REFINE

Responsive Feeding of Infants with Expressed Milk

PROTOCOL

Study Title:	**Responsive Feeding of Infants with Expressed Milk (REFINE) Study**
Version:	Version 4.1, September 27, 2019
Funding:	Nova Scotia Health Research Foundation (Establishment Grant #1025)
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Statement of Compliance

This document is a protocol for a modified, randomized cross-over trial. The study will be conducted in compliance with all stipulations of this protocol and the conditions of ethics committee approvals. I agree that the study will be conducted in accordance with the conditions outlined in the protocol (subject to any amendments). I have read and understood the protocol.

KYLY C WHITFIELD
Investigator's name

Investigator's signature

September 27, 2019.
Date

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1. Study Synopsis

1.1 Title

Responsive Feeding of Infants with Expressed Milk (REFINE) Study. Note that this study was funded under the title: 'Feeding infants in Nova Scotia: an exploratory analysis of responsive feeding with mother's milk'

1.2 Objectives

1. To assess if the volume of human milk (HM) consumed by infants differs by feeding modality (bottle feeding HM versus breastfeeding), as assessed by indirect weighs at each feed during a 24-hour period at 6 weeks, 4 months, and 6 months.
2. To determine whether infant anthropometric measurements (length, weight, head circumference) and growth rates (weight-for-age [WAZ], length-for-age [LAZ], weight-for-length [WLZ], BMI-for-age z-scores [BAZ]) differ by self-reported usual feeding modality among infants exclusively consuming human milk.
3. To objectively assess responsiveness of infant feeding practices, both at the breast and during bottle-feeding of HM, by video-recording feeding sessions in participant's homes.
4. To gain a better understanding of current infant feeding practices, including responsive feeding, among caregivers in the Halifax Regional Municipality (HRM), contextualize why women are pumping, and gain insight around how human milk is handled, stored, and prepared through open-ended one-on-one interviews with mothers.

1.3 Outcomes

The primary outcome of this study is the volume of milk consumed over a 24-hour period by feeding modality at 6 weeks, 4 months, and 6 months. Secondary outcomes include anthropometric measurements and growth rates (WAZ, LAZ, WLZ, BAZ) by usual feeding modality, responsiveness of infant feeding practices, and insights in current feeding practices in Nova Scotia.

1.4 Design

Modified, randomized cross-over study.

1.5 Study duration

This is a three-year project, to be completed between August 2018 and July 2021. The study duration for participants is approximately 20 weeks, from 6 weeks to 6 months postnatal.

1.6 Sample size

62 mother-infant dyads.

1.7 Study population: eligibility criteria

Mother-infant dyads are **eligible** to participate if:

- mothers are aged 19 years or older,
- dyads currently live in the Halifax Regional Municipality in Nova Scotia,
- mothers have no chronic diseases,
- the baby is a healthy singleton baby who is younger than 6 weeks of age, and is fed mother's milk directly from the breast and from a bottle,
- mothers plan to exclusively feed their baby mother's milk up to 6 months,
- mothers have an older child whom they successfully fed mother's milk for a minimum of 6 months,
- mothers are willing to participate in three 3-day study sessions and monthly measurement sessions, and
- mothers provide informed consent for herself and her infant to participate.

Mother-infant dyads are **ineligible** to participate if:

- the baby was born preterm (earlier than 37 weeks gestation),
- the baby was born outside the healthy weight range of 2,500 – 4,000 g (5lb 8oz to 8lb 13oz),
- the baby has a developmental delay diagnosed before the time of enrolment,
- the baby is currently receiving any medical treatment, except for vitamin D supplementation (no more than 400 IU/day),
- the mother sought prescription medical treatment for lactation (e.g. domperidone, antibiotics, prescription nipple ointment), or
- the mother plans to move in the 6 months after starting the study.

2. Investigators, Study Locations, and Funding

2.1 Study investigators

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None of the study investigators have conflicts of interests to report.

2.2 Study setting

Centre for Applied Research at Mount Saint Vincent University (47 College Rd, Halifax, Nova Scotia, B3M 2J6), and households in Halifax Regional Municipality, Nova Scotia, Canada.

2.3 Study management

The Principal Investigator and Co-Investigators will oversee the coordination of the study; they will meet monthly, or more often if required.

2.4 Serious Adverse Events Committee / Data Safety Monitoring Board

There is no necessity for a Serious Adverse Events Committee or a Data Safety Monitoring Board (DSMB) in this modified, randomized cross-over trial because of the absence of potential adverse events related to the study. The 'intervention' in this study is simply feeding infants using one of two

modalities that are already familiar to the mother and infant: feeding mother's milk both from the breast and from a bottle.

2.5 Funding

This study is funded through a Nova Scotia Health Research Foundation Establishment Grant (#1025). The funders had no role in study design; and will not play a role in collection, management, analysis, and interpretation of data, writing of the report, nor the decision to submit the report for publication.

3. Introduction, Background, and Rationale

3.1 Human milk: the optimal nutrition for infants

Human milk (HM) is the optimal food for infants with benefits beyond simply meeting the nutritional requirements of the rapidly growing infant (1,2). HM provides numerous bioactives including cytokines, immunoglobulins (particularly secretory IgA), and other anti-pathogenic components such as lactoferrin, that protect infants from bacterial and viral infections (3). It is well-established that breastfeeding lowers the risk of infection, morbidity, and morality (4). In addition, breastfeeding helps promote optimal cognitive development (3). Breastfeeding is also beneficial for mothers, lowering the risk of ovarian and breast cancers (for every 1 year increase in breastfeeding duration, there is a 6% breast cancer risk reduction), and type 2 diabetes (1). For all these reasons, the World Health Organization (WHO) recommends exclusive breastfeeding for the first 6 months, and continued breastfeeding for 2 years and beyond (2).

Although HM is the optimal form of infant nutrition, breastfeeding rates, especially in high-income countries, are suboptimal. Globally, 80% of infants receive at least some HM, however, in most countries only 50% of infants are exclusively breastfed to 6 months, with rates <20% in some high-income countries (1). Almost 90% of Canadian mothers initiate breastfeeding, but by 6 months breastfeeding rates drop to 26% (5). Atlantic Canada has among the lowest rates of exclusive breastfeeding to 6 months in Canada at 23%, compared with 41% in British Columbia (5). These figures refer to consumption of human milk both from the breast, and expressed and fed by other means (e.g. by bottle).

3.2 Feeding infants expressed human milk

In high-income countries, expressing HM (pumping) has become commonplace, replacing some or all HM feedings at the breast (6). This may be attributed to technological advancements in HM pumps (6); stigmatization of breastfeeding, especially in public spaces (7); because it provides a break for mothers to leave their infants for work or other activities; and/or allows other caregivers (e.g. partners) to participate in infant feeding; or any number of other reasons.

Although current global recommendations encourage caregivers to feed expressed HM from a cup or spoon (8), bottles remain the most common feeding tool in Canada. Bottle feeding gives rise to several issues (e.g. nipple confusion (8), potential impaired cranio-facial development (9)), however most importantly here, if 'paced feeding' is not practiced, gravity and caregivers control the feed with little control or effort on behalf of the infant (10).

The Nova Scotia Department of Health and Wellness has a user-friendly *Breastfeeding Basics* resource for new mothers that promotes HM consumption at the breast, and also provides recommendations for HM expression, storage, and re-heating (50). However, there is little guidance on bottle feeding practices, other than not to prop a bottle (dental carie prevention). The *Loving Care: Birth to Six Months* resource also advises caregivers against propping bottles, again to prevent tooth decay, but also to prevent ear infections and choking (51).

The very limited research on pumping to date has been conducted in the US, where most women pumped after returning to work (6). With this, we face a knowledge gap in Canada, where longer, government-supported maternity leaves may influence the rates of pumping and feeding HM in bottles, and reasoning for doing so. More trusted, evidence-based resources such as these may be required to provide guidance on responsive infant feeding, particularly if caregivers feed with bottles.

3.3. Responsive feeding

Responsive feeding is a reciprocal, appropriate, and timely reaction to verbal and non-verbal cues between the caregiver-infant dyad during feeding interactions (52). Responsive feeding promotes infant's attention to internal hunger and satiety cues (53). Conversely, non-responsive feeding, typically characterized by caregiver's controlling or pressuring feeding styles, can override these cues (52). Feeding at the breast is thought to instill responsive feeding behaviours, including self-regulation of learned hunger-satiety cues, that likely carry over into childhood and beyond (11–13).

Most responsive feeding research to date has compared infants consuming HM at the breast to infants consuming human milk substitutes (HMS; e.g. infant formula) from a bottle, which is problematic given the known sociodemographic differences between these groups of mothers (54). This mechanism among HM-fed infants, or the 'how' rather than the 'what' of infant feeding, has received less attention among researchers, and is the focus of this study.

3.4. Responsive feeding and infant energy intake

Although the WHO defines exclusive breastfeeding as consumption of HM (with no other food or drink) at the breast or as expressed HM (14), there is little evidence on which to base this equality in relation to hunger-satiety cue development.

The rate of growth of infants differs between infants fed HM versus HMS (11): breastfed infants tend to be leaner at 12 months compared with infants fed HMS (15). Infants have an innate ability to self-regulate energy intake (16). The Davis Area Research on Lactation, Infant Nutrition and Growth (DARLING) Study, a seminal study comparing milk intake among matched infants consuming either HM or HMS, found that at 3, 6, 9, and 12 months, HMS-fed infants consumed significantly more milk than their breastfed peers (17). These findings may be related to the effort required to remove milk from the breast, as milk flow from bottles requires significantly less effort (i.e. gravity) (10). When HMS is fed, caregivers tend to feed in response to the amount of milk left in the bottle regardless of infant feeding cues, leading to excess energy intake (16,18).

A recent analysis showed that children who were forced to finish bottles in the first 6 months of life had an increased odds of eating all the food on their plates at 6 years (19). In contrast, breastfed infants tend to lead the feed, determining when and how much to consume, because there are no

visual cues for the caregiver to monitor or influence intake (11). In a small study of 25 mother-infant dyads, researchers found that less HMS was consumed when mothers fed from opaque, weight-counterbalanced bottles compared to conventional clear bottles (20). Another recent report found that infants (*n*=865, 2 months old) eating from large bottles (≥6 oz) consumed 4 oz more HMS per day than peers drinking from smaller bottles (<6 oz) (21). More recently, distracted or 'mindless' infant feeding has been explored: caregivers distracted by other adults, children, televisions, or mobile devices (22) tend to increase the volume of the feed, which has been associated with more weight gain, compared with attentive feeding (12).

3.5. Summary: background and rationale

More research is required to understand whether the modality of HM consumption and responsive feeding practices influence the growth of infants. In this exploratory study, we aim to better understand the infant feeding 'climate' in the Halifax Regional Municipality, Canada.

4. Study Objectives

4.1 Primary objective

OBJ1. To assess if the volume of HM consumed by infants differs by feeding modality (bottle feeding HM versus breastfeeding), as assessed by indirect weighs at each feed during a 24-hour period at 6 weeks, 4 months, and 6 months.

4.2. Secondary objectives

OBJ2. To determine whether infant anthropometric measurements (length, weight, head circumference) and growth rates (weight-for-age [WAZ], length-for-age [LAZ], weight-for-length [WLZ], BMI-for-age z-scores [BAZ]) differ by self-reported usual feeding modality among infants exclusively consuming human milk.

OBJ3. To objectively assess responsiveness of infant feeding practices, both at the breast and during bottle-feeding of HM, by video-recording feeding sessions in participant's homes.

OBJ4. To gain a better understanding of current infant feeding practices, including responsive feeding, among caregivers in the HRM, contextualize why women are pumping, and gain insight around how human milk is handled, stored, and prepared through open-ended one-on-one interviews with mothers.

5. Study Design

This will be a modified randomized cross-over study (*n*=62 dyads; *t*=6 weeks, 4 months, and 6 months) (see **Figure 1**).

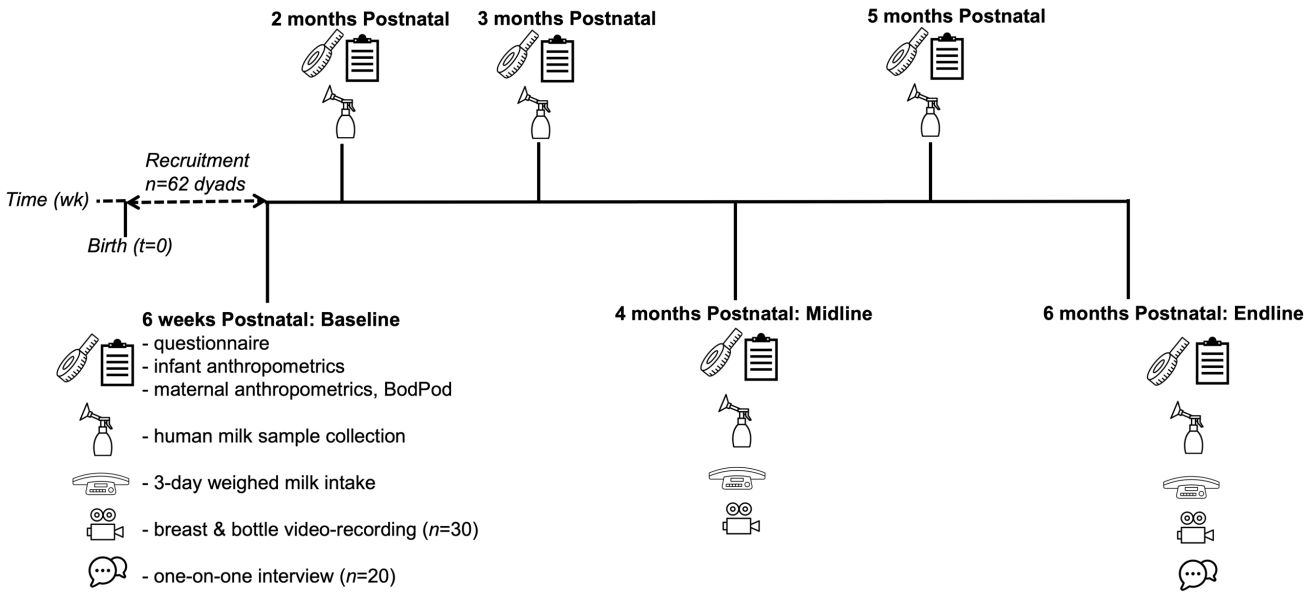

Figure 1. Pictorial display of the REFINE study data collection scheme.

Since there is high potential for inter-infant variability in milk consumption, we will employ a modified randomized cross-over study design, which allows each infant to act as their own control, limiting potential confounding (39). This is a modified design because rather than participants in different 'treatments' consuming different foods, here the modality of HM consumption – from bottle or breast – will differ (see **Figure 2**).

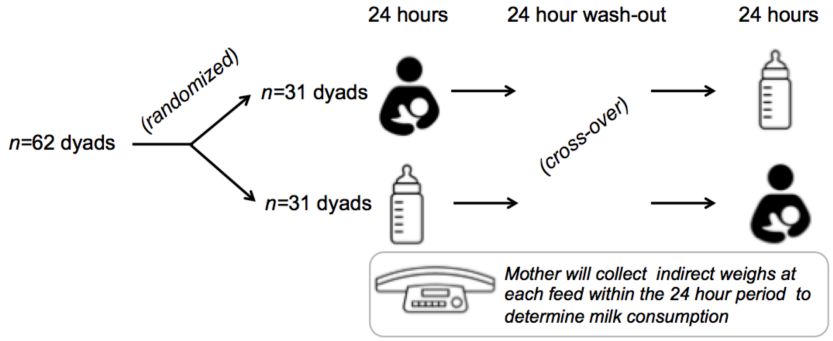

Figure 2: Pictorial display of OBJ1; this data collection will occur at 6 weeks, and 4 and 6 months.

6. Sample Size

We estimate that a sample size of 41 is required to detect a 1 oz (26 mL) difference between infants during feeds at the bottle and the breast, assuming a standard deviation of 50 mL, 90% power and an alpha of 0.05 (two samples paired means test, Stata Corp). If we used assumptions based on breastfeeding rates in Atlantic Canada (90% initiation, 23% exclusively to 6 months (5)), n=160 women would be required to ensure n=41 at endline (6 months). However, women recruited for this study a) will be screened in to the study after they've reached peak milk production (23), b) will have had previous success breastfeeding to 6 months, and c) understand the study design and are

volunteering to follow this study protocol. As such, we anticipate we will retain two thirds of participants after screening into this study, so will aim to recruit 62 dyads.

7. Recruitment and Eligibility

7.1 Recruitment

We will recruit 62 mother-infant dyads <6 weeks postnatal via convenience sampling (over 18 months; timeline below). We will engage with families in the early postnatal period through advertisements delivered via social media, and posters/pamphlets distributed via doctors offices, Le Leche League meetings, and local community centres and day care centers. Mothers who express an interest in participating will be contacted via phone to undergo intensive screening to provide more information about the study, including what is involved, potential risks (e.g. maintaining milk supply, nipple confusion) and benefits, and review eligibility criteria. Once participants are enrolled we will schedule a training session at 5 weeks postpartum in preparation for the in-home weighing during week 6.

7.2 Eligibility criteria

Mother-infant dyads are **eligible** to participate if:

- mothers are aged 19 years or older,
- dyads currently live in the Halifax Regional Municipality in Nova Scotia,
- mothers have no chronic diseases,
- the baby is a healthy singleton baby who is younger than 6 weeks of age, and is fed mother's milk directly from the breast and from a bottle,
- mothers plan to exclusively feed their baby mother's milk up to 6 months,
- mothers have an older child whom they successfully fed mother's milk for a minimum of 6 months,
- mothers are willing to participate in three 3-day study sessions and monthly measurement sessions, and
- mothers provide informed consent for herself and her infant to participate.

Mother-infant dyads are **ineligible** to participate if:

- the baby was born preterm (earlier than 37 weeks gestation),
- the baby was born outside the healthy weight range of 2,500 – 4,000 g (5lb 8oz to 8lb 13oz),
- the baby has a developmental delay diagnosed before the time of enrolment,
- the baby is currently receiving any medical treatment except for vitamin D supplementation (no more than 400 IU/day),
- the mother sought prescription medical treatment for lactation (e.g. domperidone, antibiotics, prescription nipple ointment), or
- the mother plans to move in the 6 months after starting the study.

7.3 Participant withdrawal

Participants are free to withdraw from the study at any time without consequence. Participants who withdraw from the study will not be replaced. Any data collected on that participant up to the time of withdrawal will be retained for analysis.

8. Study Procedures

At each timepoint (6 weeks, 4 months, 6 months) infants will: be randomized using a balanced design (to control for order effect) to consume HM from a bottle or from the breast for 24 hours; will then undergo a wash-out period in which they will be fed HM *as they usually would* for 24 hours; then will complete the second 'treatment' (bottle or breast) for 24 hours (see **Figure 2**). Due to the nature of the intervention, this study will not be blinded. The study will be scheduled from the Tuesday through Thursday during the week the infant reaches 6 weeks, 4 months, and 6 months of age. Mid-week is ideal for data collection as the mother-infant dyads are most likely to be in their usual routine. Mothers will use their own feeding equipment (bottles, etc.) to ensure that both infants and mothers are comfortable with the equipment, and we collect data from the most realistic scenario. Mothers who typically hand express milk will be loaned a hospital-grade HM pump.

8.1 Indirect weights

Mothers will complete an indirect weigh twice at each feed within the 24 hour treatment phases to measure infant's HM intake. Using a well-established method (24), mothers simply place their infant on the scale before the feed, then again after the feed is finished (without changing diapers or clothing between weighs). The volume of milk consumed for each feed is determined by calculating the weight change between the two weights, divided by the specific gravity of human milk (1.032 g/mL) (24). During the data collection week, mothers will be loaned a Seca Infant Scale (Model 727), which is accurate to 1 g, and uses direct wireless transmission of weight, limiting participant bias and burden.

If infants consume more or less milk than usual in their first treatment, the 24 hour wash-out will allow infants to return to their baseline usual energy intake before the second treatment. Latin Square randomization will be employed to prevent order effect.

Compliance to indirect weighs will be assessed via maternal self-report. We will provide mothers with 3 sheets with 24 slots, and will ask them to 'tick off' breast- and bottle-feeds during the 3-day intervention. From this, we will know whether the dyad maintained the intervention for the 24-hour feeding period (e.g. whether they actually feed only from the breast during the 24-hour breastfeeding 'treatment'), and can cross-compare this to the timestamps from the automatically assessed infant indirect weights (via Seca Infant Scale Model 727).

8.2. Infant growth monitoring

Infant anthropometric measurements (length, weight, head circumference) and growth rates (WAZ, LAZ, WLZ, BAZ) will be measured at baseline (6 weeks postnatal) and monthly from 2 – 6 months. Standard methodologies will be employed (25), and all measurements should take <5 minutes to

complete. Mothers will be reminded via text message/call to drop by the MAMA Lab at the Centre for Applied Research in Human Health to have these measurements completed. Mothers will also be given the option of having a research assistant complete these measures in her home.

8.3. Questionnaires

Mothers will complete a self-administered questionnaire at baseline (6 weeks postnatal) and monthly from 2 – 6 months, to collect information on demographics, socioeconomic status, usual infant feeding practices and dietary intake (including introduction of complementary foods), infant feeding equipment (electronic breast pump, brand of bottles and nipples), and some limited maternal dietary intake/supplement/herbal product information. This questionnaire will also include the validated Household Food Insecurity Access Scale (26) and Intuitive Eating Scale-2 (IES-2) (27).

8.4 Mothers' height and body composition

We will also measure mother's height, and body composition (using BODPOD) during the monthly visits.

8.5. Human milk samples

We will collect milk samples from mothers during the monthly visits (samples will be stored in "BioBank", MAMA Lab's -80°C freezer, for future analysis). Milk samples will be collected using our Medela Hospital Grade pump, or, if mothers are more comfortable, their own pump. One full breast expression (single breast) will be collected from the breast women self-identify as being more 'full' (the breast not most recently emptied). Time of day, time since last meal, breast side, and milk volume (weight of milk to 1 g) will be recorded. We will aliquot 12 mL of sample (<1tbsp) immediately using sterile, one-time-use materials and store samples in the -80°C freezer, and return the rest of the milk to the mother to feed to the infant (or dispose of the rest of the milk if she prefers).

8.6 Video recording

We will invite a sub-set of participants to join in an additional data collection endeavour, video-recording breast- and bottle-feeding sessions in their home. At each timepoint (6 weeks, 4 months, 6 months) we will invite the same 30 participants to have their feeding sessions video-recorded to objectively assess and analyze responsiveness of infant feeding practices using the Nursing Child Assessment Satellite Training (NCAST) Caregiver/Parent-Child Interaction Feeding Scale (28).

The researcher will set up three tripod-mounted video cameras in a room where ≥50% of infant feeds are typically conducted (e.g. living room or nursery): one camera will be focused on the infant's face, one on the mother's face, and one will be placed approximately 10-12 feet from the feeding dyad to capture the entire feed (29). We will provide the mother with a sign, which she will be asked to hold up immediately before the start of the feed, and immediately after the end of the feed, which will indicate the feeding session. Any video footage not within this feeding window will not be analyzed, and will be permanently deleted. This feeding session will be recorded as a digital media file. The researchers will step out of the room during the feeding session as not to interfere with the usual feeding practices.

8.7 Interviews

At two timepoints (t=6-8 weeks, and t=20-22 weeks) the same 20 mothers will be randomly invited to participate in open-ended semi-structured one-on-one interviews. These will be subsequently transcribed verbatim and thematically analyzed.

8.8. Participant remuneration

Participants will be compensated after each of the data collection points: $75 for each 3-day food intake measurement session (maximum of 3, =$225), $10 for each anthropometric measurement and milk collection session (maximum of 6, =$60), $20 for the video recording session (n=30 only; maximum of 3, =$60), and $20 for an interview (n=20 only; maximum of 2, =$40). Moreover, if they wish, we will provide mothers with all of their baby's growth information and their body composition information (approx. $35 value per measurement). Free lactation consultant services will be made available to mothers who cite concern about breastfeeding, maintaining milk supply, or other related issues.

9. Adverse Event Reporting

As described in *2.6 Serious Adverse Events Committee / Data Safety Monitoring Board,* there will be no Serious Adverse Events Committee or Data Safety Monitoring Board assembled for this study, because of the absence of potential adverse events from the study. The participants will be asked to feed their infants as they normally would. Inclusion criteria indicates that women already need to be actively expressing milk, so mothers and infants will be familiar with pumping and feeding with a bottle. No invasive data collection techniques will be used. The infants' anthropometric measures will be collected using standard techniques. The feeding sessions will be video recorded in privacy of participant's homes. The questionnaires and interview guides do not impose any possible harms greater than those encountered by participants in their everyday life.

Since some of the data will be collected in participant's homes, there is potential of unanticipated discoveries (e.g. spousal abuse). Since these would be incidental and the RAs, as well as PI are not experts in uncovering such information, they will inform the appropriate authorities. For example, if living conditions seem unsafe or there is risk/evidence of abuse, a report to the Halifax Regional Police will be filed as per https://www.halifax.ca/fire-police/police/programs-services/victim-services-halifax/domestic-violence.

10. Data analysis

Quantitative data will be analysed in SPSS (descriptive and inferential statistics). The WHO Anthro plug-in for SPSS will be used to plot growth rates. Feeding responsiveness will be assessed using NCAST Parent-Child Interaction Feeding Scale. Qualitative data from interviews will be transcribed verbatim (e.g. Trint software with manual corrections) and thematically analyzed in MAXQDA.

OBJ1. Within-dyad 24 hour intake of HM (g), by treatment (bottle versus breast), will be assessed by paired t-tests, for each timepoint (6 weeks, 4, and 6 months). We will also assess between-dyad 24 hour HM intake (g) (independent t-tests at each time point). Descriptive statistics will be computed: mean (SD) for continuous variables (maternal age, annual household income), or n (%) for categorical

variables (maternal education, hedonic scale responses for usual infant feeding practices). We will also build general linear models to calculate estimated marginal means (95% CI) of HM intake by feeding modality, adjusted for potential confounders (maternal age, education, and socioeconomic status).

OBJ2. Growth rates will be computed for each child using WHO Anthro plug-in for SPSS; we will assess each child for growth trajectory and percentile changes from baseline (6 weeks). Descriptive statistics will be computed for mother's anthropometrics and body composition. Using categories of usual infant feeding modality (questionnaire from Objective 1; predominantly breastfed/predominately bottle-fed HM/equal mix feeding) we will compute and compare measures (length, weight, head circumference), percentiles for growth charts (WAZ, WLZ, LAZ, BAZ), and mother's measures using one-way ANOVA (with least significant difference adjustment for multiple comparisons between usual feeding modality) at each time point.

OBJ3. Videos will be analysed using the NCAST Parent-Child Interaction Feeding Scale, a standardized scale with published validity and reliability measures to assess observable behaviors that describe caregiver/parent child interactions (55). We will also compute correlations between NCAST infant responsive feeding and IES-2 maternal intuitive eating scores (27).

OBJ4. Research assistants will conduct one-on-one interviews, and will transcribe transcripts verbatim (e.g. Trint software with manual corrections). Thematic analysis with inductive, open coding will be employed to allow patterns, codes, and categories to emerge from the data (MAXQDA software).

11. Administrative Aspects, and Data Security and Management

11.1 Obtaining informed consent

Recruitment posters will advise interested parties to contact the research team via email. An RA will provide a copy of the consent form to the interested individual in advance of a telephone screening interview where the individual will be asked to confirm eligibility over the phone. They will then set up a date and time for an in-person meeting with the potential participant to go over the consent form in more detail (see **Appendix**). Interested individuals will be advised to ask questions and take time before they provide written, informed consent. The RA will make sure to emphasize that the participation in this study is completely voluntarily and that an individual can decide not to participate or to withdraw at any time without consequence.

Note: **mothers are the study participants**. We will obtain consent from the mother, including permission for the infant to be involved with the study (e.g. to be fed as part of the study).

11.2 Ethics

Ethics approval has been obtained from the Research Ethics Boards of the following institutions:

- Mount Saint Vincent University (#2018-155)
- University of Prince Edward Island (#6008074)

This research will be registered with clinicaltrials.gov.

11.3 Confidentiality and data security

Participants will be given a code unique to our study. A key linking the subject code to participant information will be kept on a password protected computer in a secure area in the office in the MAMA Lab at MSVU. There is no need for co- investigators elsewhere to have information linking participant names with their unique identifier.

This unique identifier will not be derived from personal identifiers. All electronic data files will be stored on password protected tablets, computers and/or secure servers accessible only to members of the research team. Archived electronic data files and any hard copies of data, consent forms or other papers containing data will be stored in locked filing cabinets in locked research rooms at the MAMA Lab.

All identifying information will be removed from the interview transcripts before data analysis. The only identifying information that cannot be removed are the faces and voices of the participants on the video-recorded feeding sessions, since these are needed to be included in order to score the feeding interaction. However, once the videos are scored using adapted NCAST Parent-Child Interaction Feeding Scale, no identifying data will be entered into the database for analysis.

All data will be saved for at least 5 years following the publication of research findings, at which point it will be permanently destroyed. Data regarding the primary objective of this randomized cross-over trial will be kept for 25 years. Electronic data will be permanently deleted from computers and hard drives using file-shredding software. Paper documents will be shredded. Milk samples will be stored for 5 years in -80°C freezers, then destroyed following biological safety protocols. During this time, only the PI will have access to these data/samples, and the PI will be responsible for destroying data/samples at the appropriate time.

11.4 Modifications to the protocol

This study will be conducted per the current version of the protocol. Any change to the protocol document or related study tools that affects the scientific intent, study design, or participant safety, or that may affect a participant's willingness to continue participation in the study, will be considered an amendment, and therefore will be written and filed as such.

11.5 Protocol deviations

Protocol deviations will be documented and reported to the Principal Investigator if data collection for the primary outcome does not fall within ± 4 days at Week 6, or ± 7 days at Months 4 and 6, of the specified data collection date.

11.6 Study closure

The Principal Investigator (or designee) may terminate the study prematurely if data become available which raise concern about the safety of the study treatment(s) that have potential to cause unacceptable risks to subjects. If premature study closure occurs, the Principal Investigator (or designee) will contact all participants within two weeks, and written notification must be sent to the Ethics Committees, study funder, and trial registry.

12. Use of Data, and Dissemination

12.1 Academic dissemination

Results of this study will be presented at academic nutrition, public health, and lactation conferences (i.e. Canadian Nutrition Society Annual Meeting, International Society for Research in Human Milk and Lactation Conference), in peer-reviewed, academic journals, as well as through Master's Theses. Authorship will be determined based on the International Committee of Medical Journal Editors Authorship Guidelines. There is no plan to use professional writers for dissemination.

12.2 Layperson dissemination

We will create various lay outputs from this study that can be used as teaching resources by healthcare providers working with families, or can be accessed directly by families. These may include short video clips, infographics, or 'hot tips,' which we will make available online and (if applicable) in print for distribution at local agencies (public health, in hospitals, community centers, etc). We will host a Dissemination Workshop open to the public (families, media, clinicians, public health, all sectors) to share the main outcomes of the study, and to officially 'launch' resources online.

13. References

1. Victora CG, Bahl R, Barros AJD, Franca GVA, Horton S, Krasevec J, Murch S, Sankar MJ, Walker N, Rollins NC. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. Lancet. Elsevier Ltd; 2016;387:475–90.
2. Kramer MS, Kakuma R. The optimal duration of exclusive breastfeeding: a systematic review. World Health Organization. Switzerland; 2002.
3. Van De Perre P. Transfer of antibody via mother's milk. Vaccine. 2003;21:3374–6.
4. Lamberti LM, Fischer Walker CL, Noiman A, Victora C, Black RE. Breastfeeding and the risk for diarrhea morbidity and mortality. BMC Public Health. BioMed Central Ltd; 2011;11:S15.
5. Gionet L. Breastfeeding trends in Canada [Internet]. Ottawa, Canada; 2013. Available from: http://www.statcan.gc.ca/pub/82-624-x/2013001/article/11879-eng.htm
6. Felice JP, Cassano PA, Rasmussen KM. Pumping human milk in the early postpartum period: its impact on long-term practices for feeding at the breast and exclusively feeding human milk in a longitudinal survey cohort. Am J Clin Nutr. 2016;103:1267–77.
7. West JM, Power J, Hayward K, Joy P. An exploratory thematic analysis of the breastfeeding experience of students at a Canadian university. J Hum Lact. 2017;33:205–13.
8. Howard CR, Howard FM, Lanphear B, Eberly S, DeBlieck EA, Oakes D, Lawrence RA. Randomized clinical trial of pacifier use and bottle-feeding or cupfeeding and their effect on breastfeeding. Pediatrics. 2003;111:511–8.
9. Viggiano D, Fasano D, Monaco G, Strohmenger L. Breast feeding, bottle feeding, and non-nutritive sucking; effects on occlusion in deciduous dentition. Arch Dis Child. 2004;89:1121–3.
10. Li R, Fein SB, Grummer-Strawn L. Association of breastfeeding intensity and bottle-emptying behaviors at early infancy with infants' risk for excess weight at late infancy. Pediatrics. 2008;122:S77–84.
11. Bartok CJ, Ventura AK. Mechanisms underlying the association between breastfeeding and obesity. Int J Pediatr Obes. 2009;4:196–204.
12. Golen RB, Ventura AK. Mindless feeding: is maternal distraction during bottle-feeding associated with overfeeding? Appetite. Elsevier Ltd; 2015;91:385–92.
13. Brown A, Lee M. Breastfeeding during the first year promotes satiety responsiveness in children aged 18-24 months. Pediatr Obes. 2012;7:382–90.
14. World Health Organization. World Health Organization Infant Feeding Recommendation [Internet]. Geneva, Switzerland; 2017. Available from: http://www.who.int/nutrition/topics/infantfeeding_recommendation/en/
15. Dewey KG. Growth characteristics of breast-fed compared to formula-fed infants. Biol Neonate. 1998;74:94–105.
16. Dewey KG. Is breastfeeding protective against child obesity? J Hum Lact. 2003;19:9–18.
17. Heinig MJ, Nommsen LA, Peerson JM, Lonnerdal B, Dewey KG. Energy and protein intakes of breast-fed and formula-fed infants during the first year of life and their association with growth velocity: the DARLING study. Am J Clin Nutr. 1993;58:152–61.
18. Ventura AK, Inamdar LB, Mennella JA. Consistency in infants' behavioural signalling of satiation during bottle-feeding. Pediatr Obes. 2015;10:180–7.
19. Li R, Scanlon K, May A, Rose C, Birch L. Bottle-feeding practices during early infancy and eating behaviors at 6 years of age. Pediatrics. 2014;134:S70–7.
20. Ventura AK, Golen RP. A pilot study comparing opaque, weighted bottles with conventional, clear bottles for infant feeding. Appetite. 2015;85:178–84.

21. Wood CT, Skinner AC, Yin HS, Rothman RL, Sanders LM, Delamater A, Ravanbakht SN, Perrin EM. Association between bottle size and formula intake in 2-month-old infants. Acad Pediatr. Elsevier Inc; 2016;16:254–9.
22. Golen RP, Ventura AK. What are mothers doing while feeding their infants? Exploring the prevalence of maternal distraction during infant feeding interactions. Early Hum Dev. 2015;91:787–91.
23. Hill PD, Aldag JC, Chatterton RT, Zinaman M. Comparison of milk output between mothers of preterm and term infants: the first 6 weeks after birth. J Hum Lact. 2005;21:22–30.
24. Miller EM, Aiello MO, Fujita M, Hinde K, Milligan L, Quinn EA. Field and laboratory methods in human milk research. Am J Hum Biol. 2013;25:1–11.
25. Cogill B. Anthropometric Indicators Measurement Guide. Washington, DC; 2003.
26. Coates J, Swindale A, Bilinsky P. Household Food Insecurity Access Scale (HFIAS) for Measurement of Food Access: Indicator Guide (v. 3). Washington, DC; 2007.
27. Tylka TL, Kroon Van Diest AM. The Intuitive Eating Scale-2: item refinement and psychometric evaluation with college women and men. J Couns Psychol. 2013;60:137–53.
28. Oxford ML, Findlay DM (Eds. . NCAST Caregiver/Parent-Child Interaction Feeding Manual (2nd ed.). Seattle: NCAST Programs, University of Washington, School of Nursing; 2015.
29. Whitfield KC, Ventura AK. Exploration of responsive feeding during breastfeeding versus bottle feeding of human milk: a within-subject pilot study. Breastfeed Med [Internet]. 2019;In Press. Available from: https://www.liebertpub.com/doi/10.1089/bfm.2019.0069

Appendix: Consent forms *(see next 13 pages).*

REFINE STUDY
CONSENT FORM

Introduction

We invite you to take part in the research study called *Responsive Feeding of Infants with Expressed Milk (REFINE Study)* This form gives information about the study. Before you decide if you want to participate, it is important that you understand the purpose of the study, what you will be asked to do, and the risks and benefits. We will explain all information before asking for your consent to participate. A member of the research team will be available to answer any questions. You may decide not to participate. You may also withdraw from the study at any time without any problems. Your participation is entirely voluntary.

Who is conducting the study?

Dr. Kyly Whitfield, Principal Investigator, Assistant Professor
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This study is funded by Nova Scotia Health Research Foundation. This study is registered on clinicaltrials.gov with an identifier NCT04041505. The researchers have no conflicts of interest to report.

What is the study about?

Breastfeeding has health benefits for both mothers and babies. Mother's milk is the best food for babies. How babies eat this milk is changing as pumping becomes more popular. Health professionals long thought that feeding a bottle of pumped breastmilk was the same as breastfeeding. Yet, there is research showing that *how* the baby is getting mother's milk is also important. It may have long-term impacts, for instance on baby's ability to understand if s/he is hungry or full.

We plan to invite 62 mother-infant pairs in the Halifax Regional Municipality to participate in this study. We will follow babies eating mother's milk from both the breast and a bottle from 6 weeks to 6 months. We aim to better understand how infants eat, grow and interact with caregivers during feeding.

Who can participate?

You will chat with a member of the research team to determine if you can participate in this study.

You may be eligible to participate if you:

- are 19 years or older,
- currently live in the Halifax Regional Municipality in Nova Scotia,
- have no chronic diseases,
- have a healthy singleton baby who is younger than 6 weeks of age who is fed mother's milk directly from the breast and from a bottle,
- plan to exclusively feed your baby mother's milk up to 6 months,
- have an older child whom you successfully fed mother's milk for a minimum of 6 months, and
- are willing to participate in three 3-day study sessions and monthly measurement sessions.

You are not eligible to participate if:

- your baby was born preterm (earlier than 37 weeks gestation),
- your baby was born outside the healthy weight range of 2,500 – 4,000 g (5lb 8oz – 8lb,13oz),
- your baby has a diagnosed developmental delay diagnosed before the time of enrollment,
- your baby is currently receiving any medical treatment, except for vitamin D supplementation (no more than 400 IU/day),
- you sought prescription medical treatment for lactation (e.g. domperidone, antibiotics, prescription nipple ointment), or
- you plan to move in the next 6 months.

Taking part in this study is completely voluntary. You do not need to answer any questions that you don't feel comfortable answering. You may choose not to take part or may leave the study at any time. You do not have to give a reason for your decision.

What will participation in this study look like?

Questionnaires
The study will begin when your baby is 6 weeks old and finish when your baby is 6 months old. After you sign this consent form, we will ask you to complete a questionnaire. It will ask questions about yourself (such as your age, ethnicity, diet, and eating attitudes and behaviours), and about your baby (such as details of the delivery, and how you usually feed your baby). It will likely take you about 30 minutes to fill out. We will then ask you to fill out a shorter questionnaire each month from 2 to 6 months. Each of these questionnaires is likely to take about 10 minutes to fill out.

Milk intake
At three time points (when your baby is 6 weeks, 4 months, and 6 months old) you will set up an

appointment with a research team member. She or he will come to your home to help set up equipment for a 3-day feeding session. We will ask you to follow specific instructions for 3 days, usually from Tuesday through Thursday. We will ask you to feed your baby only from the breast for the first day, as usual (breast and bottle) for the second day, and from a bottle for the third day (or the other way around: bottle-usual-breast). During the first and third day we will ask you to weigh your baby before and after each feeding. We will give you a scale and train you how to use it. Members of the research team will be available by phone from 8 am to 10 pm daily to answer any questions.

Growth and body composition, and milk samples
Each month we will measure your baby's growth: weight, length, and head circumference (~7 minutes). We will also measure your body composition using a BODPOD (~15 minutes, 3 minutes inside BODPOD). The BODPOD is a device that uses changing air pressure to calculate fat and lean body mass. Ideally you will come to MSVU with your baby so that we can conduct all measures. The other option is for a research team member to come to your home to measure your baby's growth.

During these visits we will also ask you to give a milk sample. This is optional, and we will ask you to provide separate consent at the end of this consent form. You can use the hospital grade pump in our research centre. The other option is for you to use your own pump if you're more comfortable with it. These milk samples will be identified only with your Study ID. The samples will be stored in our -80°C freezer for future analysis for nutrient content and other compounds such as bioactives and hormones.

Caregiver-infant feeding behaviours
We will randomly invite some of the mothers to participate in a video-recorded feeding sessions. If you're selected and invited to participate, we will give you a separate consent form. <u>This part is additional and it is not required for your participation in the study.</u>

Understanding infant feeding in Nova Scotia
We will randomly invite some of the mothers to participate in a one-on-one interview about infant feeding. If you're selected and invited to participate, we will give you a separate consent form. <u>This part is additional and it is not required for your participation in the study.</u>

Participation in this study is entirely voluntary. It will not cost you anything. As a thank you for your time, we will provide the following: $75 for each 3-day milk intake session (6 weeks, 4 months, and 6 months), $10 for each growth measurement session. We will also give you all of your baby's growth information and your body composition information (approx. $35 value per measurement). You will receive compensation after each of the data collection sessions. If you decide to withdraw the during one of the data collection points, you will still receive compensation for that session. If you have any difficulties with breastfeeding as a result of participation in this study, we will arrange an appointment with a lactation consultant free of charge.

Confidentiality

Your confidentiality will be respected. Your records will be kept in a locked cabinet in the Milk and Micronutrient Assessment Lab (MAMA Lab) at Mount Saint Vincent University. All electronic data will be stored on a university-based, password protected server. We will give you a unique study number as a participant in this study. Only this number will be used on any research-related information collected about you during the course of this study. Your identity [i.e. your name or any other information that could

identify you] will be kept confidential. Only Principal Investigator will have access to any data that contains your personal information (such as this consent form). The list that matches your name to the unique study number will not be removed or released.

Only the research team will view and analyze the information gathered as part of this study. The results of the study may be presented at scientific meetings, published in a scientific journal and used for Master's Theses. If the results are published, only group values will be reported. Pseudonyms will be used if your interview responses are quoted. All data will be kept on a locked database for 25 years and then securely destroyed.

Please note that data will be kept confidential within the confines of the law. For instance, if we come across an evidence of abuse in a course of this study, we are obligated to report it to appropriate authorities, such as Halifax Regional Police.

Risks

We do not believe there are any risks involved with participation in this study.

Benefits

You will receive your baby's growth information and your body composition data as a participant of this study. You will have the benefit of contributing to research. We hope that the results of this study can be used to inform future research, public policy and education programs about the feeding of young children.

Questions and further information

Participation in this study is completely voluntary. Also, you have the option to stop participating and withdraw from the study at any time without any problems.

If you have any questions or would like further information about this research, please contact Dr. Kyly Whitfield, the Principal Investigator, at kyly.whitfield@msvu.ca, or by phone at (902) 457-5978.

If you have questions about how this study is being conducted and wish to speak with someone who is not directly involved in the study, you may contact the MSVU Research Office at (902) 457-6350 or via e-mail at research@msvu.ca.

You can also contact the UPEI Research Ethics Board at (902) 620-5104, or by email at reb@upei.ca if you have any concerns about the ethical conduct of this study.

Research Results

A summary of research results will be made available online at mamalab.ca. The ethical components of this research study have been reviewed by the Research Ethics Boards at Mount Saint Vincent University and the University of Prince Edward Island.

Consent Form for Research Participation

PARTICIPANT AUTHORIZATION:
I have read or had read to me this information and authorization form. I have had the chance to ask questions. My questions have been answered to my satisfaction before moving forward. I understand the nature of the study. I also understand the potential risks. I understand that I have the right to withdraw from the study at any time without any problems. I have received a copy of the Consent Form for future reference.

I freely agree to participate in this research study.

☐ YES ☐ NO

OPTINAL FOLLOW-UP

We would like to keep your contact information in case there are opportunities to follow-up with you and your child for future research. For example, we could contact you asking if you would like your child to use the BODPOD after they reach 2 years. There is no obligation to agree to future research participation now. We are simply asking to keep your phone number and email address in a locked database for potential future use. This is in no way required for participation in the current study.

I agree to allow the research team to contact me in the future about other research participation opportunities.

☐ YES ☐ NO

OPTIONAL MILK SAMPLE

We would like to collect milk samples, identified only with your Study ID. These will be stored in our -80°C freezer for future analysis for nutrient content and other compounds such as bioactives and hormones.

I agree to provide milk samples to be entered into a Milk BioBank at MSVU for future analysis.

☐ YES ☐ NO

Print name of Participant: _____

Date: _____ Signature: _____

STATEMENT BY PERSON PROVIDING INFORMATION ON STUDY AND OBTAINING CONSENT
I have explained the nature and demands of the research study and judge that the participant named above understands the nature and demands of the study. I have explained the nature of the consent process to the participant and judge that they understand that participation is voluntary and that they may withdraw at any time from participating.

Print name of Person Explaining Consent: _____

Date: _____ Signature: _____

REFINE STUDY
CONSENT FORM FOR VIDEO RECORDING FEEDING SESSION

Introduction
This is a consent form specific to the video-recorded feeding session as part of the larger study called *Responsive Feeding of Infants with Expressed Milk (REFINE Study).*This form will provide information specifically about the video-recording portion of the study. Before you decide if you want to participate, it is important that you understand the purpose of the study, what you will be asked to do, and the risks and benefits. We will give you all of this information before asking for your consent to participate. A member of the research team will be available to answer any questions. You may decide not to participate. You may also withdraw from the study at any time without any problems. Your participation is entirely voluntary.

Who is conducting the study?
Dr. Kyly Whitfield, Principal Investigator, Assistant Professor
Department of Applied Human Nutrition, Mount Saint Vincent University
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This study is funded by Nova Scotia Health Research Foundation. The researchers have no conflicts of interest to report.

What is the study about?
Breastfeeding has health benefits for both mothers and babies. Mother's milk is the best food for babies. How babies eat this milk is changing as pumping becomes more popular. Health professionals long thought that feeding a bottle of pumped breastmilk was the same as breastfeeding. Yet, there is research showing that *how* baby is getting mother's milk is also important. It may have long-term impacts, for instance on baby's ability to understand if she/he is hungry or full.

Watching the interaction between infants and mothers during feeding can be very informative. It can

provide insight into the "*how"* of feeding. Researchers can watch video-recorded feeding sessions, and objectively score interactions using a validated tool. It is called the NCAST Parent-Child Interaction Feeding Scale. However, most researchers film feeding sessions in a laboratory, where interactions are usually not "normal". We want to capture interactions in your own home, where you are used to feeding your baby.

We are randomly inviting 30 participants from the overall study to participate in the video-recording sessions.

Who can participate?
Mothers already participating in the larger study are eligible to participate.

Taking part in this study is completely voluntary. You may choose not to take part or may leave the study at any time during the data collection. You do not have to give a reason for your decision.

What will participation in this study look like?
At each timepoint (6 weeks, 4 and 6 months), we will video-record one breastfeeding and one bottle-feeding session. These feeding sessions will be video-recorded using small video cameras in the space where you usually feed your baby. The research assistant will set up 3 video cameras, start the recording, and leave the room. We will give you a paper sign and ask you to hold it up before starting the feed and immediately after ending the feed. Please feed your baby the way you normally do. We will delete any video footage not within this window without viewing.

We will transport the videos on the memory card with the video camera back to the laboratory. We will then export the files to the password-protected folder and permanently delete them from the memory card. All electronic files will be stored in a password protected folder and on an external hard drive in a locked drawer in a locked office. In all cases, files will be password protected. The files will be kept for a minimum of five years and then securely destroyed.

Participation in this study is entirely voluntary. It will not cost you anything. As a thank you for your time and participation, you will receive $20 for each video recording.

If you wish to withdraw from this sub-study at the time of video recording, the videos will be permanently deleted without viewing. You will receive compensation. If you decide to withdraw after the research assistant has already picked up the videos and added them to the study dataset, the videos will be kept for analysis.

Confidentiality
Your confidentiality will be respected. Your records will be kept in a locked cabinet in the Milk and Micronutrient Assessment Lab (MAMA Lab) at Mount Saint Vincent University. All electronic data will be stored on a university-based, password protected server. We will give you a unique study number as a participant in this study. Only this number will be used on any research-related information collected about you during the course of this study. Your identity [i.e. your name or any other information that could identify you] will be kept confidential. Only Principal Investigator will have access to any data that contains your personal information (such as this consent form). The list that matches your name to the unique study number will not be removed or released.

Only the research team will view and analyze the information gathered as part of this study. The results of the study may be presented at scientific meetings, published in a scientific journal and used for Master's

Theses. If the results are published, only group values will be reported. Pseudonyms will be used if your interview responses are quoted. All data will be kept on a locked database for 5 years and then securely destroyed.

Please note that data will be kept confidential within the confines of the law. For instance, if we come across an evidence of abuse in a course of this study, we are obligated to report it to appropriate authorities, such as Halifax Regional Police.

Option to use your videos for educational purposes
For the purposes of this research project, all videos will be viewed by the research team only. However, some mothers may choose to provide permission for these videos to be used for educational purposes, such as showing clips of the videos in relevant university classes to teach students about infant feeding, or for the production of a future educational movie clip. For example, nutrition students may need to explain good feeding behaviours in their future careers; if we capture you interacting with your baby in a positive way, it could be a terrific, and highly memorable, teaching tool to help these students remember this positive behaviour. **Note that this is a possible secondary use of the video recordings and is in no way required for your participation in this study.** If you would like to provide this permission to use these videos, please indicate this on the last page of this consent form.

Risks
We do not believe there are any risks involved with participation in this study.

Benefits
You will receive your baby's growth information and your body composition data as a participant of this study. You will have the benefit of contributing to research. We hope that the results of this study can be used to inform future research, public policy and education programs about the feeding of young children. If you would like, we will provide you with a copy of the feeding session videos.

Questions and further information
Participation in this study is completely voluntary. Also, you have the option to stop participating and withdraw from the study at any time without any problems.

If you have any questions or would like further information about this research, please contact Dr. Kyly Whitfield, the Principal Investigator, at kyly.whitfield@msvu.ca, or by phone at (902) 457-5978.

If you have questions about how this study is being conducted and wish to speak with someone who is not directly involved in the study, you may contact the MSVU Research Office at (902) 457-6350 or via e-mail at research@msvu.ca.

You can also contact the UPEI Research Ethics Board at (902) 620-5104, or by email at reb@upei.ca if you have any concerns about the ethical conduct of this study.

Research Results
A summary of research results will be made available online at mamalab.ca. The ethical components of this research study have been reviewed by the Research Ethics Boards at Mount Saint Vincent University and the University of Prince Edward Island.

Consent Form for Research Participation

PARTICIPANT AUTHORIZATION

I have read or had read to me this information and authorization form. I have had the chance to ask questions. My questions have been answered to my satisfaction before moving forward. I understand the nature of the study. I also understand the potential risks. I understand that I have the right to withdraw from the study at any time without any problems. I have received a copy of the Consent Form for future reference.

I freely agree to participate in this research study and agree for myself and my baby to be video-recorded.

☐ YES ☐ NO

OPTIONAL – USE OF VIDEOS FOR EDUCATION PURPOSES

Do you provide permission for the video-recordings of you and your baby to be repurposed for educational purposes (e.g. viewing in university classes, for the production of an educational video, etc) after the research study is complete?

☐ YES ☐ NO

Print name of Participant: _____

Date: _____ Signature:_____

STATEMENT BY PERSON PROVIDING INFORMATION ON STUDY AND OBTAINING CONSENT

I have explained the nature and demands of the research study and judge that the participant named above understands the nature and demands of the study. I have explained the nature of the consent process to the participant and judge that they understand that participation is voluntary and that they may withdraw at any time from participating.

Print name of Person Explaining Consent: _____

Date: _____ Signature: _____

REFINE STUDY
CONSENT FORM FOR ONE-ON-ONE INTERVIEW

Introduction
This is a consent form specific to the one-on-one interview regarding infant feeding. This is as part of the larger study called *Responsive Feeding of Infants with Expressed Milk (REFINE Study)*. This form will give information about the one-on-one interview portion of the study. Before you decide if you want to participate, it is important that you understand the purpose of the study, what you will be asked to do, and the risks and benefits. We will give you all of this information before asking for your consent to participate. A member of the research team will be available to answer any questions you may have. You may decide not to participate. You may also withdraw from the study at any time without any problems. Your participation is entirely voluntary.

Who is conducting the study?
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Phone: (613) 533-2669. Email: erna.snelgroveclarke@queensu.ca

This study is funded by Nova Scotia Health Research Foundation. The researchers have no conflicts of interest to report.

What is the study about?

It is known that breastfeeding is the best way to feed babies for the first 6 months. Yet, there isn't as much research on *how* or *why* mother's milk is fed to Canadian infants. We want to hear from mothers about things such as why you pump milk, how you store and feed it to your baby. We will also ask about your perceptions and experiences feeding your infant, if or where you got information or advice about infant feeding, and about whether you've ever experienced stigma regarding how you've fed your baby.

We are randomly inviting 20 participants from the overall study for these in-depth one-on-one interviews.

Who can participate?

Every mother already enrolled in the larger study is eligible to participate in these interviews. Taking part in this study is completely voluntary. You may choose not to take part or may leave the study at any time. You do not have to give a reason for your decision.

What will participation in this study look like?

You will be asked to come to Mount Saint Vincent University, or the researcher will come to your home for the interview. The interviews will take about 1-1.5 hours and will be audio recorded. We will transcribe the interview verbatim, but will replace any names you use with pseudonyms.

We will ask to do a second interview with you when your baby is between 20-22 weeks old.

Participation in this study is entirely voluntary and will not cost you anything. As a thank you for your time and participation, you will receive $20 at the end of each visit. If you decide to withdraw from the study during an interview, you will still receive compensation. In this case, the audio recording of your interview will be destroyed.

Confidentiality

Your confidentiality will be respected. Your records will be kept in a locked cabinet in the Milk and Micronutrient Assessment Lab (MAMA Lab) at Mount Saint Vincent University. All electronic data will be stored on a university-based, password protected server. We will give you a unique study number as a participant in this study. Only this number will be used on any research-related information collected about you during the course of this study. Your identity [i.e. your name or any other information that could identify you] will be kept confidential. Only Principal Investigator will have access to any data that contains your personal information (such as this consent form). The list that matches your name to the unique study number will not be removed or released.

Only the research team will view and analyze the information gathered as part of this study. The results of the study may be presented at scientific meetings, published in a scientific journal and used for Master's Theses. If the results are published, only group values will be reported. Pseudonyms will be used if your interview responses are quoted. All data will be kept on a locked database for 25 years and then securely destroyed.

Please note that data will be kept confidential within the confines of the law. For instance, if we come across an evidence of abuse in a course of this study, we are obligated to report it to appropriate authorities, such as Halifax Regional Police.

Risks

We do not believe there are any risks involved with participation in this study.

Benefits

You will not receive direct benefits from participating in this study. You will have the benefit of contributing to research. We hope that the results of this study can be used to inform future research, public policy and education programs about the feeding of young children.

Questions and further information

Participation in this study is completely voluntary. Also, you have the option to stop participating and withdraw from the study at any time without any problems.

If you have any questions or would like further information about this research, please contact Dr. Kyly Whitfield, the Principal Investigator, at kyly.whitfield@msvu.ca, or by phone at (902) 457-5978.

If you have questions about how this study is being conducted and wish to speak with someone who is not directly involved in the study, you may contact the MSVU Research Office at (902) 457-6350 or via e-mail at research@msvu.ca.

You can also contact the UPEI Research Ethics Board at (902) 620-5104, or by email at reb@upei.ca if you have any concerns about the ethical conduct of this study.

Research Results

A summary of research results will be made available online at mamalab.ca. The ethical components of this research study have been reviewed by the Research Ethics Boards at Mount Saint Vincent University and the University of Prince Edward Island.

Consent Form for Research Participation

PARTICIPANT AUTHORIZATION
I have read or had read to me this information and authorization form. I have had the chance to ask questions. My questions have been answered to my satisfaction before moving forward. I understand the nature of the study. I also understand the potential risks. I understand that I have the right to withdraw from the study at any time without any problems. I have received a copy of the Consent Form for future reference. I freely agree to participate in this research study.

INTERVIEW
We would like to invite you for one-on-one interview. We will ask you to tell us about things such as why you pump milk, how you store and feed milk, your perceptions and experiences feeding your infant, if or where you obtained information or advice about infant feeding, and about whether you've ever experienced stigma regarding how you've fed your infant.
I agree to be interviewed as a part of this research study.

☐ YES ☐ NO

AUDIO RECORDING
We would like to audio record your interview in order to analyze it later on. We will transcribe it verbatim, clean from any identifiers and substitute all names with pseudonyms.
I agree for my interview to be audio recorded.

☐ YES ☐ NO

QUOTES
There is a possibility that we would like to quote your interview responses in publications and presentations. We will substitute your name with a pseudonym.
I agree for my interview responses to be quoted in publications and presentations.

☐ YES ☐ NO

Print name of Participant: _____

Date: _____ Signature: _____

STATEMENT BY PERSON PROVIDING INFORMATION ON STUDY AND OBTAINING CONSENT
I have explained the nature and demands of the research study and judge that the participant named above understands the nature and demands of the study. I have explained the nature of the consent process to the participant and judge that they understand that participation is voluntary and that they may withdraw at any time from participating.

Print name of Person Explaining Consent: _____Date: _____Signature: _____