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Associations between use of expressed human milk at two weeks postpartum and human milk feeding practices to six months: a prospective cohort study with vulnerable women in Toronto, Canada

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ABSTRACT

Objectives: To examine whether use of expressed human milk in the first two weeks postpartum is associated with cessation of human milk feeding and non-exclusive human milk feeding up to six months.

Design: pooled data from two prospective cohort studies

Setting: three Canada Prenatal Nutrition Program (CPNP) sites serving vulnerable families in Toronto, Canada

Participants: 337 registered CPNP clients enrolled prenatally from 2017-2020; 315 (93%) were retained to six months postpartum. Exclusions: pregnancy loss or participation in prior related study; for Study B: preterm birth (<34 weeks); plan to move outside Toronto; not intending to feed human milk; hospitalization of mother or baby at two weeks postpartum.

Primary and Secondary Outcome Measures: *Main exposure variable*: any use of expressed human milk at two weeks postpartum. *Outcomes*: cessation of human milk feeding by six months; non-exclusive human milk feeding to four months and six months postpartum.

Results: All participants initiated human milk feeding and 80% continued for six months. Exclusive human milk feeding was practiced post-discharge to four months by 28% and to six months by 16%. At two weeks postpartum, 34% reported use of expressed human milk. Any use of expressed human milk at two weeks was associated with cessation of human milk feeding before six months postpartum (aOR

2.66; 95% CI: 1.41-5.05) and with non-exclusive human milk feeding to four months (aOR 2.19; 95% CI 1.16-4.14) and six months (aOR 3.65; 95% CI 1.50-8.84).

Conclusions: Early postpartum use of expressed human milk predicted early cessation and non-exclusive human milk feeding for four and six months postpartum among vulnerable women living in an urban Canadian context and accessing community perinatal programs. Further research is needed to determine whether early use of expressed human milk is a marker of lactation difficulties or undermines longer-term breastfeeding practices.

Registration: Clinicaltrials.gov NCT03400605, NCT03589963.

Key words: human milk, milk expression, lactation, infant feeding

ARTICLE SUMMARY

Strengths and limitations of this study:

- This is one of the first studies to examine expressed human milk use by vulnerable women, with high study retention (93%).
- Infant feeding data were collected prospectively at 4 time points from two weeks to six months postpartum, limiting the recall period which improves data accuracy.
- Analysis of associations between expressed human milk use and later human milk feeding practices focused on the first two weeks postpartum when lactation is being established.
- Data collection did not include intentions to pump or feed expressed human milk, reasons for use of expressed human milk or maternal employment status.
- Participants were registered in community perinatal programs and 74% had access to free, in-home skilled lactation support so findings may not be generalizable.

BACKGROUND

The World Health Organization (WHO) recommendation that all infants receive exclusive human milk (HM) feeding for the first six months of life in order to optimize health and development outcomes is an important global public health goal.[1] The WHO definition does not differentiate between feeding HM directly at the breast and HM expressed either by hand or use of a breast pump and fed to the infant via a cup, bottle or other device.[2] Over the past two decades breast pump use has become widespread in high-income countries and the provision of expressed HM is now a major component of HM feeding for many families with term-born infants.[3-5] Several studies have found high rates of obtaining pumps by the early postpartum period including use of expressed HM during the hospital stay.[4, 6, 7] However, there is growing evidence that expressed HM is not equivalent to HM obtained through direct feeding at the breast. Observational studies with large sample sizes have found that provision of expressed HM but no formula is associated with higher risks of otitis media, wheezing and rapid weight gain within the first year of life in comparison to exclusive feeding at the breast.[8-10] These findings have prompted the call for more nuanced assessment of HM feeding practices to include data on pumping and use of expressed HM.[11, 12]

In addition to concerns about health effects, use of expressed HM feeding has been associated with shorter duration of any and exclusive HM feeding, although findings are mixed.[13] It is likely that this inconsistency relates to variations between studies in factors such as infant age at the start of pumping or expressed HM feeding, and reasons for providing and degree of reliance on expressed HM. Recent analyses of longitudinal prospective cohort studies have found that pumping and/or expressed HM feeding earlier in the postpartum period, for non-elective reasons (ie. to manage difficulties feeding at the breast or return to work) and with higher frequency is associated with early cessation of any and exclusive HM feeding.[7, 14-16] However, the samples in these studies tend to be biased towards

women of higher-socioeconomic status so may not reflect expressed HM feeding practices of more vulnerable women.

In this paper we report expressed HM feeding practices and associated HM feeding outcomes over the first six months postpartum among women with term-born infants recruited through the Canada Prenatal Nutrition Program (CPNP; a national program designed to serve socially and/or economically vulnerable women) at three sites in Toronto. Our objectives were to examine: i) the prevalence of expressed HM use at two weeks and two, four and six months postpartum; and ii) associations between use of expressed HM at two weeks and HM feeding outcomes (cessation before six months and non-exclusive HM feeding to four and six months postpartum).

METHODS

Study setting and participants

This analysis utilizes infant feeding data collected prospectively from birth mothers in two studies conducted within a research program designed to examine the potential for delivering postnatal lactation support through the CPNP. The CPNP is a federally funded initiative implemented through community agencies with the aims of improving birth outcomes and HM feeding in vulnerable Canadian families.[17] CPNP activities vary between sites based on local needs and available partnerships, but are usually implemented as weekly drop-in programs. Core services include group health and nutrition education, provision of food and/or grocery vouchers, individual supports such as nutrition counseling, and referrals to other community services.[17]

Participants in both studies were registered in the CPNP at one of three specific sites in Toronto, Canada, and were recruited prenatally. The population of the combined catchment areas of the three CPNP sites is over 180,000. Detailed methods for both studies have been published previously. Study A was a prospective cohort study of infant feeding practices among clients of a CPNP site offering skilled

postnatal lactation support with additional charitable funding from The Sprott Foundation.[18] Study B was a pre/post intervention study designed to examine the effectiveness of implementing similar lactation support services in two other CPNP sites.[19] Inclusion criteria were prenatal registration in one of the CPNP sites, and for Study B, intention to feed human milk and to continue living in Toronto with the infant. Exclusion criteria were pregnancy loss and for Study A, participation in a prior related study. Exclusion criteria for Study B were preterm birth (<34 weeks gestation), medical issue affecting feeding and hospitalization of either the mother or infant at two weeks postpartum. Recruitment was conducted from August 2017-January 2020 for Study A and from November 2018-March 2020 for Study B. Due to the COVID-19 pandemic, Study B was suspended in March 2020 following a brief intervention period and incomplete recruitment of the post-intervention group, but data collection was completed with all enrolled participants.

All participants in Study A and those recruited to the post-intervention group in Study B had access to two free, in-home visits from an International Board Certified Lactation Consultant (IBCLC) for postpartum lactation support, with additional visits approved for complex needs. This service was promoted prenatally and offered pro-actively by telephone call around the time of birth. Double-electric breast pumps were provided by the IBCLCs as needed, but criteria for pump provision were more flexible for Study A participants as the lactation support was provided as a community program rather than a research intervention.

Patient and public involvement statement

Participants in this study were not clinical patients but clients of community perinatal services. At the time of the study, no engagement committee existed for these service-users to inform the research. The community programs had participant feedback mechanisms in place regarding service delivery. Community program staff were directly involved in the design, implementation, interpretation of findings and reporting of this research, including contributing service-user perspectives.

Data collection

All data collection for Study A was conducted by JF and for Study B by AM or a Mandarin speaking research assistant. Data collection occurred either in person at the participating CPNP sites or by telephone. Professional interpreter services were used for Study A participants who did not speak English (n=14) and Study B participants who did not speak either English or Mandarin (n=20).

In Studies A and B, infant feeding data were collected prospectively at two weeks and two, four and six months postpartum using the same standardized and validated interviewer-administered questionnaire used previously by our group.[20, 21] In Study B, data were also collected at postpartum months one, three and five, but only the time points shared with Study A are reported here. At each time point, participants reported the average number of milk feeds provided to their infant per 24 hours, divided into feeds at the breast, expressed HM feeds and formula feeds. Expressed HM or formula use as a top-up after feeding at the breast was recorded as well as provision of other liquids and introduction of solids. The recall period was two weeks. Infant sex and in-hospital formula supplementation (yes/no) were recorded at the first postpartum contact. Participants who stopped all HM feeding were asked to recall the last date they provided any HM to their infant and main reasons for cessation.

Participants were categorized as yes or no for any HM feeding, exclusive HM feeding and any expressed HM feeding at each postpartum time point. Exclusive HM feeding was defined as provision of HM only, either at the breast or expressed, with the exception of vitamins, medicines and infrequent (less than daily) water feeds. In accordance with WHO and Health Canada guidance to introduce solids 'around' six months postpartum, participants who introduced solids up to 14 days prior to six months but otherwise provided only HM were classified as exclusively HM feeding at six months postpartum.[1, 22] Participants who were exclusively HM feeding at two weeks, two months and four months were classified as practicing exclusive HM feeding post-discharge to four months, and those who were also

exclusively HM feeding at six months were classified as practicing exclusive HM feeding post-discharge to six months. Hospital formula supplementation (yes/ no) was considered an independent predictor of HM feeding outcomes.[23]

Maternal socio-demographic data were collected via interviewer-administered questionnaire prenatally in Study B and at two weeks postpartum in Study A. Socio-demographics included maternal age (years); parity (primiparous, multiparous); education level (high school or less, post-secondary); length of time in Canada (<1 year, 1 to <3 years, ≥3 years, born in Canada); and ethnicity. Participants self-reported their ethnicity using a standardized list of geographically-based options developed and validated for a large birth cohort study based in Toronto.[24] Based on the distribution of responses to the list of geographically-based ethnicities, five categories were defined for analysis (East Asian, Other Asian, African, Latin American, and European/Caribbean/Other).

In Study A, household income was assessed at two weeks postpartum and classified as above or below the Statistics Canada size-adjusted Low Income Cut-Off.[25] In Study B, household income adequacy was assessed at six months postpartum and classified as meeting all, most, some, very little or none of regular household expenses, using standardized questions from Statistics Canada's Employment Insurance Coverage Survey.[26] Participants in Study B were also asked about receipt of federal Employment Insurance maternity leave benefits (yes/no). In both studies, food insecurity was assessed at six months postpartum using the Household Food Security Survey Module of the Canadian Community Health Survey, and classified as none, marginal, moderate, severe based on the number of affirmative responses.[27, 28]

Receipt of the IBCLC services (yes/no) and number of IBCLC visits (0, 1, >1) was recorded from CPNP site records for Study A participants and from research records of eligible Study B participants. Although some participants received breast pumps through the IBCLCs, we did not collect data on the use of these pumps or participants' access to pumps through other sources.

In Study B only, the Breastfeeding Self-Efficacy Scale-Short Form was administered at two weeks postpartum.[29] This is a validated and widely used 14-item scale which produces a score from 14-70, with higher scores indicating greater breastfeeding self-efficacy.

Statistical analysis

Descriptive statistics were calculated for all variables of interest. Continuous measures such as age were summarized using means and standard deviations whereas categorical measures were summarized using counts and percentages. For Study B only, a t-test was used to compare mean breastfeeding self-efficacy scores between participants who did and did not use expressed HM at two weeks postpartum.

Associations between any expressed HM use at two weeks postpartum and HM feeding outcomes were first assessed by chi-square tests then studied further using multivariable logistic regression analysis. Participants with data for all exposure variables and the outcome measure were included each model. Outcome measures were: i) cessation of any HM feeding before six months postpartum; ii) non-exclusive HM feeding post-discharge to four months postpartum; and iii) non-exclusive HM feeding post-discharge to six months postpartum. The global recommendation is exclusive HM feeding for six months,[1] but a separate analysis of Study B data showed that this practice was frequently compromised after four months by introduction of solids and non-formula fluids.[30] We therefore assessed non-exclusive HM feeding to both four and six months in order to examine associations with and without the influence of complementary feeding.

Potential exposure variables considered for inclusion in the multivariable logistic regression analysis were: maternal age, education level, parity, years in Canada, geographically-based ethnicity, infant sex, any household food insecurity, household food insecurity category, hospital formula supplementation, and access to IBCLC services through the CPNP. Each potential variable was first assessed in bivariate screening for its association with each outcome, using chi-square tests for

categorical variables and t-tests for continuous variables. Variables with p-values less than 0.15 in bivariate screening were included in the multivariable logistic regression models for each outcome. Prior to modeling, multicollinearity was assessed using tolerance statistics. A tolerance value of <0.4 was used as the cut-point for the presence of multicollinearity. In such cases, only one member of a correlated set would be retained for the multivariable model.

The models were developed to meet the statistical requirements for the number of covariates in a valid logistic regression model. If the model did not have numerical tolerance for all identified covariates, those deemed most relevant to the objective and with lowest p-values were retained. Model fit was assessed using the Hosmer-Lemeshow goodness-of-fit test and area under the curve. Results are presented using odds ratios and their associated 95% confidence intervals.

We also conducted an exploratory analysis with the subsample of participants who had access to IBCLC services through the CPNP sites. We followed the procedures described above to assess the effect of receiving IBCLC visits on the association between expressed HM use at two weeks postpartum and HM feeding outcomes. In addition to the potential exposure variables noted above, bivariate screening included the number of IBCLC visits received (0, 1 or >1) and multivariable logistic regression models tested for the interaction between expressed HM use and the number of IBCLC visits. If the interaction was not significant, the interaction term was removed and the model rerun.

All statistical analyses were performed using IBM SPSS Statistics for Windows, version 26 (IBM Corp., Armonk, N.Y., USA).

RESULTS

There were 287 potential participants for Study A and 215 for Study B, of whom 337 were enrolled and 331 provided infant feeding data (Fig. 1). Study retention was high (93%), and 315 participants provided data on expressed HM feeding at six months postpartum. Fourteen participants attended more than one CPNP site and enrolled in both studies simultaneously, and three participants

enrolled in both studies but for separate pregnancies. Only the Study A record was retained for each of these participants in the pooled dataset, in order to account for their access to IBCLC services. The mean age of participants was 32 years, the majority (66%) had post-secondary education and 50% were primiparous (Table 1). Ethnic diversity was high in our sample, and 91% of participants were immigrants to Canada, with 38% having lived in Canada for less than three years. Nearly half (44%) reported household food insecurity.

Table 1. Participant characteristics

Characteristic	Indicator	n (%)
Age (N=330)	mean age (SD): 31.9 years (4.9)	
Education (N=331)	≤ high school post-secondary	113 (34.1) 218 (65.9)
Parity (N=330)	primiparous multiparous	167 (50.6) 163 (49.4)
Newcomer status (N=331)	<1 year in Canada 1 to <3 years in Canada ≥3 years in Canada born in Canada	46 (13.9) 80 (24.2) 175 (52.9) 30 (9.1)
Ethnicity (N=326)	East Asian Other Asian African Latin American European/Caribbean/Other	129 (39.6) 51 (15.6) 42 (12.9) 59 (18.1) 45 (13.8)
Infant sex (N=331)	male female	176 (53.2) 155 (46.8)
Household food security (N=316)	secure marginal insecurity moderate insecurity severe insecurity	176 (55.7) 31 (9.8) 74 (23.4) 35 (11.1)
Household income (Study A only; N=197)	below Low Income Cut-Off above Low Income Cut-Off don't know/prefer not to answer	108 (54.8) 71 (36.0) 18 (9.1)
Proportion of regular expenses met by household income[a] (Study B only; N=124)	all most some very little none don't know/prefer not to answer	60 (48.4) 30 (24.2) 21 (16.9) 10 (8.1) 1 (0.8) 2 (1.6)

Receipt of maternity benefits[b] (Study B only; N=124)	no	85 (68.5)
	yes	38 (30.6)
	don't know/prefer not to answer	1 (0.1)

[a]Categorical variable from Statistics Canada Employment Insurance Coverage Survey, used to assess household income adequacy to meet regular expenses during the first six months postpartum. [b]Categorical variable used to assess receipt of maternity benefits through the federal Employment Insurance program, which has eligibility criteria based on prior employment.

All participants initiated HM feeding but in-hospital formula supplementation was common (57%) (Table 2). Eighty per cent of participants continued feeding HM for at least six months but exclusivity was low. Of the total sample, only 28% practiced exclusive HM feeding post-discharge to four months, and 16% to six months. Nearly three-quarters of all study participants had access to IBCLC services through the CPNP sites. Of these, 72% used the service, with 36% receiving one visit, 30% receiving two visits, and 6% receiving more than two visits.

Table 2. Infant feeding practices and utilization of IBCLC services (N=333)

Indicator	n (%)
Initiated human milk feeding	333 (100.0)
Infant received formula in hospital (N=325)	186 (57.2)
Continued human milk feeding for 6 months (N=323)	257 (79.6)
Exclusively fed human milk for at least 4 months (N=320)	91 (28.4)
Exclusively fed human milk for 6 months (N=322)	52 (16.1)
Access to IBCLC services through the CPNP	245 (73.6)
Received ≥1 IBCLC visit (N=245)	177 (72.2)

IBCLC=International Board Certified Lactation Consultant. CPNP=Canada Prenatal Nutrition Program.

At two weeks postpartum, 34% of participants reported using expressed HM (Table 3). The frequency dropped at each subsequent data collection point to 8% at six months. Nine participants (3%) provided expressed HM at all time points, while 49% never provided expressed HM. Most participants who provided expressed HM used it for at least one daily feed at all time points (75% at 2 weeks, 78% at 2 and 4 months, and 69% at 6 months). The provision of expressed HM as a top-up to feeds at the

breast was greatest at two weeks postpartum (6%), and by six months only one participant was using expressed HM in this way (Table 3).

Table 3. Expressed human milk feeding practices

Time Point	any expressed HM n (%)	daily expressed HM feeds n (%)	occasional expressed HM feeds n (%)	daily expressed HM top-ups n (%)
2 weeks	107 (33.8) N=317	80 (25.5) N=314	7 (2.2) N=314	20 (6.4) N=314
2 months N=319	79 (24.8)	62 (19.4)	11 (3.4)	7 (2.2)
4 months N=319	46 (14.4)	36 (11.3)	7 (2.2)	4 (1.3)
6 months N=315	26 (8.3)	18 (5.7)	7 (2.2)	1 (0.3)

HM=human milk. Occasional=less than daily frequency. Top-ups=expressed HM provided immediately after feeding at the breast. Note: both daily expressed HM feeds and top-ups to were provided by 3 participants at 2 weeks and by 1 participant at 2 months.

For Study B participants (n=112), the mean breastfeeding self-efficacy score at two weeks postpartum was significantly lower among those using expressed HM [mean (Standard Deviation): 47.8 (13.6) vs. 58.6 (10.6); p<0.001].

Table 4 presents the associations between any use of expressed HM at two weeks postpartum and HM feeding outcomes. All multivariable regression models demonstrated goodness-of-fit based on the Hosmer-Lemeshow test (p>0.05) and area under the curve (>0.7). In the adjusted analyses, expressed HM use at two weeks postpartum was associated with cessation of HM feeding before six months (OR 2.66; 95% CI: 1.41-5.05) and with non-exclusive HM feeding to four months (OR 2.19; 95% CI: 1.16-4.14) and to six months (OR 3.65; 95% CI: 1.50-8.84). In-hospital formula supplementation was also associated with cessation of HM feeding before six months (OR 2.37; 95% CI 1.16-4.84) and non-exclusive HM feeding to four months (OR 4.46; 95% CI 2.47-8.02) and six months (OR 3.45; 95% CI 1.67-7.15). Other variables significantly associated with cessation of HM feeding were multiparity (OR 2.52; 95% CI 1.31-4.86), not having access to IBCLC visits through the CPNP (OR 2.21; 95% CI 1.08-4.52)

and ethnicity (p=0.02). Participants of self-reported African origin were least likely to stop HM feeding before six months postpartum in comparison with all other ethnicity categories (Supplemental File 1). Ethnicity was not associated with exclusivity of HM feeding but education below post-secondary was associated with non-exclusive HM feeding for six months (OR 2.48; 95% CI 1.11-5.52).

Table 4. Multivariable logistic regression results: associations between expressed human milk use at two weeks postpartum and human milk feeding outcomes

Model	Outcome (sample size for unadjusted; adjusted)	Odds Ratio (95% Confidence Intervals)			
		Unadjusted	p-value	Adjusted	p-value
1	Cessation before 6 months (N=309; N=296)	3.01 (1.69-5.35)	**<0.001**	2.66 (1.41-5.05)	**0.003**
2	Non-exclusive human milk feeding post-discharge for 4 months (N=311; N=300)	2.70 (1.51-4.84)	**0.001**	2.19 (1.16-4.14)	**0.016**
3	Non-exclusive human milk feeding post-discharge for 6 months (N=310; N=299)	4.00 (1.74-9.23)	**0.001**	3.65 (1.50-8.84)	**0.004**

IBCLC=International Board Certified Lactation Consultant. Model 1 adjusted for parity, hospital formula, ethnicity and access to IBCLC services; Model 2 adjusted for hospital formula and ethnicity; Model 3 adjusted for hospital formula, ethnicity and post-secondary education.

In the subsample of participants with access to IBCLC services through the CPNP sites, expressed HM use at two weeks was associated with HM feeding cessation (OR 4.66; 95% CI 2.10-10.34) and non-exclusive HM feeding to six months (OR 3.44; 95% CI 1.12-10.61) in the multivariable regression models (Table 5). There was also an association with non-exclusive HM feeding to four months in unadjusted analysis but significance was not retained in the adjusted model (OR 1.50; 95% CI 0.69-3.28). There was no significant interaction between the number of IBCLC visits and use of expressed HM at two weeks postpartum in any of the models. However, not receiving an IBCLC visit compared with receipt of either 1 or >1 visit was an independent predictor of HM feeding cessation (p=0.003). Receipt of >1 IBCLC visit compared with 1 visit was associated with non-exclusive HM feeding for six months (OR 3.74; 95% CI 1.35-10.31). These models demonstrated goodness-of-fit based on the Hosmer-Lemeshow test (p>0.05) and area under the curve (>0.7).

Table 5. Multivariable logistic regression results: associations between expressed human milk use at two weeks postpartum and human milk feeding outcomes in the subsample with access to IBCLC services through the CPNP

Model	Outcome (sample size for unadjusted; adjusted)	Odds Ratio (95% Confidence Intervals)			
		Unadjusted	p-value	Adjusted	p-value
4	Cessation before 6 months (N=234; N=231)	2.87 (1.43-5.74)	**0.003**	4.66 (2.10-10.34)	**<0.001**
5	Non-exclusive human milk feeding post-discharge for 4 months (N=233; N=223)	2.15 (1.08-4.27)	**0.028**	1.50 (0.69-3.28)	0.305
6	Non-exclusive human milk feeding post-discharge for 6 months (N=234; N=229)	4.55 (1.55-13.36)	**0.006**	3.44 (1.12-10.61)	**0.031**

IBCLC=International Board Certified Lactation Consultant. Model 4 adjusted for parity and number of IBCLC visits; Model 5 adjusted for hospital formula, ethnicity and number of IBCLC visits; Model 6 adjusted for hospital formula and number of IBCLC visits.

DISCUSSION

In this prospective study, expressed HM use was common in a multi-ethnic cohort of socially and economically vulnerable women, with the highest prevalence at two weeks postpartum (34%). In adjusted analysis, use of expressed HM at two weeks postpartum, regardless of the intensity of use, was associated with cessation of any HM feeding before six months and with non-exclusive HM feeding to both four and six months postpartum. These findings demonstrate that early postpartum use of expressed HM may not support longer-term recommended HM feeding practices.

There are few prior studies examining the association between early postpartum expressed HM use and later HM feeding practices, and differences in study methods limit comparability. In an Australian cohort study, 46% of participants (n=914) provided expressed HM during the postpartum hospital stay; in adjusted analysis, not feeding exclusively at the breast in the first 24-48 hours predicted cessation of any and exclusive HM feeding before six months, but the specific association between expressed HM feeding and later practices was not assessed.[6] In an American study (n=946), expressing HM within the first three weeks postpartum predicted HM feeding cessation by 12 weeks, while pumping after three weeks was protective of continued HM feeding.[31] A pooled analysis of two

cohort studies in Hong Kong (n=2450) found that only exclusive use of expressed HM at one month postpartum predicted cessation of any HM feeding before six months, and did not find a significant association with exclusive HM feeding in the adjusted analysis.[16] However, "exclusive expressed HM" was determined by the proportion of HM feeds, not all feeds, that were expressed HM, and use of formula or other milks was not reported. In addition, by one month postpartum, 35% of the sample had already stopped any HM feeding and were not included in the analysis.

Secondary analyses of the Infant Feeding Practices Study II in the United States found that pumping before 1.5 months postpartum, regularly, and for non-elective reasons (such as difficulties feeding at the breast or return to work) increased the risk of cessation of both any and exclusive HM feeding.[14, 15] We did not collect data on reasons for expressed HM use, but based on the patterns we observed, we hypothesize that our findings reflect the use of expressed HM as a strategy to manage the early stages of lactation and suggest it may be a marker of difficulties feeding at the breast. This aligns with our finding that breastfeeding self-efficacy scores were significantly lower among Study B participants using expressed HM at two weeks postpartum. Other studies have found difficulties feeding at the breast and concerns about milk supply to be commonly reported reasons for expressed HM use during the hospital stay,[6, 32] and up to 4.5 months postpartum.[3, 4, 33] These are also the most common reasons reported for early cessation of any and exclusive HM feeding.[34, 35] Using expressed HM to address early lactation concerns may result in disruption to the establishment of a full milk supply, which relies on frequent suckling and effective milk removal by the infant.[36] Use of a high quality breast pump which mimics infant suckling may assist in this process, but this requires frequent pumping sessions with full drainage of the breasts.[36] We also found that, in addition to expressed HM use, in-hospital formula supplementation and not having access to IBCLC services through the CPNP predicted early cessation of HM feeding in our cohort.

Taken together, these findings reinforce long-standing guidance on the need for both hospitals and community services to support women to successfully establish and maintain lactation through prenatal preparation, access to skilled lactation support from birth, enhanced breastfeeding self-efficacy and maternal mental health care.[32, 37-40]. These findings also suggest that breast pump provision should be embedded within a larger framework of lactation education and skilled support to avoid or reduce potential unintended negative influences on continued HM feeding. Explicit information on the benefits and risks of pumping is currently lacking in Canadian infant feeding guidelines.[22]

The findings have implications for strengthening the specific programs that provided the context for this study, and beyond. Three-quarters of participants had access to free, in-home IBCLC visits for postpartum lactation support and 72% of these did receive at least one visit. The results suggest this specific localized intervention could be strengthened through greater focus on the establishment of lactation, including prenatal preparation.[41] Maternal mental health care is also critical in this study population, as immigrant women are at higher risk of postpartum depression.[42]

Strengths and limitations

Strengths of this study include prospective data collection at multiple time points over the first six months postpartum with a short recall period to improve data accuracy.[43] Data collection included the proportion of feeds that were expressed HM and the use of expressed HM as a top-up to feeding at the breast, which provide more nuanced understanding of expressed HM feeding practices. There were high recruitment and retention rates in both Study A and B, which we attribute to the embeddedness of the lead researchers (AM and JF) in the weekly CPNP programs, which helped build trust and rapport with vulnerable study participants.[44]

A limitation is that we did not collect data on pump ownership or use, which are needed for a full understanding of HM production and feeding practices.[45] We also did not assess participants' intentions regarding pump use or expressed HM feeding, reasons for providing expressed HM,

experiences with lactation difficulties in the early postpartum period or employment status. Inclusion of these data is recommended for future studies. We were unable to include income or breastfeeding self-efficacy as potential covariates in our regression analyses as these data were not collected consistently between the two studies. The multivariable regression models assessing associations with HM feeding cessation and non-exclusive HM feeding for six months did not have room for all potential predictors identified in bivariate screening, while few predictors were identified for non-exclusive HM feeding for four months. Thus, we may not have identified or included all relevant covariates, although all models demonstrated goodness-of-fit. The findings are not generalizable to other CPNP sites or to the population in general, and all data were self-reported by participants. This introduces risk of recall and social desirability biases, which may have resulted in higher than actual rates of any and exclusive HM feeding. These biases were mitigated through the use of prospective data collection with a short recall period, rapport building with participants and collecting data on all infant feeding practices, not just HM.

CONCLUSION

In a multi-ethnic cohort of vulnerable women attending the CPNP at three sites in Toronto, expressed HM use was highest at two weeks postpartum, and this was associated with increased risk of early HM feeding cessation and non-exclusive HM feeding for four and six months postpartum. These findings suggest that feeding expressed HM in the early postpartum period may be a marker of lactation difficulties, but further research is needed to confirm this. The majority of study participants had access to free, in-home IBCLC visits through the participating CPNP sites, and this study provides insights to strengthen and tailor this intervention. A greater focus on prenatal preparation for lactation and access to skilled lactation support in the immediate postpartum period is recommended to assist in the establishment of effective feeding at the breast and to build breastfeeding self-efficacy in order to enable women to achieve their HM feeding goals.

Author contributions

AM contributed to the design and conceptualization of the work, led implementation and data collection for Study B, conducted primary data analysis for this work, drafted the manuscript and finalized it for submission. JF contributed to the design and conceptualization of the work, led implementation and data collection for Study A, assisted with data analysis for this work and critically reviewed the manuscript. SS, BU, YN and CR facilitated the integration of research activities into the community CPNP programs and critically reviewed the manuscript. EDR contributed to the design and conceptualization of the work, including the designs of both Study A and B, and critically reviewed the manuscript. CLD contributed to the design and conceptualization of the work, including the design of Study B, and critically reviewed the manuscript. AK provided oversight to the statistical analysis and critically reviewed the manuscript. DLO and DWS gave oversight to the design and conceptualization of the study and to Study A and B, provided support for data collection and analysis, and critically reviewed the manuscript. All authors gave final approval of the manuscript.

Competing Interests

None declared.

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Data sharing

The datasets generated and/or analyzed for this study are not publicly available in order to protect participant anonymity and confidentiality.

Ethics statement

Ethics approval was obtained for Studies A and B from the Office of Research Ethics at the University of Toronto (protocol #34482 and #35845, respectively). Study B was also approved by the Research Ethics Board of Toronto Public Health (#2018-11). All participants provided written informed consent to participate.

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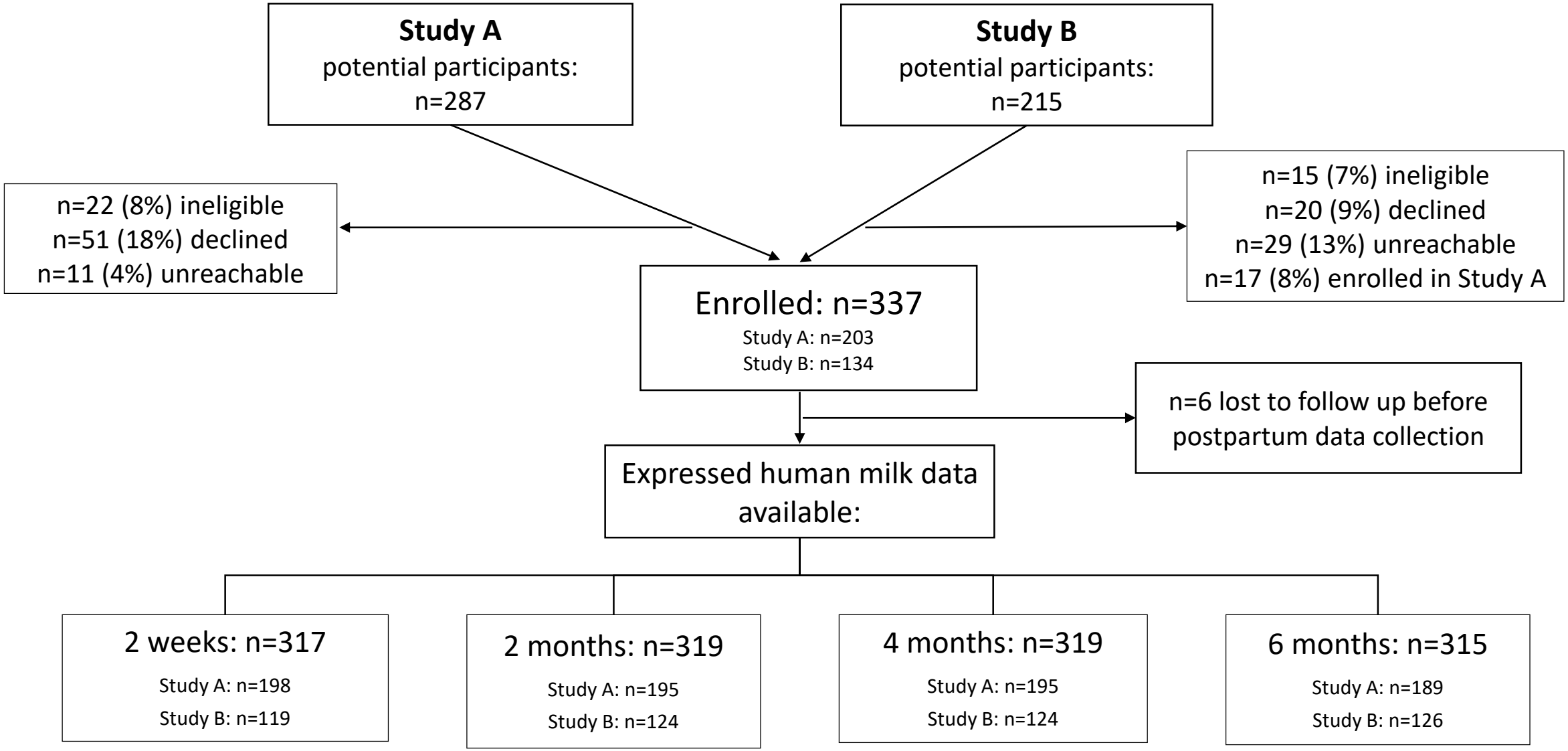
List of figures

Figure 1. Participant flow diagram

Supplemental file

Supplemental Table 1. Multivariable logistic regression analysis: between-category comparison for association between ethnicity and cessation of any human milk feeding by 6 months postpartum


Study A
potential participants:
n=287
Study B
potential participants:
n=215
n=22 (8%) ineligible
n=51 (18%) declined
n=11 (4%) unreachable
n=15 (7%) ineligible
n=20 (9%) declined
n=29 (13%) unreachable
n=17 (8%) enrolled in Study A
Enrolled: n=337
Study A: n=203
Study B: n=134
n=6 lost to follow up before postpartum data collection
Expressed human milk data available:
2 weeks: n=317
Study A: n=198
Study B: n=119
2 months: n=319
Study A: n=195
Study B: n=124
4 months: n=319
Study A: n=195
Study B: n=124
6 months: n=315
Study A: n=189
Study B: n=126

Supplemental Table 1. Multivariable logistic regression analysis: between-category comparison for association between ethnicity and cessation of any human milk feeding by 6 months postpartum.

Ethnicity category*	Adjusted Odds Ratio (95% Confidence Intervals)	p-value
East Asian	5.03 (1.06-23.92)	0.042
Other Asian	6.43 (1.17-35.43)	0.033
European/Caribbean/Other	14.42 (2.63-78.97)	0.002
Latin American	9.48 (1.82-49.53)	0.008

*Reference category: African ethnicity.

Model adjusted for expressed human milk use at two weeks postpartum, parity, hospital formula, and access to IBCLC services through the CPNP.

IBCLC=International Board Certified Lactation Consultant; CPNP=Canada Prenatal Nutrition Program.

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*
Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2-3
Objectives	3	State specific objectives, including any pre-specified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	4-5
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	n/a
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-7
Bias	9	Describe any efforts to address potential sources of bias	5, 16-17
Study size	10	Explain how the study size was arrived at	9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8-9
		(*b*) Describe any methods used to examine subgroups and interactions	9
		(*c*) Explain how missing data were addressed	8
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	n/a

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	n/a
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9/Fig 1
		(b) Give reasons for non-participation at each stage	9/Fig 1
		(c) Consider use of a flow diagram	Fig 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9-11
		(b) Indicate number of participants with missing data for each variable of interest	Tables p.10-14
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	9/Fig 1
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	11
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	13-14
		(*b*) Report category boundaries when continuous variables were categorized	n/a
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	12-14
Discussion			
Key results	18	Summarise key results with reference to study objectives	14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	16-17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	17
Generalisability	21	Discuss the generalisability (external validity) of the study results	17
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	18

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.
Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Associations between use of expressed human milk at two weeks postpartum and human milk feeding practices to six months: a prospective cohort study with vulnerable women in Toronto, Canada

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Associations between use of expressed human milk at two weeks postpartum and human milk feeding practices to six months: a prospective cohort study with vulnerable women in Toronto, Canada

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Associations between use of expressed human milk at two weeks postpartum and human milk feeding practices to six months: a prospective cohort study with vulnerable women in Toronto, Canada

ABSTRACT

Objectives: To examine whether use of expressed human milk in the first two weeks postpartum is associated with cessation of human milk feeding and non-exclusive human milk feeding up to six months.

Design: pooled data from two prospective cohort studies

Setting: three Canada Prenatal Nutrition Program (CPNP) sites serving vulnerable families in Toronto, Canada

Participants: 337 registered CPNP clients enrolled prenatally from 2017-2020; 315 (93%) were retained to six months postpartum. Exclusions: pregnancy loss or participation in prior related study; Study B: preterm birth (<34 weeks); plan to move outside Toronto; not intending to feed human milk; hospitalization of mother or baby at two weeks postpartum.

Primary and Secondary Outcome Measures: *Main exposure variable*: any use of expressed human milk at two weeks postpartum. *Outcomes*: cessation of human milk feeding by six months; non-exclusive human milk feeding to four months and six months postpartum.

Results: All participants initiated human milk feeding and 80% continued for six months. Exclusive human milk feeding was practiced post-discharge to four months by 28% and to six months by 16%. At two weeks postpartum, 34% reported use of expressed human milk. Any use of expressed human milk at two weeks was associated with cessation of human milk feeding before six months postpartum (aOR

2.66; 95% CI: 1.41-5.05) and with non-exclusive human milk feeding to four months (aOR 2.19; 95% CI 1.16-4.14) and six months (aOR 3.65; 95% CI 1.50-8.84).

Conclusions: Early postpartum use of expressed human milk predicted early cessation and non-exclusive human milk feeding for four and six months postpartum among vulnerable women living in an urban Canadian context and accessing community perinatal programs. Further research is needed to determine whether early use of expressed human milk is a marker of lactation difficulties or undermines longer-term human milk feeding practices.

Registration: Clinicaltrials.gov NCT03400605, NCT03589963.

Key words: human milk, milk expression, lactation, infant feeding

ARTICLE SUMMARY

Strengths and limitations of this study:

- This is one of the first studies to examine expressed human milk use by vulnerable women.
- Infant feeding data were collected prospectively at 4 time points from two weeks to six months postpartum, limiting the recall period to improve data accuracy.
- Analysis of associations between expressed human milk use and later human milk feeding practices focused on the first two weeks postpartum when lactation is being established.
- Data collection did not include intentions to pump or feed expressed human milk, reasons for use of expressed human milk or maternal employment status.

BACKGROUND

The World Health Organization (WHO) recommendation that all infants receive exclusive human milk (HM) feeding for the first six months of life in order to optimize health and development outcomes is an important global public health goal.[1] The WHO definition does not differentiate between

feeding HM directly at the breast and HM expressed either by hand or use of a breast pump and fed to the infant via a cup, bottle or other device.[2] Over the past two decades breast pump use has become widespread in high-income countries and the provision of expressed HM is now a major component of HM feeding for many families with term-born infants.[3-5] Several studies have found high rates of obtaining pumps by the early postpartum period including use of expressed HM during the hospital stay.[4, 6, 7] However, there is growing evidence that expressed HM is not equivalent to HM obtained through direct feeding at the breast. Observational studies with large sample sizes have found that provision of expressed HM but no formula is associated with higher risks of otitis media, wheezing and rapid weight gain within the first year of life in comparison to exclusive feeding at the breast.[8-10] These findings have prompted the call for more nuanced assessment of HM feeding practices to include data on pumping and use of expressed HM.[11, 12]

In addition to concerns about health effects, use of expressed HM feeding has been associated with shorter duration of any and exclusive HM feeding, although findings are mixed.[13] It is likely that this inconsistency relates to variations between studies in factors such as infant age at the start of pumping or expressed HM feeding, and reasons for providing and degree of reliance on expressed HM. Recent analyses of longitudinal prospective cohort studies have found that pumping and/or expressed HM feeding earlier in the postpartum period, for non-elective reasons (ie. to manage difficulties feeding at the breast or return to work) and with higher frequency is associated with early cessation of any and exclusive HM feeding.[7, 14-16] However, the samples in these studies tend to be biased towards women of higher-socioeconomic status so may not reflect expressed HM feeding practices of more vulnerable women.

In this paper we report expressed HM feeding practices and associated HM feeding outcomes over the first six months postpartum among women recruited through the Canada Prenatal Nutrition Program (CPNP; a national program designed to serve socially and/or economically vulnerable women)

at three sites in Toronto. Our objectives were to examine: i) the prevalence of expressed HM use at two weeks and two, four and six months postpartum; and ii) associations between use of expressed HM at two weeks and HM feeding outcomes (cessation before six months and non-exclusive HM feeding to four and six months postpartum).

METHODS

Study setting and participants

This analysis utilizes infant feeding data collected prospectively from birth mothers in two studies conducted within a research program designed to examine the potential for delivering postnatal lactation support through the CPNP. The CPNP is a federally funded initiative implemented through community agencies with the aims of improving birth outcomes and HM feeding among vulnerable women, such as those with low income or education, newcomers, adolescents, single parents and those with a history of trauma or substance use.[17] CPNP activities vary between sites based on local needs and available partnerships, but are usually implemented as weekly drop-in programs. Core services include group health and nutrition education, provision of food and/or grocery vouchers, individual supports such as nutrition counseling, and referrals to other community services.[17]

Participants in both studies were registered in the CPNP at one of three specific sites in Toronto, Canada, and were recruited prenatally. The population of the combined catchment areas of the three CPNP sites is over 180,000. Detailed methods for both studies have been published previously. Study A was a prospective cohort study of infant feeding practices among clients of a CPNP site offering skilled postnatal lactation support with additional charitable funding from The Sprott Foundation.[18] Study B was a pre/post intervention study designed to examine the effectiveness of implementing similar lactation support services in two other CPNP sites.[19] The target sample size for Study B was 210, based on an anticipated 20 percentage point difference in exclusive HM feeding at four months

postpartum between the pre- and post-intervention groups, with 80% power, alpha=0.05, and allowance for 10% attrition.[19]

Inclusion criteria were prenatal registration in one of the CPNP sites, and for Study B, intention to feed human milk and to continue living in Toronto with the infant. Exclusion criteria were pregnancy loss and for Study A, participation in a prior related study. Exclusion criteria for Study B were preterm birth (<34 weeks gestation), medical issue affecting feeding and hospitalization of either the mother or infant at two weeks postpartum. Recruitment was conducted from August 2017-January 2020 for Study A and from November 2018-March 2020 for Study B. Due to the COVID-19 pandemic, Study B was suspended in March 2020 following a brief intervention period and incomplete recruitment of the post-intervention group, but data collection was completed with all enrolled participants. Data from Study B participants recruited to both the pre- and post-intervention groups were pooled with Study A data for the current analysis.

All participants in Study A and those recruited to the post-intervention group in Study B had access to two free, in-home visits from an International Board Certified Lactation Consultant (IBCLC) for postpartum lactation support, with additional visits approved for complex needs. This service was promoted prenatally and offered pro-actively by telephone call around the time of birth. Double-electric breast pumps were provided by the IBCLCs as needed, but criteria for pump provision were more flexible for Study A participants as the lactation support was provided as a community program rather than a research intervention.

Patient and public involvement statement

Participants in this study were not clinical patients but clients of community perinatal services. At the time of the study, no engagement committee existed for these service-users to inform the research. The community programs had participant feedback mechanisms in place regarding service

delivery. Community program staff were directly involved in the design, implementation, interpretation of findings and reporting of this research, including contributing service-user perspectives.

Data collection

All data collection for Study A was conducted by JF and for Study B by AM or a Mandarin speaking research assistant. Data collection occurred either in person at the participating CPNP sites or by telephone. Professional interpreter services were used for Study A participants who did not speak English (n=14) and Study B participants who did not speak either English or Mandarin (n=20).

In Studies A and B, infant feeding data were collected prospectively at two weeks and two, four and six months postpartum using the same standardized and validated interviewer-administered questionnaire used previously by our group.[20, 21] In Study B, data were also collected at postpartum months one, three and five, but only the time points shared with Study A are reported here. At each time point, participants reported the average number of milk feeds provided to their infant per 24 hours, divided into feeds at the breast, expressed HM feeds and formula feeds. Expressed HM or formula use as a top-up after feeding at the breast was recorded as well as provision of other liquids and introduction of solids. The recall period was two weeks. Infant sex and in-hospital formula supplementation (yes/no) were recorded at the first postpartum contact. Participants who stopped all HM feeding were asked to recall the last date they provided any HM to their infant and main reasons for cessation.

Participants were categorized as yes or no for any HM feeding, exclusive HM feeding and any expressed HM feeding at each postpartum time point. Exclusive HM feeding was defined as provision of HM only, either at the breast or expressed, with the exception of vitamins, medicines and infrequent (less than daily) water feeds. In accordance with WHO and Health Canada guidance to introduce solids 'around' six months postpartum, participants who introduced solids up to 14 days prior to six months but otherwise provided only HM were classified as exclusively HM feeding at six months postpartum.[1,

22] Participants who were exclusively HM feeding at two weeks, two months and four months were classified as practicing exclusive HM feeding post-discharge to four months, and those who were also exclusively HM feeding at six months were classified as practicing exclusive HM feeding post-discharge to six months. Hospital formula supplementation (yes/ no) was considered an independent predictor of HM feeding outcomes.[23]

Maternal socio-demographic data were collected via interviewer-administered questionnaire prenatally in Study B and at two weeks postpartum in Study A. Socio-demographics included maternal age (years); parity (primiparous, multiparous); education level (high school or less, post-secondary); length of time in Canada (<1 year, 1 to <3 years, ≥3 years, born in Canada); and ethnicity. Participants self-reported their ethnicity using a standardized list of geographically-based options developed and validated for a large birth cohort study based in Toronto.[24] Based on the distribution of responses to the list of geographically-based ethnicities, five categories were defined for analysis (East Asian, Other Asian, African, Latin American, and European/Caribbean/Other).

Gestational age at birth was assessed using participant-reported due dates and infant birth dates. Participants who gave birth before 37 completed weeks of gestation were classified as having a preterm birth, with late preterm defined as 34 to <37 completed weeks and moderate preterm as 32 to <34 completed weeks.[25]

In Study A, household income was assessed at two weeks postpartum and classified as above or below the Statistics Canada size-adjusted Low Income Cut-Off.[26] In Study B, household income adequacy was assessed at six months postpartum and classified as meeting all, most, some, very little or none of regular household expenses, using standardized questions from Statistics Canada's Employment Insurance Coverage Survey.[27] Participants in Study B were also asked about receipt of federal Employment Insurance maternity leave benefits (yes/no). In both studies, food insecurity was assessed at six months postpartum using the Household Food Security Survey Module of the Canadian

Community Health Survey, and classified as none, marginal, moderate, severe based on the number of affirmative responses.[28, 29]

Receipt of the IBCLC services (yes/no) and number of IBCLC visits (0, 1, >1) was recorded from CPNP site records for Study A participants and from research records of Study B participants recruited to the post-intervention group. Although some participants received breast pumps through the IBCLCs, we did not collect data on the use of these pumps or participants' access to pumps through other sources.

In Study B only, the Breastfeeding Self-Efficacy Scale-Short Form was administered at two weeks postpartum.[30] This is a validated and widely used 14-item scale which produces a score from 14-70, with higher scores indicating greater breastfeeding self-efficacy.

Statistical analysis

Descriptive statistics were calculated for all variables of interest. Continuous measures such as age were summarized using means and standard deviations whereas categorical measures were summarized using counts and percentages. For Study B only, a t-test was used to compare mean breastfeeding self-efficacy scores between participants who did and did not use expressed HM at two weeks postpartum.

Associations between any expressed HM use at two weeks postpartum and HM feeding outcomes were first assessed by chi-square tests then studied further using multivariable logistic regression analysis. Participants with data for all exposure variables and the outcome measure were included each model. Outcome measures were: i) cessation of any HM feeding before six months postpartum; ii) non-exclusive HM feeding post-discharge to four months postpartum; and iii) non-exclusive HM feeding post-discharge to six months postpartum. The global recommendation is exclusive HM feeding for six months,[1] but a separate analysis of Study B data showed that this practice was frequently compromised after four months by introduction of solids and non-formula fluids.[31] We

therefore assessed non-exclusive HM feeding to both four and six months in order to examine associations with and without the influence of complementary feeding.

Potential exposure variables considered for inclusion in the multivariable logistic regression analysis were: maternal age, education level, parity, years in Canada, geographically-based ethnicity, infant sex, any household food insecurity, household food insecurity category, hospital formula supplementation, and access to IBCLC services through the CPNP. Preterm birth was not considered as the frequency count fell below 10%. Each potential variable was first assessed in bivariate screening for its association with each outcome, using chi-square tests for categorical variables and t-tests for continuous variables. Variables with p-values less than 0.15 in bivariate screening were included in the multivariable logistic regression models for each outcome. Prior to modeling, multicollinearity was assessed using tolerance statistics. A tolerance value of <0.4 was used as the cut-point for the presence of multicollinearity. In such cases, only one member of a correlated set would be retained for the multivariable model.

The models were developed to meet the statistical requirements for the number of covariates in a valid logistic regression model. If the model did not have numerical tolerance for all identified covariates, those deemed most relevant to the objective and with lowest p-values were retained. Model fit was assessed using the Hosmer-Lemeshow goodness-of-fit test and area under the curve. Results are presented using odds ratios and their associated 95% confidence intervals.

As preterm birth could not be included as a covariate, we conducted a sensitivity analysis including only participants with term-born infants. We also conducted an exploratory analysis with the subsample of participants who had access to IBCLC services through the CPNP sites. We followed the procedures described above to assess the effect of receiving IBCLC visits on the association between expressed HM use at two weeks postpartum and HM feeding outcomes. In addition to the potential exposure variables noted above, bivariate screening included the number of IBCLC visits received (0, 1 or

>1) and multivariable logistic regression models tested for the interaction between expressed HM use and the number of IBCLC visits. If the interaction was not significant, the interaction term was removed and the model rerun.

All statistical analyses were performed using IBM SPSS Statistics for Windows, version 26 (IBM Corp., Armonk, N.Y., USA).

RESULTS

There were 287 potential participants for Study A and 215 for Study B, of whom 337 were enrolled and 331 provided infant feeding data (Fig. 1). Study retention was high (93%), and 315 participants provided data on expressed HM feeding at six months postpartum. Fourteen participants attended more than one CPNP site and enrolled in both studies simultaneously, and three participants enrolled in both studies but for separate pregnancies. Only the Study A record was retained for each of these participants in the pooled dataset, in order to account for their access to IBCLC services. The mean age of participants was 32 years, the majority (66%) had post-secondary education and 50% were primiparous (Table 1). Almost all participants had term-born infants, and of the 11 (3%) who gave birth before 37 weeks' gestation, ten were classified as late preterm and one was moderately preterm. Ethnic diversity was high in our sample, and 91% of participants were immigrants to Canada, with 38% having lived in Canada for less than three years. Nearly half (44%) reported household food insecurity.

Table 1. Participant characteristics

Characteristic	Indicator	n (%)
Age (N=330)	mean age (SD): 31.9 years (4.9)	
Education (N=331)	≤ high school post-secondary	113 (34.1) 218 (65.9)
Parity (N=330)	primiparous multiparous	167 (50.6) 163 (49.4)

Newcomer status (N=331)	<1 year in Canada 1 to <3 years in Canada ≥3 years in Canada born in Canada	46 (13.9) 80 (24.2) 175 (52.9) 30 (9.1)
Ethnicity (N=326)	East Asian Other Asian African Latin American European/Caribbean/Other	129 (39.6) 51 (15.6) 42 (12.9) 59 (18.1) 45 (13.8)
Infant sex (N=331)	male female	176 (53.2) 155 (46.8)
Preterm birth (N=326)	no yes	315 (96.6) 11 (3.4)
Household food security (N=316)	secure marginal insecurity moderate insecurity severe insecurity	176 (55.7) 31 (9.8) 74 (23.4) 35 (11.1)
Household income (Study A only; N=197)	below Low Income Cut-Off above Low Income Cut-Off don't know/prefer not to answer	108 (54.8) 71 (36.0) 18 (9.1)
Proportion of regular expenses met by household income[a] (Study B only; N=124)	all most some very little none don't know/prefer not to answer	60 (48.4) 30 (24.2) 21 (16.9) 10 (8.1) 1 (0.8) 2 (1.6)
Receipt of maternity benefits[b] (Study B only; N=124)	no yes don't know/prefer not to answer	85 (68.5) 38 (30.6) 1 (0.1)

[a]Categorical variable from Statistics Canada Employment Insurance Coverage Survey, used to assess household income adequacy to meet regular expenses during the first six months postpartum. [b]Categorical variable used to assess receipt of maternity benefits through the federal Employment Insurance program, which has eligibility criteria based on prior employment.

All participants initiated HM feeding but in-hospital formula supplementation was common (57%) (Table 2). Eighty per cent of participants continued feeding HM for at least six months but exclusivity was low. Of the total sample, only 28% practiced exclusive HM feeding post-discharge to four months, and 16% to six months. Nearly three-quarters of all study participants had access to IBCLC services through the CPNP sites. Of these, 72% used the service, with 36% receiving one visit, 30% receiving two visits, and 6% receiving more than two visits.

Table 2. Infant feeding practices and utilization of IBCLC services (N=333)

Indicator	n (%)
Initiated human milk feeding	333 (100.0)
Infant received formula in hospital (N=325)	186 (57.2)
Continued human milk feeding for 6 months (N=323)	257 (79.6)
Exclusively fed human milk for at least 4 months (N=320)	91 (28.4)
Exclusively fed human milk for 6 months (N=322)	52 (16.1)
Access to IBCLC services through the CPNP	245 (73.6)
Received ≥1 IBCLC visit (N=245)	177 (72.2)

IBCLC=International Board Certified Lactation Consultant. CPNP=Canada Prenatal Nutrition Program.

At two weeks postpartum, 34% of participants reported using expressed HM (Table 3). The frequency dropped at each subsequent data collection point to 8% at six months. Nine participants (3%) provided expressed HM at all time points, while 49% never provided expressed HM. Most participants who provided expressed HM used it for at least one daily feed at all time points (75% at 2 weeks, 78% at 2 and 4 months, and 69% at 6 months). The provision of expressed HM as a top-up to feeds at the breast was greatest at two weeks postpartum (6%), and by six months only one participant was using expressed HM in this way (Table 3).

Table 3. Expressed human milk feeding practices

Time Point	any expressed HM n (%)	daily expressed HM feeds n (%)	occasional expressed HM feeds n (%)	daily expressed HM top-ups n (%)
2 weeks	107 (33.8) N=317	80 (25.5) N=314	7 (2.2) N=314	20 (6.4) N=314
2 months N=319	79 (24.8)	62 (19.4)	11 (3.4)	7 (2.2)
4 months N=319	46 (14.4)	36 (11.3)	7 (2.2)	4 (1.3)
6 months N=315	26 (8.3)	18 (5.7)	7 (2.2)	1 (0.3)

HM=human milk. Occasional=less than daily frequency. Top-ups=expressed HM provided immediately after feeding at the breast. Note: both daily expressed HM feeds and top-ups to were provided by 3 participants at 2 weeks and by 1 participant at 2 months.

For Study B participants (n=112), the mean breastfeeding self-efficacy score at two weeks postpartum was significantly lower among those using expressed HM [mean (Standard Deviation): 47.8 (13.6) vs. 58.6 (10.6); p<0.001].

Table 4 presents the associations between any use of expressed HM at two weeks postpartum and HM feeding outcomes. All multivariable regression models demonstrated goodness-of-fit based on the Hosmer-Lemeshow test (p>0.05) and area under the curve (>0.7). In the adjusted analyses, expressed HM use at two weeks postpartum was associated with cessation of HM feeding before six months (OR 2.66; 95% CI: 1.41-5.05) and with non-exclusive HM feeding to four months (OR 2.19; 95% CI: 1.16-4.14) and to six months (OR 3.65; 95% CI: 1.50-8.84). In-hospital formula supplementation was also associated with cessation of HM feeding before six months (OR 2.37; 95% CI 1.16-4.84) and non-exclusive HM feeding to four months (OR 4.46; 95% CI 2.47-8.02) and six months (OR 3.45; 95% CI 1.67-7.15). Other variables significantly associated with cessation of HM feeding were multiparity (OR 2.52; 95% CI 1.31-4.86), not having access to IBCLC visits through the CPNP (OR 2.21; 95% CI 1.08-4.52) and ethnicity (p=0.02). Participants of self-reported African origin were least likely to stop HM feeding before six months postpartum in comparison with all other ethnicity categories (Supplemental File 1). Ethnicity was not associated with exclusivity of HM feeding but education below post-secondary was associated with non-exclusive HM feeding for six months (OR 2.48; 95% CI 1.11-5.52).

Table 4. Multivariable logistic regression results: associations between expressed human milk use at two weeks postpartum and human milk feeding outcomes

Model	Outcome (sample size for unadjusted; adjusted)	Odds Ratio (95% Confidence Intervals)			
		Unadjusted	p-value	Adjusted	p-value
1	Cessation before 6 months (N=309; N=296)	3.01 (1.69-5.35)	**<0.001**	2.66 (1.41-5.05)	**0.003**
2	Non-exclusive human milk feeding post-discharge for 4 months (N=311; N=300)	2.70 (1.51-4.84)	**0.001**	2.19 (1.16-4.14)	**0.016**
3	Non-exclusive human milk feeding post-discharge for 6 months (N=310; N=299)	4.00 (1.74-9.23)	**0.001**	3.65 (1.50-8.84)	**0.004**

IBCLC=International Board Certified Lactation Consultant. Model 1 adjusted for parity, hospital formula, ethnicity and access to IBCLC services; Model 2 adjusted for hospital formula and ethnicity; Model 3 adjusted for hospital formula, ethnicity and post-secondary education.

These findings were consistent in the sensitivity analysis including only participants with term-born infants. In the subsample of participants with access to IBCLC services through the CPNP sites, expressed HM use at two weeks was associated with HM feeding cessation (OR 4.66; 95% CI 2.10-10.34) and non-exclusive HM feeding to six months (OR 3.44; 95% CI 1.12-10.61) in the multivariable regression models (Table 5). There was also an association with non-exclusive HM feeding to four months in unadjusted analysis but significance was not retained in the adjusted model (OR 1.50; 95% CI 0.69-3.28). There was no significant interaction between the number of IBCLC visits and use of expressed HM at two weeks postpartum in any of the models. However, not receiving an IBCLC visit compared with receipt of either 1 or >1 visit was an independent predictor of HM feeding cessation (p=0.003). Receipt of >1 IBCLC visit compared with 1 visit was associated with non-exclusive HM feeding for six months (OR 3.74; 95% CI 1.35-10.31). These models demonstrated goodness-of-fit based on the Hosmer-Lemeshow test (p>0.05) and area under the curve (>0.7).

Table 5. Multivariable logistic regression results: associations between expressed human milk use at two weeks postpartum and human milk feeding outcomes in the subsample with access to IBCLC services through the CPNP

Model	Outcome (sample size for unadjusted; adjusted)	Odds Ratio (95% Confidence Intervals)			
		Unadjusted	p-value	Adjusted	p-value
4	Cessation before 6 months (N=234; N=231)	2.87 (1.43-5.74)	**0.003**	4.66 (2.10-10.34)	**<0.001**
5	Non-exclusive human milk feeding post-discharge for 4 months (N=233; N=223)	2.15 (1.08-4.27)	**0.028**	1.50 (0.69-3.28)	0.305
6	Non-exclusive human milk feeding post-discharge for 6 months (N=234; N=229)	4.55 (1.55-13.36)	**0.006**	3.44 (1.12-10.61)	**0.031**

IBCLC=International Board Certified Lactation Consultant. Model 4 adjusted for parity and number of IBCLC visits; Model 5 adjusted for hospital formula, ethnicity and number of IBCLC visits; Model 6 adjusted for hospital formula and number of IBCLC visits.

DISCUSSION

In this prospective study, expressed HM use was common in a multi-ethnic cohort of socially and economically vulnerable women with primarily term-born infants, with the highest prevalence at two weeks postpartum (34%). In adjusted analysis, use of expressed HM at two weeks postpartum, regardless of the intensity of use, was associated with cessation of any HM feeding before six months and with non-exclusive HM feeding to both four and six months postpartum. These findings demonstrate that early postpartum use of expressed HM may not support longer-term recommended HM feeding practices.

Prior studies have reported high rates of expressed HM use in high-income countries, with some evidence of lower rates among vulnerable women, such as those with lower education or income.[3, 8, 32] To our knowledge, the only other relevant Canadian data are from the Canadian Healthy Infant Longitudinal Development cohort study (n=2553), in which 55% of participants providing any HM at three months postpartum reported some expressed HM use; 74% continued breastfeeding for at least six months.[8] We found a similar rate of continued breastfeeding but a lower prevalence of expressed HM use. Further studies of expressed HM use in Canada and among vulnerable sub-populations are needed.

There are few prior studies examining the association between early postpartum expressed HM use and later HM feeding practices, and differences in study methods limit comparability. Rates of any and exclusive HM feeding also vary between studies. In an Australian cohort study, 46% of participants (n=914) provided expressed HM during the postpartum hospital stay and 68% were still providing some amount of HM at six months.[6] In adjusted analysis, not feeding exclusively at the breast in the first 24-48 hours predicted cessation of any and exclusive HM feeding before six months, but the specific association between expressed HM feeding and later practices was not assessed, and exclusive HM feeding referred to milk feeds only.[6] In an American study (n=946) in which 71% of participants

continued HM feeding for at least 12 weeks, expressing HM within the first three weeks postpartum predicted HM feeding cessation by 12 weeks, while pumping after three weeks was protective of continued HM feeding.[33] A pooled analysis of two cohort studies in Hong Kong (n=2450) found that only exclusive use of expressed HM at one month postpartum predicted cessation of any HM feeding before six months, and did not find a significant association with exclusive HM feeding in the adjusted analysis.[16] However, "exclusive expressed HM" was determined by the proportion of HM feeds, not all feeds, that were expressed HM, and use of formula or other milks was not reported. The rate of continued HM feeding to six months was low in this study (29%), and by one month postpartum, 35% of the sample had already stopped any HM feeding and were not included in the analysis.[16]

Secondary analyses of the Infant Feeding Practices Study II in the United States found that pumping before 1.5 months postpartum, regularly, and for non-elective reasons (such as difficulties feeding at the breast or return to work) increased the risk of cessation of both any and exclusive HM feeding.[14, 15] We did not collect data on reasons for expressed HM use, but based on the patterns we observed, we hypothesize that our findings reflect the use of expressed HM as a strategy to manage the early stages of lactation and suggest it may be a marker of difficulties feeding at the breast. This aligns with our finding that breastfeeding self-efficacy scores were significantly lower among Study B participants using expressed HM at two weeks postpartum. Other studies have found difficulties feeding at the breast and concerns about milk supply to be commonly reported reasons for expressed HM use during the hospital stay,[6, 34] and up to 4.5 months postpartum.[3, 4, 32] These are also the most common reasons reported for early cessation of any and exclusive HM feeding.[35, 36] Using expressed HM to address early lactation concerns may result in disruption to the establishment of a full milk supply, which relies on frequent suckling and effective milk removal by the infant.[37] Use of a high quality breast pump which mimics infant suckling may assist in this process, but this requires frequent pumping sessions with full drainage of the breasts.[37] We also found that, in addition to expressed HM

use, in-hospital formula supplementation and not having access to IBCLC services through the CPNP predicted early cessation of HM feeding in our cohort.

Taken together, these findings reinforce long-standing guidance on the need for both hospitals and community services to support women to successfully establish and maintain lactation through prenatal preparation, access to skilled lactation support from birth, enhanced breastfeeding self-efficacy and maternal mental health care.[33, 38-41]. These findings also suggest that breast pump provision should be embedded within a larger framework of lactation education and skilled support to avoid or reduce potential unintended negative influences on continued HM feeding. Explicit information on the benefits and risks of pumping is currently lacking in Canadian infant feeding guidelines.[22]

The findings have implications for strengthening the specific programs that provided the context for this study, and beyond. Three-quarters of participants had access to free, in-home IBCLC visits for postpartum lactation support and 72% of these did receive at least one visit. The results suggest this specific localized intervention could be strengthened through greater focus on the establishment of lactation, including prenatal preparation.[42] Maternal mental health care is also critical in this study population, as immigrant women are at higher risk of postpartum depression.[43]

Strengths and limitations

Strengths of this study include prospective data collection at multiple time points over the first six months postpartum with a short recall period to improve data accuracy.[44] Data collection included the proportion of feeds that were expressed HM and the use of expressed HM as a top-up to feeding at the breast, which provide more nuanced understanding of expressed HM feeding practices. There were high recruitment and retention rates in both Study A and B, which we attribute to the embeddedness of the lead researchers (AM and JF) in the weekly CPNP programs, which helped build trust and rapport with vulnerable study participants.[45]

A limitation is that we did not collect data on pump ownership or use, which are needed for a full understanding of HM production and feeding practices.[46] We also did not assess participants' intentions regarding pump use or expressed HM feeding, reasons for providing expressed HM, experiences with lactation difficulties in the early postpartum period or employment status. Inclusion of these data is recommended for future studies. We were unable to include income or breastfeeding self-efficacy as potential covariates in our regression analyses as these data were not collected consistently between the two studies. The multivariable regression models assessing associations with HM feeding cessation and non-exclusive HM feeding for six months did not have room for all potential predictors identified in bivariate screening, while few predictors were identified for non-exclusive HM feeding for four months. Thus, we may not have identified or included all relevant covariates, although all models demonstrated goodness-of-fit. The findings are not generalizable to other CPNP sites or to the population in general, and all data were self-reported by participants. This introduces risk of recall and social desirability biases, which may have resulted in higher than actual rates of any and exclusive HM feeding. These biases were mitigated through the use of prospective data collection with a short recall period, rapport building with participants and collecting data on all infant feeding practices, not just HM.

CONCLUSION

In a multi-ethnic cohort of vulnerable women attending the CPNP at three sites in Toronto, expressed HM use was highest at two weeks postpartum, and this was associated with increased risk of early HM feeding cessation and non-exclusive HM feeding for four and six months postpartum. These findings suggest that feeding expressed HM in the early postpartum period may be a marker of lactation difficulties, but further research is needed to confirm this. The majority of study participants had access to free, in-home IBCLC visits through the participating CPNP sites, and this study provides insights to strengthen and tailor this intervention. A greater focus on prenatal preparation for lactation and access

to skilled lactation support in the immediate postpartum period is recommended to assist in the establishment of effective feeding at the breast and to build breastfeeding self-efficacy in order to enable women to achieve their HM feeding goals.

Author contributions

AM contributed to the design and conceptualization of the work, led implementation and data collection for Study B, conducted primary data analysis for this work, drafted the manuscript and finalized it for submission. JF contributed to the design and conceptualization of the work, led implementation and data collection for Study A, assisted with data analysis for this work and critically reviewed the manuscript. SS, BU, YN and CR facilitated the integration of research activities into the community CPNP programs and critically reviewed the manuscript. EDR contributed to the design and conceptualization of the work, including the designs of both Study A and B, and critically reviewed the manuscript. CLD contributed to the design and conceptualization of the work, including the design of Study B, and critically reviewed the manuscript. AK provided oversight to the statistical analysis and critically reviewed the manuscript. DLO and DWS gave oversight to the design and conceptualization of the study and to Study A and B, provided support for data collection and analysis, and critically reviewed the manuscript. All authors gave final approval of the manuscript.

Competing Interests

None declared.

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Data sharing

The datasets generated and/or analyzed for this study are not publicly available in order to protect participant anonymity and confidentiality.

Ethics statement

Ethics approval was obtained for Studies A and B from the Office of Research Ethics at the University of Toronto (protocol #34482 and #35845, respectively). Study B was also approved by the Research Ethics Board of Toronto Public Health (#2018-11). All participants provided written informed consent to participate.

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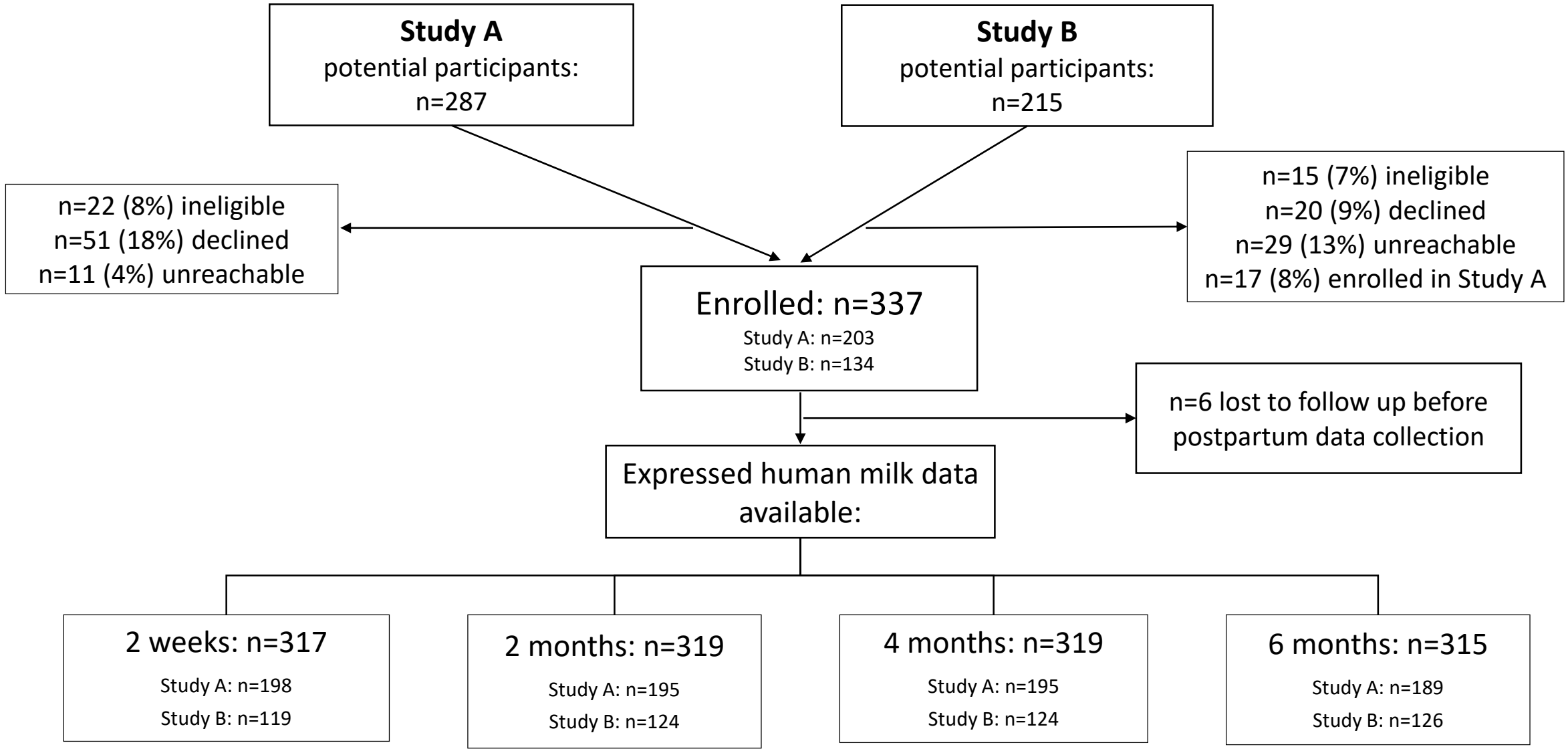
List of figures

Supplemental file


Study A
potential participants:
n=287
Study B
potential participants:
n=215
n=22 (8%) ineligible
n=51 (18%) declined
n=11 (4%) unreachable
n=15 (7%) ineligible
n=20 (9%) declined
n=29 (13%) unreachable
n=17 (8%) enrolled in Study A
Enrolled: n=337
Study A: n=203
Study B: n=134
n=6 lost to follow up before postpartum data collection
Expressed human milk data available:
2 weeks: n=317
Study A: n=198
Study B: n=119
2 months: n=319
Study A: n=195
Study B: n=124
4 months: n=319
Study A: n=195
Study B: n=124
6 months: n=315
Study A: n=189
Study B: n=126

Supplemental Table 1. Multivariable logistic regression analysis: between-category comparison for association between ethnicity and cessation of any human milk feeding by 6 months postpartum.

Ethnicity category*	Adjusted Odds Ratio (95% Confidence Intervals)	p-value
East Asian	5.03 (1.06-23.92)	0.042
Other Asian	6.43 (1.17-35.43)	0.033
European/Caribbean/Other	14.42 (2.63-78.97)	0.002
Latin American	9.48 (1.82-49.53)	0.008

*Reference category: African ethnicity.

Model adjusted for expressed human milk use at two weeks postpartum, parity, hospital formula, and access to IBCLC services through the CPNP.

IBCLC=International Board Certified Lactation Consultant; CPNP=Canada Prenatal Nutrition Program.

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2-3
Objectives	3	State specific objectives, including any pre-specified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4-5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	4-5
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	n/a
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5-7
Bias	9	Describe any efforts to address potential sources of bias	5, 16-17
Study size	10	Explain how the study size was arrived at	9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8-9
		(*b*) Describe any methods used to examine subgroups and interactions	9
		(*c*) Explain how missing data were addressed	8
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	n/a

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	n/a
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9/Fig 1
		(b) Give reasons for non-participation at each stage	9/Fig 1
		(c) Consider use of a flow diagram	Fig 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9-11
		(b) Indicate number of participants with missing data for each variable of interest	Tables p.10-14
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	9/Fig 1
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	11
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	13-14
		(*b*) Report category boundaries when continuous variables were categorized	n/a
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	12-14
Discussion			
Key results	18	Summarise key results with reference to study objectives	14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	16-17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	17
Generalisability	21	Discuss the generalisability (external validity) of the study results	17
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	18

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.
Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.