgently needed. Peer counseling programs are relatively inexpensive, easy to replicate, and have been shown to increase breastfeeding duration among term infants in low income populations, in a range of settings.¹²⁻¹⁸ According to the literature, in-depth, in-person peer contacts are most effective at increasing breastfeeding rates among low income mothers of term infants.^{12,14} As far as we are aware, no previous studies have used peer counselors in the

NICU, thus we based our methodology on successful peer counseling programs for mothers of term infants.

III Study Design and Methods

A. Study Design

This was a randomized controlled trial with enrollment occurring between February 2002 and August 2004. The last infant was followed until December 2004. Mother/baby pairs were followed for 12 weeks after the birth of the infant. The purpose of this study was to determine whether peer counselors impacted breastfeeding duration rates for mothers of premature infants in the NICU. Secondary objectives were to determine whether peers increased overall amounts of breast milk received, and whether peers increased rates of exclusive breastfeeding.

B. Population Studied

The study was conducted in the Boston Medical Center (BMC), 15-bed, Level III NICU. BMC is an inner-city teaching hospital with 2000 births per year, and the only Baby-Friendly hospital in Massachusetts. Baby-Friendly status is granted by the World Health Organization and UNICEF to institutions that meet specific standards for breastfeeding promotion and support. Approximately 350 infants per year are admitted to the NICU, and approximately 65% of these infants are African American.

C. Sample Selection

Within 72 hours of giving birth, eligible women were approached on the postpartum unit and asked if they would like to participate in a study about breastfeeding in the NICU. Eligible women spoke English, French, or Spanish; were eligible to breastfeed,¹⁹ chose to do so, and had an otherwise healthy premature infant between 26 and 37 weeks gestational age in the BMC NICU. Infants were average for gestational age singletons. Infants younger than 26 weeks were excluded because the elevated rate of mortality and serious complications in this gestational age group may have affected feeding data regardless of the mother's wishes or intentions.

Consenting women were randomly assigned to receive peer support (IG) or standard of care (CG). Peers were women with breastfeeding experience drawn from the BMC community. Peers were trained at a five-day breastfeeding course, educated on the unit in NICU procedures and breastfeeding techniques, and attended regular, mandatory BMC breastfeeding training days.²⁰

The IG received one peer counselor visit within 72 hours of birth, and thereafter was in contact with the peer counselor on a weekly basis for six weeks. The program guidelines required peers to meet in person with the mother, whenever possible, while the infant remained in the NICU. After the infant was discharged, contact was by telephone. Infant feeding status was assessed by a research assistant (RA) unaware of the mother's group assignment. Data were obtained from the medical record while the infant was

hospitalized, and by maternal recall by telephone after discharge. The bedside feeding chart was examined for the 48 hour period immediately preceding the date of the infant's 2, 4, 8, and 12 week birthday. If the infant was not taking food at that time, the RA retraced the feeding information until obtaining a 48 hour period of feeds. In the case of phone calls, the mother was called on the 2, 4, 8, and 12 week birthday and asked to report the number of breast and/or formula feeds the infant had received in the previous 48 hours. The feeds were totaled and infants were placed into one of four categories: exclusively breastfed, mostly breastfed, mostly formula fed, and exclusively formula fed.

Statistical Techniques Employed

Analyses followed two separate approaches based on two different temporal views of the subjects and their breastfeeding behavior. First we examined subjects' breastfeeding behavior at each of the four observation periods (2,4,8 and 12 weeks) separately to determine whether there were significant differences between IG and CG mothers' breastfeeding at each observation point. Chi-squared tests of independence were used to test the hypothesis of no difference between the proportions of IG and CG mothers' providing any breastmilk, mostly breastmilk (more than 50%), and exclusively breastmilk at each observation period. The sample was also stratified by major race/ethnicity categories and tests of differences between IG and CG mothers' breastfeeding performed for each race/ethnicity subgroup separately.

In a second set of analyses all observations were pooled across observation periods and survival time or "time to event" analyses performed using a Cox Proportional Hazard model to test overall differences in duration of breastfeeding (time to termination of breastfeeding) over the four observation periods. Kaplan-Meier Survival Curves were also plotted to graphically depict differences in time to termination of breastfeeding for mothers in the two groups over the four observation periods.

IV. Presentation of Findings

A total of 101 mother-infant pairs were enrolled; 48 were assigned to the Intervention Group (IG) and 53 to the (CG). Groups were equivalent on all measured sociodemographic factors, including birthweight (IG = 1914 gms; CG = 1840 gms); gestational age (26-32 weeks IG = 29%; CG = 30%); gender; length of hospital stay and maternal ethnicity, educational status, age, parity, and breastfeeding history.

At initial contact with the IG, peer counselors discussed pumping techniques in 100% of cases; helped the mother to pump in 72.1% of cases; accompanied the mother to the NICU in 72.1 % of cases, and helped the mother to breastfeed, provide kangaroo care, or both in 30.23% of cases.

At each data collection point, women with peer counselors were significantly more likely to receive any amount of breast milk than control group women who received standard of care. At each outcome point after the two week birthday, IG babies were also significantly more likely to receive "mostly (more than 50%) breast milk" than CG babies. Measurement at each outcome point for exclusive breastfeeding showed a trend

towards higher exclusivity in the IG, but the results did not reach statistical significance. This lack of significance was probably due in part to small sub-sample sizes.

A Cox Proportional Hazards model reflecting data pooled across all time points demonstrated a significant positive overall relationship between IG and any breast milk ($p < 0.001$), indicated by significantly longer times to termination for breastfeeding among IG mothers. Separate survival models showed no significant relationship between IG and exclusive breastfeeding, but did show a significant positive relationship between IG and mother feeding mostly (more than 50%) breast milk ($p = 0.002$).

V. Discussion of Findings

A. Conclusions to be Drawn from Findings

In this randomized controlled trial, peer counselors increased breastfeeding duration in the NICU, and increased the amount of breast milk consumed by the infant. Although trends were observed, peers were not shown to increase significantly the rate of exclusive breastfeeding.

Because the benefits of breastfeeding are, in most studies, shown to be dose dependent, increasing the amount of breast milk consumed by prematures, either by extending duration, or increasing the number of breast versus formula feeds, is an important contribution to their short and long term health. We conclude therefore that our intervention was effective, and that its effectiveness is likely to have contributed to the health of our premature infant population.

B. Explanation of Limitations or Possible Distortion of Findings

This study has a number of limitations. Although we focused on premature infants, the majority of infant subjects were between 32 and 37 weeks gestational age. Resulting subsample sizes were not large enough to provide sufficient statistical power to determine if the intervention's overall impacts were similar in the younger gestational age group. Second, the study was conducted in a Baby-Friendly Hospital. Whether the environment of a Baby-Friendly Hospital contributed to the success of the peer counselor intervention cannot be determined conclusively. It is notable, however, that significant intervention effects were observed even though mothers in both study groups received Baby-Friendly standard of care. Third, sample-size limitations contributed to our inability to demonstrate a significant difference in the amount of exclusive breastfeeding, although our data showed a trend towards a positive impact on exclusivity. With a larger sample size, these data may have reached significance.

Another limitation of the study was loss to follow up: 11 women in the peer group, and seven in the control group, were lost by the end of the study, for a total loss of 18/101 (18%) of the study population by the 12 week data collection point. The reason for loss was most commonly that the telephone was disconnected, or that the women were simply unreachable by phone, despite the fact that we collected main home telephone numbers, cell phone numbers, and other contact information for the pediatrician. Given the low

income population, with high numbers of immigrants and high migration, this was to be expected. The Cox Proportional Hazard model takes loss to follow-up (censoring) into account in estimating the survival functions and significance of differences across the two groups. Loss to follow-up was unlikely to affect either group more than the other. Thus, except for reducing sub-sample sizes and statistical power, we do not believe this factor impacted our results.

C. Comparison with Findings of Other Studies

This is the first study we are aware of to report the effect of peer counselors on duration of breastfeeding among premature infants.

However, these results add to the literature already describing the effectiveness of peer counseling programs at increasing breastfeeding rates.^{12,14,15,17,18,25} Not all peer programs have equal success, and comparisons are difficult because peer counseling programs vary tremendously in their methodology. We believe that the effectiveness of this particular program was due to a careful intervention design which included elements shown to be most successful in previously published peer counseling studies. Face to face contact, a specific checklist of goals for the peer at the critical first meeting, as well as close supervision of – and support for – the peers were all important. Peers had immediate daily access to the lactation consultant working on the unit, and to the project managers. At the same time the lactation consultant and project managers' in-person presence helped to ensure peer consistency, accuracy of knowledge, and reliability.

D. Possible Application of Findings to Actual MCH Health Care/Delivery Situations

Peer counseling programs are inexpensive to operate, and should be considered as options in the hospital setting as well as for women at home. In light of current investments at the national level in breastfeeding peer counseling as part of the WIC program, we would strongly advocate that peer programs be established with clear guidelines, and thoroughly evaluated, with an eventual goal of consistency between programs. Presently, reliable consistency is lacking.

E. Policy Implications

Peer counselors increased breastfeeding duration among premature infants in an inner-city NICU. Peer counseling programs would help to increase breastfeeding in this vulnerable population, and would offer many benefits to the child and the mother. Attention should be paid to the emotional and support needs of women who are attempting to provide breast milk for their hospitalized premature infants.

F. Suggestions for Further Research

Larger studies looking at the effects of peer counseling on different racial and ethnic groups, and looking more closely at the issue of exclusivity, are warranted. Our results

suggest that this is a cost effective way of improving the short and long term health of fragile infants in the NICU, and that further investigation would be valuable.

VI List of Products

Merewood, A; Philipp, BL. *Peer counselors for breastfeeding women in the hospital setting: Trials, training, tributes, and tribulations.* J Hum Lact, 2003; 19(1):72-76

Merewood A, Philipp BL, Chamberlain LB, Malone K, Cook JT, Bauchner H. *Using peer support to improve breastfeeding rates among premature infants: An RCT.* Platform presentation accepted for the Pediatric Academic Societies' annual meeting, Washington, DC, May 14-17 2005.

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Draft of Paper to be submitted for publication (not yet complete)

Peer Counselors Increase Breastfeeding rates in the Neonatal Intensive Care Unit:

Results of a Randomized Controlled Trial

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We would like to thank our peer counselors, Luz Lopez, Dawn Kennedy, and Karen Gunter for their work on this project.

Abstract

Context: The health benefits associated with human milk are particularly critical in premature infants, but breastfeeding rates are below average in this vulnerable population, and significant obstacles exist for women of low socioeconomic status when breastfeeding premature infants. Peer counseling programs are relatively inexpensive, easy to replicate, and have been shown to increase breastfeeding rates among mothers of term infants who do not traditionally breastfeed.

Objective: The objective of this study was to determine whether breastfeeding peer counselors impacted breastfeeding duration rates among premature infants in the Neonatal Intensive Care Unit.

Design: The study was a randomized controlled trial conducted between February 2002 and August 2004. Mother/baby pairs were followed for 12 weeks after the birth of the infant.

Setting: The study was conducted in the Boston Medical Center, Level III, Neonatal Intensive Care Unit. Boston Medical Center is an inner-city teaching hospital with 2000 births per year, and the only Baby-Friendly hospital in Massachusetts. Baby-Friendly status is granted by the World Health Organization and UNICEF to institutions that meet specific standards for breastfeeding promotion and support.

Patients: Boston Medical Center has 2000 births per year. Approximately 350 infants per year are admitted to the NICU, and approximately 65% of infants in intensive care are African American. Eligible women spoke English, Spanish, or French, chose and were medically eligible to breastfeed, and had otherwise healthy premature infants aged between 26 and 37 weeks gestational age admitted to the NICU. Infants were average for

gestational age singletons. Overall, 577 women were assessed for eligibility; 452 were excluded for not meeting inclusion criteria; 14 refused to participate, and three were excluded for other reasons (such as, missed by research assistant). Thus, 108 pairs were enrolled and randomized, seven pairs were excluded after randomization (see Figure 1) for a total of 101 mother-infant pairs followed. Of these, 48 were assigned to the intervention group and 53 to the control group.

Intervention: The intervention group received breastfeeding support from a trained peer counselor within 72 hours of birth, and thereafter weekly for six weeks; the control group received standard of care treatment.

Main outcome measures: Feeding status at 2, 4, 8, and 12 weeks postpartum was the main outcome measure, and was assessed by a research assistant unaware of the mother's group assignment. Data were obtained from the medical record while the infant was hospitalized, and by maternal recall by telephone after discharge.

Results: Groups were equivalent on all measured sociodemographic factors, including birthweight, gestational age, length of hospital stay and maternal ethnicity, educational status, age, parity, and breastfeeding history. The average gestational age of the infants was 32 weeks (range 26.3 – 37) with a mean birthweight of 1875g (median 1845; range 682 – 3005g). At each outcome point, IG mothers were significantly more likely to give any amount of breastmilk (e.g. at 4 weeks IG 98% vs CG 79% ($p=0.005$); at 8 weeks IG 83% vs CG 57% ($p=0.007$); at 12 weeks IG 73% vs CG 49% ($p=0.026$)). A survival curve reflecting all time points indicated a significant positive relationship between IG and any breastmilk ($p<0.001$). Separate survival curves showed no significant relationship between IG and exclusive breastfeeding, but did show a significant positive

relationship between IG and mother feeding mostly (more than 50%) breast milk ($p=0.002$).

Conclusions: Peer counselors increased breastfeeding duration and amount of breastfeeding among premature infants in an inner-city NICU. Peer counseling programs would help to increase breastfeeding in this vulnerable population.

Introduction

National data for breastfeeding rates among premature infants are not available, but regional data suggest these rates are low. In Massachusetts, breastfeeding initiation rates among term infants in 2002 were 76%, while initiation rates among premature infants were 68%.¹ Moreover, infants with the lowest gestational ages had the lowest breastfeeding rates (56% initiation among infants born between 24 and 27 weeks, compared to 69% among infants born at 36 weeks gestational age).¹ Nationally, breastfeeding rates are lowest,^{2,3} and rates of prematurity are highest, among African Americans, suggesting that breastfeeding rates nationally in premature infants will be below average.

Given that the risks of formula feeding for premature infants are particularly high, and have been associated with adverse health outcomes such as increased necrotizing enterocolitis,⁴ delayed brain stem maturation⁵, decreased scoring on cognitive and developmental tests,⁶⁻⁹ and decreased visual development,^{10 11} human milk feeding of prematures is highly desirable. Strategies to increase breastfeeding rates in the NICU are urgently needed. Peer counseling programs have successfully raised breastfeeding rates among term infants in low income populations in a range of settings.¹²⁻¹⁸ The objective of this study was to determine whether peer counselors impacted breastfeeding duration rates in the NICU. Secondary objectives were to determine whether peers increased overall amounts of breast milk received, and whether peers increased rates of exclusive breastfeeding.

Methods

This randomized controlled trial was performed in the Level III, 15-bed NICU at Boston Medical Center, an inner-city teaching hospital, and the only Baby-Friendly™ hospital in Massachusetts. Baby-Friendly status is awarded by the World Health Organization and UNICEF to hospitals which meet the Ten Steps to Successful Breastfeeding. Eligible women had an otherwise healthy premature infant between 26 and 37 weeks gestational age infant in the BMC NICU, spoke English, French, or Spanish; were eligible to breastfeed according to the 1997 guidelines from the American Academy of Pediatrics,¹⁹ and chose to do so. Women were excluded when incapacitated by illness or birth complications preventing enrollment. Infants with GA below 26 weeks were excluded due to high rates of mortality and prevalence of severe medical complications. The study received approval from the Boston University Medical Center Institutional Review Board .

Within 72 hours of giving birth, eligible women were approached about study participation, and consenting women were randomly assigned to receive peer support (IG) or standard of care (CG) (Table 1). Peers were women with breastfeeding experience drawn from the BMC community. Over the course of the study we employed two African American women; one Mexican woman, one white woman, and one white/Native American woman. Two of these women were also employed at BMC as lay childbirth assistants, and two were former teenage mothers. Peers were trained at a five-day breastfeeding course (operated by The Center for Breastfeeding, part of the Healthy Children Project <http://www.healthychildren.cc/index4.htm>). They were also trained on the unit, in NICU procedures and breastfeeding techniques, and at regular, mandatory

BMC breastfeeding training days for maternity staff throughout the course of their employment.²⁰

IG mothers received one peer counselor visit within 72 hours of birth, and were in contact thereafter with the peer counselor on a weekly basis for six weeks. The peer counseling model was based on published studies which demonstrate that, among peer counseling programs for low income mothers of term infants, in-depth, in-person peer contacts are most effective.^{12,14} Emphasis was thus placed on face to face contact, with in-person peer counselor meetings lasting at least 30 minutes. The program guidelines required peers to meet in person with the mother, whenever possible, while the infant remained in the NICU. After the infant was discharged, contact was by telephone unless the mother chose to come to the hospital and meet the peer. This method was chosen to ensure that the intervention was practical, and the results generalizable. Peers followed written guidelines (available on request) for each contact, to establish consistency of care between IG women.

Infant feeding status was assessed by a research assistant unaware of the mother's group assignment at 2, 4, 8 and 12 weeks postpartum. Data were obtained from the medical record while the infant was hospitalized, and by maternal recall by telephone after discharge. The bedside feeding chart was examined for the 48 hour period immediately preceding the date of the infant's 2, 4, 8, and 12 week birthday. If the infant was not taking food at that time, the RA retraced the history in the medical record and recorded data from the 48 hour period immediately prior to feeds being halted. In the case of phone calls, the mother was called on the 2, 4, 8, and 12 week birthday (or as soon as possible thereafter, if she was not reachable on the exact day), and asked to report the

number of breast and/or formula feeds the infant had received in the previous 48 hours. The feeds were totaled and infants were placed into one of four categories: exclusively breastfed, mostly breastfed, mostly formula fed, and exclusively formula fed. For example, if the mother reported two formula feeds and 10 breastfeeds in the previous 48 hours, the infant was considered to be “mostly breastfed”. We have used such classifications effectively in previous research.²¹⁻²³

Sample sizes

To estimate sample sizes needed for the survival analyses, knowing that we could accrue subjects for only 72 hours after each birth and that we would follow up each subject dyad for a maximum of 12 weeks, we estimated median survival time for control pairs of 4 weeks, and for treatment pairs 8 weeks, based on estimated breastfeeding duration data for full-term births receiving standard-of-care in our Baby-Friendly hospital. We also assumed a ratio of control to treatment subject dyads at the end of follow up of 0.75, expecting more control dyads to be lost to follow-up (censored) than treatment dyads. Using a Type I error probability of $\alpha = 0.05$, and a Type II error probability or power of $\beta = 0.80$, this led to sample size estimates of 50 control and 50 intervention dyads. Actual sample sizes at completion were 53 control and 48 intervention dyads.

For logistic regression analyses, we assumed, based on estimated breastfeeding duration data for our hospital, that on average about two-thirds of control group dyads would breastfeed at some level at any of the observation periods. We also estimated the relative risk of failure (not breastfeeding at all) at any of the observation periods for the intervention dyads relative to control dyads at 0.5. These estimates together with the

same probabilities of Type I and Type II errors, and an average ratio of control to treatment dyads over all observation periods equal to the ratio of control to treatment dyads at end of follow-up (0.75), yield sample sizes of about 50 dyads for both the treatment and control group.

Description of analysis

Data analyses followed two approaches based on different temporal views of mother-child dyads and their breastfeeding behavior. First we examined breastfeeding behavior at each of the four observation periods (2,4,8 and 12 weeks) separately to test for significant differences between IG and CG mothers' breastfeeding at each observation point. Chi-squared tests of independence were used to test the hypothesis of no difference between proportions of IG and CG mothers' providing any breastmilk, mostly breastmilk (more than 50%), and exclusively breastmilk at each observation period. The sample was also stratified by major race/ethnicity categories and tests of differences between IG and CG mothers' breastfeeding performed at each observation period for each race/ethnicity subgroup separately.

In a second set of analyses all observations were pooled across observation periods and survival time or "time to event" analyses performed using a Cox Proportional Hazard model to test overall differences in duration of breastfeeding (time to termination of breastfeeding) over the four observation periods. Kaplan-Meier Survival Curves were also plotted to graphically depict differences in time to termination of breastfeeding over the four observation periods.

Results

Over 500 mother-infant pairs were assessed for eligibility and 469 were excluded (Figure 1). A total of 101 mother-infant pairs were enrolled; 48 were assigned to the IG and 53 to the CG. Fourteen women refused to participate, leaving 108 who were randomized to the intervention and control groups. Of the 53 enrolled in the intervention group, 5 did not receive the allocated intervention (3 subjects changed their mind after enrolment, one mother had a positive drug test and was therefore not eligible to breastfeed, and one infant died), leaving a total of 48 women in the intervention group (IG). Of the 55 women randomized to the control group, two were subsequently withdrawn from the study – both were found to have a positive drug test, and were thus ineligible to breastfeed, leaving 53 in the control group. These two groups were equivalent on all measured sociodemographic factors, including birthweight (IG = 1914 gms; CG = 1840 gms); gestational age (26-32 weeks IG = 29%; CG = 30%); gender; length of hospital stay and maternal ethnicity, educational status, age, parity, and breastfeeding history. (Table 1).

Peer counselors were requested to keep records of how completely the intervention was performed. In a few cases peers failed to keep records. (Table 2) For the initial contact, 43/48 records were completed. These records show that the peer counselor discussed pumping techniques in 100% (43/43) of documented cases; helped the mother to pump in 72.1% (31/43) of cases; accompanied the mother to the NICU in 72.1 % (31/43) of cases, and helped the mother to breastfeed, kangaroo care, or both in 30.2% (13/43) of cases. After the initial contact, peers maintained a record of where the infant was located and whether the intervention was performed by telephone or in person.

At 4, 8, and 12 weeks, women in the intervention group were significantly more likely to receive any breast milk and mostly breast milk than women in the control group. For example, at 8 weeks after birth, 64% of women in the intervention group provided mostly breast milk compared with 35% in the control group (Table 3). No significant difference in exclusive breastfeeding was found between groups.

A survival curve reflecting all time points indicated a significant positive relationship between IG and any breast milk ($p < 0.001$) (Figure 2). Separate survival curves showed no significant relationship between IG and exclusive breastfeeding, but did show a significant positive relationship between IG and mother feeding mostly (more than 50%) breast milk ($p = 0.002$).

Because race is a factor in breastfeeding duration among term infants (39% of White US infants are breastfeeding at six months compared to 24% of Black infants)²⁴, and because of the high incidence of prematurity among Blacks, we further examined the data with respect to ethnicity, focusing on Blacks.

In bivariate analysis restricted to Black subjects (total $n = 70$), women in the intervention group were significantly more likely to give “any breastmilk” and “mostly breastmilk” at 2, 4, 8, and 12 weeks (Table 4).

Discussion

In this randomized controlled trial, peer counselors increased breastfeeding duration in the NICU, and increased the amount of breast milk consumed by the infant. Although trends were observed, peer counselors did not significantly increase exclusivity of breastfeeding. Because the benefits of breastfeeding are, in most studies, shown to be dose dependent, increasing the amount of breast milk consumed by premature infants,

either through extending duration, or increasing the number of breast versus formula feeds, is an important contribution to their short and long term health.

Differences in the effects of peer intervention were evident across different ethnic groups, *with Blacks and Hispanics most consistently showing significant positive associations between peer intervention and continuation of breastfeeding. Once I understand the results properly I can add something to this in the discussion.*

These results add to the literature already describing the effectiveness of peer counseling programs at increasing breastfeeding rates.^{12,14,15,17,18,25} Not all peer programs have equal success, and comparisons are difficult because peer counseling programs vary tremendously in their content and how they are implemented. We believe that the effectiveness of this particular program was due to a careful design which included the elements shown to be most successful in previously published peer counseling studies - face to face contact, a specific checklist of goals for the peer at the first meeting, and close supervision of, and support for, the peers. Peers had immediate daily access to the lactation consultant working on the unit, and to the project managers; at the same time the lactation consultant and the project managers' in-person presence helped to ensure peer consistency, accuracy of knowledge, and reliability. In the light of current investment at the national level by the US Department of Agriculture in breastfeeding peer counseling as part of the WIC program, we would strongly advocate that peer programs be established with clear guidelines. Although operating a peer counseling program can be challenging,²⁰ it is manageable in the hospital setting.

This study has a number of limitations. Although we focused on premature infants, the majority of infants were between 32 and 37 weeks gestational age. We did

not have sufficient power to determine if our impact was similar in the younger gestational age group. Second, the study was conducted in a Baby-Friendly Hospital. How much the environment of a Baby-Friendly Hospital contributed to our success cannot be determined. However, xxx. We were not able to increase the amount of exclusive breast-feeding. However, the amount of breast milk that is needed to convey the many numerous benefits of breastfeeding is largely unknown and xxx. Lastly, 18 women were lost to follow-up over the course of the study. However, the analysis conducted reflects this lost to follow-up.

Conclusion

Many groups, including the AAP, ACOG, AAFP, CDC and U.S. DHHS (type out) recognize the importance of prolonged breast feeding. This is likely more important in premature infants, because of the many health risks they face. We found that peer counselors increased breastfeeding duration among premature infants in an inner-city NICU. Peer counseling programs would help to increase breastfeeding in this vulnerable population.

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Table 1: Baseline Sociodemographic features of the study sample

	Intervention	Control	P Value
Infants	(N=48)	(N=53)	
Birthweight			
Mean (range)	1914.4 (724-3320)	1840 (682-3005)	N/S
Gestational age			
Mean (range)	32.6 (26.3-37)	32.7 (26.4-36.3)	N/S
≥ 26 to < 32 weeks (N)	14	16	
≥ 32 to ≤ 37 weeks (N)	34	37	
Sex			
Male N (%)	25/48 (52%)	30/53 (57%)	N/S
Female N (%)	23/48 (48%)	23/53 (43%)	
APGAR Score			
1 min. mean (range)	6.6 (0-9)	6.2 (0-9)	N/S
5 min. mean (range)	8.0 (3-9)	7.8 (1-9)	
Length hospital stay mean(range)	27.15(2-81)	25.2 (1-104)	N/S
Mothers			
Insurance status			
Medicaid N (%)	27/48 (56.3%)	27/53 (50.9%)	N/S
Private/HMO N (%)	8/48 (16.7%)	4/53 (7.5%)	
Other N (%)	13/48 (27.1%)	22/53 (41.5%)	
Race/ethnicity			
Black non-Hispanic N (%)	35/48 (72.9%)	35/53 (66.0%)	N/S
White non-Hispanic N (%)	3/48 (6.2%)	2/53 (3.8%)	
Hispanic N (%)	5/48 (10.4%)	14/53 (26.4%)	
Other N (%)	5/48 (10.4%)	2/53 (3.8%)	
US-born N (%)	12/48 (25.0%)	17/53 (32.1%)	N/S
Non US- born N (%)	36/48 (75.0%)	36/53 (67.9%)	
Parity			
Primiparous N (%)	23/48 (47.9%)	22/53 (41.5%)	N/S
Multiparous N (%)	25/48 (52.1%)	31/53 (58.5%)	

Type of delivery

Vaginal N (%)	26/48 (54.2%)	23/53 (43.4%)	N/S
C/ Section N (%)	22/48 (45.8%)	30/53 (56.6%)	

Marital status

Married N (%)	15/48 (31.2%)	17/53 (32.1%)	N/S
Single N (%)	30/48 (62.5%)	36/53 (67.9%)	
Divorced/widowed N (%)	3/48 (6.3%)	0	

Education

Did not complete high school	6/48 (12.5%)	8/53 (15.1%)	N/S
High school graduate	18/48 (37.5%)	21/53 (39.6%)	
Bachelor's degree or higher	24/48 (50%)	24/53 (45.2%)	

Employment status

Employed N (%)	21/48 (43.8%)	21/53 (39.6%)	N/S
Unemployed N (%)	27/48 (56.3%)	28/53 (52.8%)	
Other N (%)	0	4/53 (7.5%)	

Receive WIC benefits (Yes) N (%) 33/48 (68.8%) 40/53 (75.5%) N/S

Baby's father is supportive N (%) 30/48 (62.5%) 34/53 (64.1%) N/S
of breastfeeding (Yes)

Family or friends encourage N (%) 42/48 (87.5%) 35/53 (66%) P=.0215
to breastfeed (Yes)

Has breastfed previous N (%) 23/48 (48.0%) 22/53 (41.5%) N/S
child (Yes)

Table 2 Description of peer counselor weekly contacts

	Peer Contact in person	Peer Contact by phone	Unknown
Initial Contact			
Baby located in NICU (100%, 43/43)	100% (43/43)	0% (0/43)	0% (0/43)
Week 1 Contact			
Baby in NICU (93%, 40/43)	82.5% (33/40)	15.0% (6/40)	2.5% (1/40)
Baby at home (7%, 3/43)	0% (0/3)	100% (3/3)	0% (0/3)
Week 2 Contact			
Baby in NICU (76.7%, 33/43)	69.7% (23/33)	30.3% (10/33)	0% (0/33)
Baby at home (16.3%, 7/43)	0% (0/7)	100% (7/7)	0% (0/7)
Baby at another hospital (2.3%, 1/43)	0% (0/1)	100% (1/1)	0% (0/1)
Lost to follow-up (4.7%, 2/43)			
Week 3 Contact			
Baby in NICU (53.5%, 23/43)	87.0% (20/23)	13.0% (3/23)	0% (0/23)
Baby at home (37.2%, 16/43)	6.3% (1/16)	93.8% (15/16)	0% (0/16)
Baby at another hospital (2.3%, 1/43)	0% (0/1)	100% (1/1)	0% (0/1)
Lost to follow-up (7%, 3/43)			
Week 4 Contact			
Baby in NICU (37.2%, 16/43)	81.3% (13/16)	17.8% (3/16)	0% (0/16)
Baby at home (46.5%, 20/43)	0% (0/20)	100% (20/20)	0% (0/20)
Baby at another hospital (2.3%, 1/43)	0% (0/1)	100% (1/1)	0% (0/1)
Lost to follow-up (14%, 9/43)			
Week 5 Contact			
Baby in NICU (21%, 9/43)	66.7% (6/9)	17.8% (3/9)	0% (0/9)
Baby at home (55.8%, 24/43)	4.2% (1/24)	95.8% (23/24)	0% (0/24)
Lost to follow-up (23.3%, 10/43)			
Week 6 Contact			
Baby in NICU (14%, 6/43)	50% (3/6)	50% (3/6)	0% (0/6)
Baby at home (44.2%, 19/43)	0% (0/19)	100% (19/19)	
Mom stopped BF (4.7%, 2/43)			
Lost to follow-up (37.2%, 16/43)			

Table 3: Percentage of mothers giving breast milk at contact points

	Intervention	Control	P Value
Any Breast milk	(N=)	(N=)	
2 Weeks	100%	89%	0.016
4 Weeks	98%	79%	0.005
8 Weeks	83%	57%	0.007
12 Weeks	73%	49%	0.026
Mostly (>50%) Breast milk	(N=)	(N=)	
2 Weeks	85%	74%	0.143
4 Weeks	78%	62%	0.084
8 Weeks	64%	35%	0.005
12 Weeks	43%	23%	0.053
Exclusive Breast milk	(N=)	(N=)	
2 Weeks	56%	43%	0.197
4 Weeks	41%	39%	0.865
8 Weeks	19%	14%	0.524
12 Weeks	11%	9%	0.197

Enrollment

Assessed for eligibility (n = 577)

Excluded (n = 469)
Not meeting inclusion criteria (n = 452)
Refused to participate (n = 14)
Other reasons (n = 3)

Randomize (N= 108)

Allocation

Allocated to intervention (n = 53)
Received allocated intervention (n = 48)
Did not receive allocated intervention (n = 5)
Reasons:
Subject's choice (n = 3)
Positive drug test (n = 1)
Baby died (n = 1)

Allocated to control (n = 55)
Received allocated control (n = 53)
Did not receive allocated control (n = 2)
Reasons:
Positive drug test (n = 1)
Lost to follow-up (n = 1)

Follow-up

Complete outcome data (4 points) (n = 37)
Three outcome points (n = 5)
Two outcome points (n = 4)
One outcome point (n = 2)
Reasons:
Lost to follow up (n = 11)

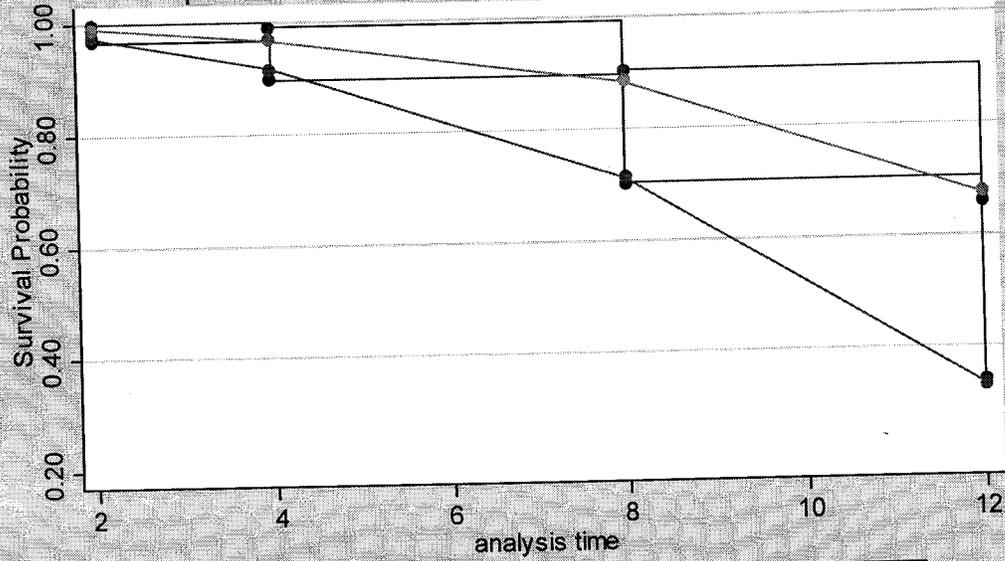
Complete outcome data (4 points) (n = 46)
Three outcome points (n = 4)
Two outcome points (n = 3)
One outcome point (n = 0)
Reasons:
Lost to follow up (n = 7)

Analysis

Subjects analyzed (n = 48)

Subjects analyzed (n = 53)

Kaplan-Meier Curve for Any Breastmilk By Group



● Observed: peer = 0 ● Observed: peer = 1
● Predicted: peer = 0 ● Predicted: peer = 1