Randomized Trial of Breastfeeding Support in Very Low-Birth-Weight Infants

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Objective: To determine if supplementary structured breastfeeding counseling (SSBC) for both parents compared with conventional hospital breastfeeding support (CHBS) improves the duration of breastfeeding in very low-birth-weight infants up to 1 year old.

Design: Randomized trial with longitudinal follow-up of infants at term, and ages 1, 3, 6, and 12 months (infant ages corrected for prematurity).

Setting: A tertiary-level neonatal intensive care unit (NICU) and geographically defined region in central-west Ontario, Canada.

Participants: Parents of infants with a birth weight less than 1500 g, who planned to breastfeed.

Interventions: The SSBC consisted of viewing a video on breastfeeding for preterm infants; individual counseling by the research lactation consultant; weekly personal contact in the hospital; and frequent postdischarge contact through the infants’ first year or until breastfeeding was discontinued. The CHBS group had standard breastfeeding support from regular staff members confined to the period of hospitalization in the NICU.

Main Outcome Measure: Duration of breastfeeding.

Results: At study entry, there were no statistically significant differences in major demographic characteristics between groups. The mean duration of breastfeeding was 26.1 weeks (SD = 20.8; median, 17.4) in the SSBC group and 24.0 weeks (SD = 20.5; median, 17.4) in the CHBS group (not statistically significant).

Conclusions: Long-term breastfeeding counseling of parents of very low-birth-weight infants in this study did not demonstrate a significant difference in duration of breastfeeding. These results may be explained by the high motivation to breastfeed in both groups, a relatively advantaged population, and the availability of community breastfeeding resources, which may have diminished any significant differences that could have resulted from a breastfeeding intervention. The results of this study, compared with previous studies of very low-birth-weight infants, indicate a new trend to longer duration of breastfeeding in preterm infants.


Current guidelines in Canada and the United States recommend that the first choice for premature infant nutrition is fortified mother’s milk. Recommendations from Canada include fortification of the milk until the infant is breastfeeding effectively, followed by exclusive breastfeeding until age 4 to 6 months (infant ages are corrected for prematurity). Despite these recommendations, there is a wide variation in the reported incidence of breastfeeding in very low-birth-weight (VLBW) infants born preterm. The percentage of women who initiate breastfeeding ranges from 33% to 91%, with the incidence in the United States in the lower range and Scandinavian countries at the higher ranges.

The duration of breastfeeding in the preterm population, according to the reported literature, also varies widely and is confounded by the range of prematurity and the definition of breastfeeding in these studies. The duration reported in previous studies ranges from approximately 2 to 6 months, with a shorter duration of breastfeeding in infants born at very low gestational ages in comparison with the more mature preterm infants. Mothers of the very premature infants have significant difficulties in making the transition from expressing milk to feeding di-
SUBJECTS AND METHODS

SUBJECTS

The setting for the study was a 33-bed, tertiary-level neonatal intensive care unit (NICU) of a teaching hospital that is the referral center for a geographically defined region in central-west Ontario, delivering approximately 29,000 infants per year. Inclusion criteria were: infants with birthweights less than 1500 g (VLBW), who were inborn or transferred with their mother within 72 hours of birth if they were outborn, and fed mother's milk by parental choice. Exclusion criteria were: multiple births; infants with severe congenital, surgical, or chromosomal abnormalities; and non–English-speaking parents. Fathers, as well as mothers, were included in this study because of the recognized importance of partners as a key support to breastfeeding success.

The sample size was based on the difference between the success rate (approximately 10%) of breastfeeding at age 3 months at the initiation of the study, and the desired success rate defined for the study, which was 30%. Using proportional tables, a level of .05, β levels of 2, and a 1-tailed test, 58 infants per group (116 infants total) were needed to detect a statistically significant difference between groups. Using formulation for survival analysis, the sample size calculation was somewhat smaller (103 infants). This type of analysis assumes that the drop-off rate of breastfeeding is exponential. In our experience and that of others, the rate of breastfeeding drops off fairly precipitously at about 6 to 8 weeks postnatally and may not be exponential. Therefore, we chose a conservative sample size of 128 infants.

All parents who met the inclusion criteria were approached by a research assistant to participate in the study. After obtaining informed consent, infants were stratified by birth weight (≤1000 g or >1000 g) and parents were randomly assigned, using random-number tables and sealed opaque envelopes, to receive either CHBS (n=64 couples) or SSBC (n=64 couples) within 72 hours of birth. The SSBC consisted of (1) viewing a video on breastfeeding preterm infants; (2) individual counseling by the research lactation consultant, who was not a member of the hospital staff; (3) weekly personal in-hospital contact; and (4) frequent postdischarge contact through the infant’s first year or until breastfeeding was discontinued. The CHBS group had standard support confined to the period of hospitalization in the NICU, which included contact with the regular hospital staff (ie, nurses, nutritionists, neonatal nurse practitioners, physicians). No specialized breastfeeding clinic was available to parents in the hospital at the time of the study, and only a limited number of staff had any formal education in lactation or breastfeeding support.

Demographic and breastfeeding history and practice information was collected by means of self-administered questionnaires that were distributed to the mothers in both groups at study entry, prior to hospital discharge, and during 3-, 6-, and 12-month follow-up visits. Partners completed questionnaires separately from mothers at study entry and at the 6-month visit. The breastfeeding questionnaires were developed from the literature and from those used in previous research by one of this article’s authors (J.P.). The questions included choices for set answers, as well as the opportunity for parents to write their comments. During hospitalization, the 24-hour volume of expressed milk was recorded once per week from the milk brought to the NICU. After discharge from the NICU, the infants were seen during their scheduled visits to the Growth and Development Clinic at the Children’s Hospital of the Hamilton Health Sciences Corporation (Hamilton, Ontario), at the “due date,” and at 3, 6, and 12 months of age. At each follow-up visit, the volume of a single feed intake was assessed by prebreastfeeding and postbreastfeeding test weights of infants done on an electric scale accurate to 1.0 g, and by feeding records and mother’s report. Breastfeeding exclusivity, or percent human milk intake of total fluid intake, was determined using the following categories: greater than 80%, 50% to 80%, less than 50%, and no breastfeeding. These categories were based on the recommendations by Labbock and Krasovec, relating to definitions of breastfeeding.

STATISTICAL ANALYSIS

Data were analyzed as groups were assigned at entry to the study. The initial analysis of the breastfeeding questionnaires was conducted using descriptive statistics. The primary outcome of interest in this study was the duration and success of breastfeeding. Duration of breastfeeding was measured as a continuous variable; that is, in weeks, and was analyzed using survival analysis techniques. For percent of human milk intake, breastfeeding exclusivity was analyzed using the χ² test of proportions at each visit. Lastly, a Cox regression model was used to determine predictors of breastfeeding duration. The level of statistical significance was set at P<.05.
The main purpose of the present study was to determine whether a supplementary structured breastfeeding counseling program (SSBC) for parents of preterm infants, compared with conventional hospital-based breastfeeding support (CHBS), will improve the duration of lactation and the success of breastfeeding after discharge from the hospital, and up to age 1 year. This study also explored nutritional and neurodevelopmental outcomes, but these will be addressed in a separate article.

## RESULTS

### STUDY ENTRY

The demographic variables of the study participants are presented in Table 1. Parents in both groups were generally aged in their late 20s to early 30s, white, living with a partner, and with a relatively high socioeconomic status. There were no significant differences between the groups in any of the infant variables. The mean duration of months that mothers in both groups planned to breastfeed was 8 months (SD, 3.6 months; range, 0.5-24 months), which was similar to the mean duration they planned to stay home from work (7.6 months; SD, 7.8 months; range, 0-60 months). These results indicate that both cohorts of parents were highly committed to breastfeeding.

### NICU BREASTFEEDING EXPERIENCE

With respect to their breastfeeding experiences in the NICU, mothers in both groups reported similar findings. There were no differences between groups in the variables related to breast milk expression and collection, nutritional information, emotional support, plans for postdischarge breastfeeding management, and general newborn care. While these nonexperimental studies reported an increase in the incidence and duration of breastfeeding as a result of their programs, the studies provided no data on the incidence or duration prior to initiation of the breastfeeding program.

The main purpose of the present study was to determine whether a supplementary structured breastfeeding counseling program (SSBC) for parents of preterm infants, compared with conventional hospital-based breastfeeding support (CHBS), will improve the duration of lactation and the success of breastfeeding after discharge from the hospital, and up to age 1 year. This study also explored nutritional and neurodevelopmental outcomes, but these will be addressed in a separate article.

### BREASTFEEDING EXPERIENCE AT HOME

More than 50% of mothers in both groups experienced breastfeeding problems at home, as reported at the 6-month assessment. The greatest percentage of problems in both

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Table 1. Demographic Variables by Study Group*

<table>
<thead>
<tr>
<th>Variable</th>
<th>SSBC (n = 64)</th>
<th>CHBS (n = 64)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant’s birth weight, mean (SD), g</td>
<td>1083 (267)</td>
<td>1103 (261)</td>
</tr>
<tr>
<td>Infant’s gestational age, mean (SD), wk</td>
<td>29 (3)</td>
<td>29 (3)</td>
</tr>
<tr>
<td>Mother’s age, mean (SD), y</td>
<td>30 (6)</td>
<td>29 (7)</td>
</tr>
<tr>
<td>Father’s age, mean (SD), y</td>
<td>32 (6)</td>
<td>33 (8)</td>
</tr>
<tr>
<td>Mode of delivery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal</td>
<td>32 (50)</td>
<td>42 (66)</td>
</tr>
<tr>
<td>Cesarean</td>
<td>32 (50)</td>
<td>22 (34)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Living with partner</td>
<td>55 (86)</td>
<td>55 (86)</td>
</tr>
<tr>
<td>Not living with partner</td>
<td>9 (14)</td>
<td>9 (14)</td>
</tr>
<tr>
<td>Have other children</td>
<td>26 (41)</td>
<td>25 (39)</td>
</tr>
<tr>
<td>Maternal education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;High school</td>
<td>10 (16)</td>
<td>10 (16)</td>
</tr>
<tr>
<td>Completed high school</td>
<td>17 (28)</td>
<td>22 (35)</td>
</tr>
<tr>
<td>Postsecondary</td>
<td>10 (16)</td>
<td>16 (26)</td>
</tr>
<tr>
<td>Completed university</td>
<td>25 (40)</td>
<td>14 (23)</td>
</tr>
<tr>
<td>Social class</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I, II</td>
<td>60 (94)</td>
<td>54 (85)</td>
</tr>
<tr>
<td>III</td>
<td>1 (2)</td>
<td>4 (6)</td>
</tr>
<tr>
<td>IV, V</td>
<td>3 (4)</td>
<td>6 (9)</td>
</tr>
</tbody>
</table>

*Data are presented as number (percentage) unless otherwise noted. SSBC indicates supplementary structured breastfeeding counseling; CHBS, conventional hospital breastfeeding support. For all comparisons, P > .05.
groups was reported at the 1-month assessment (94% vs 81% for SSBC and CHBS, respectively). Mothers in both groups reported several breastfeeding problems at home during all periods, including sore nipples, fatigue, not enough milk, infant not gaining weight, and infant not being interested in breastfeeding. There were no statistically significant differences between groups except for mothers’ reports of the infant not gaining weight, which was more frequent in the SSBC group ($P = .05$). In both groups, mothers’ reports of insufficient milk supply was the most frequent problem at home for all periods. Not surprisingly, the main reasons for discontinuing breastfeeding mirrored the problems experienced by the mothers. At all times, except at 12 months, mothers in both groups discontinued breastfeeding because they perceived that they were not producing enough breast milk. At 12 months, the main reason for discontinuation was that the infant was no longer interested in breastfeeding. It is important to note that none of the mothers in either group identified their partners as a reason for stopping breastfeeding at any given time.

Mothers in both groups reported using a wide variety of breastfeeding resources for solving breastfeeding problems at home, including health professionals, books, friends, and family. The large number of mothers who had public health nurses at the due date assessment likely reflects the fact that these infants were discharged home around that time. When all time periods were combined, the most used resource for advice on breastfeeding for both groups was the lactation consultant (which included the research lactation consultant in the study group and community lactation consultants in both groups).

**MAIN OUTCOME MEASURES**

The main outcome for this study was duration and success of breastfeeding to age 1 year. The Figure shows the analysis of breastfeeding duration based on the Kaplan-Meier test. The mean duration of breastfeeding was 26.2 weeks (SE, 2.7 weeks; 95% confidence interval [CI], 21.0–31.5; median, 17.4 weeks) in the SSBC group, and 24.2 weeks (SE, 2.7 weeks; 95% CI, 19.0–29.4; median, 17.4 weeks) in the CHBS group, which was not significantly different. Percent of human milk intake was determined through single-feed prebreastfeeding and postbreastfeeding test weights, feeding records, and mother’s report. Table 3 indicates that the breastfeeding exclusivity, by group, at all time periods was also not statistically significant. A Cox regression analysis on the combined sample determined smoking to be a significant negative factor ($P = .003$), and number of months planning to breastfeed to be a significant positive factor ($P = .003$) for breastfeeding duration. Nonsignificant factors were infant’s gestational age, mother’s time away from work, maternal age, parity, socioeconomic status, and total amount of milk pumped in 24 hours in the NICU.

**COMMENT**

In this open, randomized trial, long-term breastfeeding support of parents of VLBW infants did not result in a significant difference in the duration of breastfeeding. The high motivation to breastfeed in both groups, prior breastfeeding experience, a relatively advantaged socioeconomic population, and the widespread availability of community resources (lactation consultants, public
health nurses, family physicians, breastfeeding support groups) to support breastfeeding may have diminished any significant differences resulting from a breastfeeding support intervention. This study of parents of VLBW infants is unique in the inclusion of partners in the breastfeeding intervention and in the long-term follow-up of breastfeeding to age 1 year.

In a preintervention and postintervention study, counseling of mothers of infants in an NICU significantly increased the incidence and the mean duration of breastfeeding. However, the breastfeeding rates were higher among mothers who were white and privately insured, regardless of counseling. Similarly, positive effects of breastfeeding support in term infants from families with low socioeconomic status have been reported. Other intervention studies on VLBW infants have also demonstrated stronger and more consistent differences in cognition in infants from economically disadvantaged environments than in infants from middle-class families or families with high maternal education. It is possible that the intervention tested in the current study might demonstrate a difference in populations of VLBW infants of lower socioeconomic status, or at least in populations that are less homogeneous in terms of ethnicity, socioeconomic status, health insurance coverage, and maternal education.

The results of this study, compared with those of retrospective studies in preterm infants, indicate a trend toward longer duration of breastfeeding. Previous studies of preterm infants indicate a mean duration of breastfeeding ranging from 1.8 to 5.6 months. It is difficult to compare studies, however, because of the lack of consistency in the definition of breastfeeding and in the wide range of the birth weights and maturity of the infants included in the studies. The breastfeeding exclusivity results from this study indicate that infants generally received either greater than 80% human milk intake or no human milk intake, with few infants receiving intakes between those percentages.

In this study, there was a significant number of mothers in whom milk supply continued to be problematic for much of the infant's first year of life. For these mothers, supportive interventions alone do not seem to influence breastfeeding success. As in other studies, cigarette smoking was a negative predictor of breastfeeding duration; thus, education to reduce or eliminate smoking might improve breastfeeding outcomes. Since the decision about planned duration of breastfeeding was a positive influence on breastfeeding outcome, early education of mothers to support such planning may be useful.

With respect to implications for clinical practice, the anecdotal and research literature suggest that supporting parents of preterm infants is important to breastfeeding success. The negative results of this study should not be perceived as an indication that breastfeeding support is not helpful. Further studies are required to determine the effectiveness of this model in a more disadvantaged population and those with limited access to community resources.

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Table 3. Breastfeeding Exclusivity by Supplementary Structured Breastfeeding Counseling (SSBC) and Conventional Hospital Breastfeeding Support (CHBS) Groups at All Time Periods

<table>
<thead>
<tr>
<th>Time of Assessment, mo</th>
<th>Term</th>
<th>1</th>
<th>3</th>
<th>6</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent of Intake From Breastfeeding</td>
<td>SSBC n = 59</td>
<td>CHBS n = 58</td>
<td>SSBC n = 59</td>
<td>CHBS n = 47</td>
<td>SSBC n = 58</td>
</tr>
<tr>
<td>&gt;80</td>
<td>59</td>
<td>54</td>
<td>54</td>
<td>43</td>
<td>40</td>
</tr>
<tr>
<td>50-80</td>
<td>3</td>
<td>3</td>
<td>0</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>0-50</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>None</td>
<td>36</td>
<td>38</td>
<td>44</td>
<td>47</td>
<td>54</td>
</tr>
</tbody>
</table>

* All data are percentages. For all comparisons, P > .05.