Structured Antenatal Milk Expression Education for Nulliparous Pregnant People: Results of a Pilot, Randomized Controlled Trial in The United States

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Abstract

Background

Hand-expression, collection, and storage of breast milk during pregnancy (i.e., antenatal milk expression or AME) is a safe, potentially effective practice to reduce early, undesired formula supplementation among women with diabetes. The feasibility and potential benefits of AME in the United States (U.S.) and among non-diabetic birthing people is unknown.

Methods

The purpose of this study was to examine the feasibility of a structured AME intervention and its relationship to lactation outcomes among nulliparous birthing people in the United States. We recruited a convenience sample of 45 low-risk, nulliparous individuals at 34–36^{6/7} weeks of gestation from a hospital-based midwife practice. Participants were randomized to AME or a control group receiving breastfeeding handouts. Interventions were delivered at weekly visits at 37–40 weeks of pregnancy. The AME intervention involved technique demonstration and feedback from a lactation consultant and daily independent practice. Lactation outcomes were assessed during the postpartum hospitalization, 1–2 weeks postpartum, and 3–4 months postpartum.

Results

Of 22 participants assigned to AME, 18 received an AME education study visit. Participants reported practicing AME on 60% or more of days prior to their infant's birth. Most were able to express milk antenatally (15/18), more than half collected and froze antenatal milk (11/18), and 39% (7/18) supplemented their infants with antenatal milk after birth. No major problems were reported with AME. Perinatal and lactation outcomes, including infant gestational age at birth, neonatal intensive care unit admissions, and any or exclusive breastfeeding, appeared to be comparable between AME and control groups. There were trends toward higher breastfeeding self-efficacy and lower perceptions of insufficient milk postpartum among AME participants compared to control group participants, though AME participants exhibited higher breastfeeding self-efficacy and more favorable attitudes toward breastfeeding at baseline.

Conclusions

In a group of nulliparous birthing people in the U.S., AME education and independent practice beginning at 37 weeks of pregnancy was feasible and safe. In some cases, AME provided a back-up supply of breast milk when supplementation of direct breastfeeding was indicated or desired. The relationship

between AME and lactation outcomes requires further study within a powered sample and other populations.

Trial Registration:

This trial was retrospectively registered at ClinicalTrials.gov on May 11, 2021 under the following registration ID: NCT04929301. <https://clinicaltrials.gov/ct2/show/NCT04929301>

Background

Breast/chest feeding and/or provision of human milk (hereafter, collectively referred to as “breastfeeding”) is considered the biologically normative method to feed infants and young children, with dose-dependent health implications for lactating parents and their children.¹ Although most pregnant individuals in the United States (U.S.) intend to breastfeed after birth, only 30–45% meet their goals for breastfeeding duration and exclusivity.^{2,3} Over 80% of U.S. infants begin life breastfeeding, but by two days postpartum, 19% of breastfed infants receive formula supplementation. By 3 months, only 47% of infants are exclusively breastfeeding. By 6 months, only 26% of infants are exclusively breastfeeding, and 58% are breastfeeding at all.⁴ In a prospective cohort study following five hundred primiparous women in the U.S. who intended to exclusively breastfeed, in-hospital formula supplementation doubled the risk of non-exclusive breastfeeding at 1–2 months and tripled the risk of breastfeeding cessation by two months, even when controlling for strength of breastfeeding intentions.⁵ Primiparous individuals and those without prior breastfeeding experience appear to be particularly at risk for not meeting their prenatal breastfeeding intentions^{3,6,7} and a constellation of interrelated lactation problems. Some of these problems include unintended in-hospital formula supplementation,^{8,9} low breastfeeding self-efficacy,^{10,11} delayed onset of lactogenesis II (copious milk production following birth),^{12,13} and perception of insufficient milk.^{11,14}

Recently, interest has grown in the practice of antenatal milk expression (AME), which may partly address some of these breastfeeding challenges. AME is often a part of prenatal education in countries including Australia¹⁵ and the UK¹⁶ and involves rhythmic self-massage of breasts with one’s hands, usually commencing between 36 and 37 weeks of gestation, at which point early milk (colostrum) is available and may be collected and frozen for later use.¹⁷ Research and clinical opinions published by our group and others suggests that AME, particularly among nulliparous and diabetic pregnant people, may increase breastfeeding confidence, reduce early formula supplementation, accelerate the transition to lactogenesis-II (copious milk production typically occurring 48–72 postpartum),¹⁸ and contribute to more abundant postpartum milk production.^{19–24} A common concern about AME is that potential nipple stimulation may increase endogenous circulating oxytocin, contributing to uterine irritability and onset of labor. Yet in the largest study of AME to date—the DAME Trial, which involved 635 women with gestational or preexisting diabetes, practicing AME twice per day beginning at 36 weeks of pregnancy did

not increase the rate of preterm births, neonatal intensive care unit (NICU) admissions, neonatal or maternal morbidity. There was also a small beneficial effect of AME on exclusive breastmilk feeding in the first 24 hours post-birth (aRR 1.15).

The majority of the research on AME to date, including its feasibility, acceptability, and effect on lactation outcomes, has been conducted outside the U.S. and among women with diabetes, whose infants are at risk for formula supplementation after birth due to hypoglycemia.¹⁷ In this paper, we describe the implementation of a structured AME intervention among nulliparous, pregnant people in the U.S. without diabetes in the context of a pilot randomized controlled trial. We discuss feasibility related to recruitment, retention, and delivery/uptake of the AME intervention, as well as the relationship between breastfeeding outcomes and the AME intervention. Gender of participants was not explicitly assessed in this study, and thus gender inclusive terms are used throughout to account for participants who may not have identified as a “woman” or “mother.”

Methods

Design

In this pilot randomized controlled trial, we recruited a convenience sample of nulliparous people in their third pregnancy trimester and used sealed envelope block randomization to assign them to a structured AME intervention or an education control. Participants completed a baseline study visit between 34^{0/7} and 36^{6/7} weeks of pregnancy. Study visits to deliver the assigned intervention were scheduled weekly from 37 to 40^{6/7} weeks of pregnancy or until the infant’s birth, whichever occurred first (maximum of four visits in pregnancy). Visits were scheduled based on participant preference—often immediately following a prenatal visit in a clinical research suite adjacent to the prenatal practice. In the postpartum period, we met with participants to administer surveys during the birth hospitalization (1–4 days postpartum), at 1–2 weeks postpartum, and 3–4 months postpartum. Measured outcomes of interest at each postpartum follow-up included breastfeeding self-efficacy, perceived milk supply, perceived onset of lactogenesis II (copious milk production) postpartum, and breastfeeding continuation and exclusivity. No formal sample size estimation in terms of testing hypotheses was conducted; instead, target sample size (n = 45) was based on a predefined timeframe and budget that would generate feasibility data for a larger trial.

Participants and Setting

We recruited participants via study flyers and at prenatal visits within a hospital-based midwife practice at UPMC Magee-Womens Hospital (Pittsburgh, Pennsylvania) between December 2016 and February 2018. Eligible participants were at least 18 years old, nulliparous, pregnant with a single fetus, planned to exclusively breastfeed/provide their own milk to their infant for the first four months postpartum, did not have any known physiologic risk factors for insufficient milk supply (e.g., breast hypoplasia, polycystic ovarian syndrome, diabetes, breast reduction surgery), and did not have any conditions constituting a

high-risk pregnancy (e.g., vaginal bleeding after the first trimester, fetal congenital anomalies, polyhydramnios, currently smoking).²⁵

AME Intervention

At an introductory visit to AME during week 37 of pregnancy, participants viewed a video modeling hand-expression of milk (Breast Time of Life, available on YouTube: <https://www.youtube.com/watch?v=9gQ8119RNeI>). Participants were then invited to engage in hands-on, guided practice of AME utilizing the Marmet technique²⁶ with an International Board Certified Lactation Consultant (IBCLC; author JRD). Finally, we provided participants written and verbal instructions for safe expression, collection, and storage of antenatal milk in the home setting. At subsequent weekly study visits during pregnancy, participants met with the lactation consultant to reinforce AME technique, address questions about AME or breastfeeding, and collect a milk sample if possible. Similar to the protocol for home milk expression described by Forster et al,²⁷ participants were instructed to engage in at-home milk expression and collection one to two times per day for up to ten minutes and record this in a written diary, which was collected at subsequent study visits. Participants were provided sterile, flip-top containers (11mL Snappies® colostrum collectors) in which to collect and freeze antenatal milk and instructions on how to transport and store antenatal milk at the birth hospital.

Education Control

Participants in the education control group met with study staff during study visits in pregnancy to receive handouts from Lactation Education Resources (<https://www.lactationtraining.com/resources/educational-materials/handouts-parents>). Handouts addressed a new theme each week pertaining to breastfeeding preparation and prevention of common breastfeeding problems (e.g., Week 37: “Sore Nipples”). Control group participants did not receive any education on AME or breastfeeding from study staff or investigators.

Data Collection and Measurement

At enrollment, participants completed a survey assessing demographics, obstetric and medical history, and breastfeeding attitude (Iowa Infant Feeding Attitude Scale; score range 17–85, with higher scores indicative of more favorable attitude toward breastfeeding).²⁸ At enrollment and postpartum visits, surveys included an assessment of prenatal and postpartum breastfeeding self-efficacy, respectively (Breastfeeding Self-Efficacy Scale-SF; score range 14–70 with higher scores indicative of higher self-efficacy)^{29,30} and a combined measure of stress, anxiety, and depression (Perceived Stress Scale-4,³¹ PROMIS Emotional Distress-Anxiety 4-item bank,³² 3-item Pregnancy Risk Assessment Monitoring System (PRAMS) Depression/Anxiety³³; score range 11–55 with higher score indicative of higher levels of anxiety, stress, and depressive symptoms).

In a daily written diary, participants in the AME group tracked number and duration of daily home AME sessions, approximate volume of AME milk collected via visual estimation (using 5mL line on container), and any problems experienced with AME. At each study visit for AME participants, we recorded volume of

milk expressed, problems experienced during AME, and whether the participant had experienced any of the following during or directly after AME since the prior study visit: prolonged uterine tightening lasting longer than 1 minute, frequent uterine tightening (> 5 times in 10 minutes), vaginal bleeding, or reduced fetal movement.

We collected infant feeding data from the electronic health record (EHR) during the birth hospitalization, including initiation of breastfeeding, and receipt and total volume of expressed milk and formula. Additional data collected from the EHR included pregnancy complications and characteristics of the labor and birth. Data were abstracted independently by two researchers and any discrepancies resolved through re-review of EHR data and discussion with the first author.

Postpartum surveys assessed perception of insufficient milk using two methods: 1) a single investigator-created item asking “Do you feel you make enough breast milk to satisfy your baby?” with answer options of “yes,” “no,” or “unsure” (later dichotomized to yes=“no perceived insufficient milk” and no/unsure= “perceived insufficient milk”); and 2) combined score on both the Perceived Infant Breastfeeding Satiety and Maternal-Infant Breastfeeding Satisfaction subscales (10 items total) within the H&H Lactation Scale;³⁴ possible scores ranged from 0–70, wherein lower scores represented lower breastfeeding satisfaction and lower confidence that one was making enough milk. Postpartum surveys also assessed current infant feeding status (any breastfeeding and proportion of feeds in past 24 hours that were breastfeeding/participant’s own milk) and whether any antenatally-expressed milk had been fed to the infant. The 1–2 week postpartum survey assessed onset of lactogenesis II in days postpartum by asking, “How long did it take for your milk to come in after your baby was born (i.e., when did you notice a big increase in the amount of milk)?”, adapted from a validated assessment.³⁵

Analysis

We calculated descriptive statistics for sample characteristics, uptake of the AME intervention, and lactation and perinatal health outcomes using SPSS v. 27 (IBM Corporation, 2020). In terms of effect sizes for between group differences in lactation and perinatal outcomes, we report unadjusted odds ratios and 95% confidence intervals for categorical outcomes and Hodges-Lehmann Median Differences and 95% confidence intervals for continuous type outcomes.

Results

Sample Characteristics

Of 63 people assessed for eligibility, 45 (71%) met inclusion criteria, provided informed consent for study participation, and were enrolled in the study over a 14-month period. Two control group participants who were IBCLCs notified study staff that they were engaging in AME on their own during the study period. These participants were dropped from the analysis. Thirty-six participants completed at least one study visit for their assigned group without intervention crossover (AME: n = 18; Control: n = 18) and were included in analyses (Fig. 1). Most participants were white, married, possessed at least a Bachelor’s

degree, and planned to exclusively breastfeed to at least six months postpartum. Participants assigned to the AME and control groups were comparable in terms of demographics. Participants in the AME group had higher baseline scores on the BSES-SF and IIFAS, indicating higher breastfeeding self-efficacy and more favorable attitudes toward breastfeeding compared to control group participants. AME participants also reported lower levels of stress, anxiety, and depressive symptoms at baseline via the composite EDA/PSS measure compared to control participants (Table 1).

Table 1
Sample characteristics.

	Total (n = 36)	AME (n = 18)	Control (n = 18)
Married [n (%)]	27 (75)	14 (78)	13 (72)
Education [n (%)]			
<i>High school or less</i>	0 (0)	0 (0)	0 (0)
<i>Associate's or vocational degree/some college</i>	4 (11)	1 (6)	3 (17)
<i>Bachelor's degree</i>	18 (50)	9 (50)	9 (50)
<i>Post-graduate degree</i>	14 (39)	8 (44)	6 (33)
Maternal race [n (%)]			
<i>White/Caucasian</i>	32 (89)	17 (94)	15 (83)
<i>Black/African American</i>	2 (6)	0 (0)	2 (11)
<i>Other</i>	2 (6)	1 (6)	1 (6)
Hispanic ethnicity [n (%)]	1 (3)	1 (6)	0 (0)
WIC ^a recipient [n (%)]	2 (6)	0 (0)	2 (11)
Employed (at enrollment) [n (%)]	32 (89)	18 (100)	14 (78)
Maternal age [median (IQR)]	31.0 (5.8)	31.5 (4.5)	31.0 (7.5)
Pre-pregnancy BMI [median (IQR)]	23.1 (4.3)	23.6 (3.6)	22.6 (5.0)
Planned duration of any breastfeeding [n (%)]			
<i>Unsure</i>	6 (17)	4 (22)	2 (11)
<i>≤ 6 months</i>	0 (0)	0 (0)	0 (0)
<i>> 6 months</i>	30 (83)	14 (78)	16 (89)
Planned duration of exclusive breastfeeding [n (%)]			
<i>Unsure</i>	5 (14)	3 (17)	2 (11)

^aWIC: Special Supplemental Nutrition Program for Women, Infants, and Children, a U.S. federal assistance program serving low-income families. ^bBSES-SF: Breastfeeding Self-Efficacy Scale (PIBSS, MIBSS subscales): higher score indicative of greater breastfeeding self-efficacy; ^cIIFAS: Iowa Infant Feeding Attitude Scale: higher score indicative of more positive breastfeeding attitude; n = 17 for control group; ^dEDA/PSS: combined PROMIS Emotional Distress Anxiety 4-item bank, Perceived Stress Scale-4 item and PRAMS Depression/Anxiety 3-item, higher score indicative of greater depression/anxiety

	Total (n = 36)	AME (n = 18)	Control (n = 18)
< 6 months	5 (14)	2 (11)	3 (17)
≥ 6 months	26 (72)	13 (72)	13 (72)
Endorsed breast growth in pregnancy [n (%)]	32 (89)	15 (83)	17 (94)
Pregnancy complications			
Preeclampsia	5 (14)	4 (22)	1 (6)
Chorioamnionitis (suspected or confirmed)	5 (14)	3 (17)	2 (11)
BSES-SF score at enrollment ^b [median (IQR)]	51.0 (14.0)	53.0 (6.0)	42.0 (15.0)
IIFAS score at enrollment ^c [median (IQR)]	66.0 (8.0)	69.5 (7.3)	62.0 (8.0)
EDA/PSS score at enrollment ^d [median (IQR)]	22.0 (7.8)	20.0 (8.3)	23.0 (7.3)
^a WIC: Special Supplemental Nutrition Program for Women, Infants, and Children, a U.S. federal assistance program serving low-income families. ^b BSES-SF: Breastfeeding Self-Efficacy Scale (PIBSS, MIBSS subscales): higher score indicative of greater breastfeeding self-efficacy; ^c IIFAS: Iowa Infant Feeding Attitude Scale: higher score indicative of more positive breastfeeding attitude; n = 17 for control group; ^d EDA/PSS: combined PROMIS Emotional Distress Anxiety 4-item bank, Perceived Stress Scale-4 item and PRAMS Depression/Anxiety 3-item, higher score indicative of greater depression/anxiety			

AME Uptake and Problems/Concerns

Of the 18 participants who received the AME intervention, 5 (28%) completed all four weekly study visits before their infant's birth. For participants who completed written AME diaries, most reported that they practiced AME at least once each day (37 weeks: n = 12/15 (80%); 38 weeks: n = 11/18 (61%); 39 weeks: n = 10/14 (71%); 40 weeks: n = 7/7 (100%)). All participants reported practicing AME on at least 60% of all days between the initial AME study visit and their infant's birth. Sixteen (89%) reported practicing AME on at least 80% of all days.

Most participants (n = 15/18) were able to visualize milk during AME, 61% (n = 11/18) froze any antenatal milk, and 39% (n = 7/18) fed any antenatal milk to their infant after birth (n = 5 during the postpartum hospitalization, n = 4 in the first two weeks postpartum). Reasons for feeding AME milk postpartum have previously been described,³⁶ but briefly they included parental or hospital staff perception of inadequate milk transfer to infant at breast and unavailability of the participant for direct breastfeeding due to medical complications at birth (e.g., preeclampsia). Volume of milk expressed/collected during AME episodes varied considerably among participants, with a median total of 5.8 mL per participant over the study course. Median volume of antenatal milk expressed/collected per AME episode slightly increased from 37 to 40 weeks: 37 weeks: 0.24mL; 38 weeks: 0.22 mL; 39 weeks: 0.29 mL; 40 weeks: 0.88 mL (Table 2; Fig. 2).

No participants reported experiencing decreased fetal movement, frequent or prolonged uterine tightening, or vaginal bleeding during or directly following AME. Almost three-quarters of participants (n = 13/18) reported minor problems or concerns during or directly following AME, including: transient uterine tightening, pressure, or cramping (n = 11); increased fetal movement (n = 5); breast discomfort (n = 2); breast skin irritation (n = 1); fatigue in the hand or arm expressing (n = 2); nausea (n = 1); difficulty collecting milk due to problems visualizing placement of collection container under larger breasts (n = 1); and expressing less milk than the previous week (n = 1). There were high rates of obstetric and neonatal complications across both groups, with 36% of the sample (13/36; 8 in AME group, 5 in control group) experiencing pre-eclampsia, chorioamnionitis, and/or a NICU admission. Infant gestational age and birthweight appeared comparable between groups (Tables 1 and 3).

Table 2
AME intervention uptake from 37th week of pregnancy until infant’s birth
(n = 18)

Characteristic	Median (IQR); range
Number of AME study visits	3.0 (2.0); 1–4
Total times practicing AME independently	15.5 (14.3); 0–45
Total milk volume collected during AME (mLs)	5.8 (45.2); 0-93.3

Table 3
Perinatal and lactation outcomes.

	Total (n = 36)	AME (n = 18)	Control (n = 18)	*uOR (95% CI) or Hodges-Lehmann median difference (95% CI)
NICU admission (birth hospitalization) [n (%)]	10 (28)	6 (33)	4 (22)	1.75 (.40, 7.70)
Infant gestational age (weeks) [median (IQR)]	40 ^{1/7} (1 ^{5/7})	40 ^{2/7} (1 ^{5/7})	40 ^{1/7} (1 ^{5/7})	0 (-0 ^{6/7} , 0 ^{5/7})
Infant birthweight (grams) [median (IQR)]	3330 (416.3)	3420 (629.5)	3267.5 (421.3)	-79.0 (-363.0, 219.0)
Delivery method [n (%)]				
<i>Spontaneous vaginal</i>	23 (64)	10 (56)	13 (72)	1.0
<i>Assisted vaginal</i>	2 (6)	1 (6)	1 (6)	1.30 (.07,23.43)
<i>Cesarean section</i>	11 (31)	7 (39)	4 (22)	2.28 (.52, 9.99)
Breastfeeding initiation ≤ 2 hrs after birth [n (%)]	25 (69)	11 (61)	14 (78)	.45 (.10, 1.93)
Formula in hospital [n (%)]	14 (39)	8 (44)	6 (33)	1.60 (.41, 6.18)
<i>Number formula feeds [median (IQR)]^p</i>	5.0 (6.3)	3.5 (8.8)	6.5 (13.3)	2.0 (-6.0, 6.0)
<i>Total volume formula (mL) [median (IQR)]^p</i>	94.8 (151.1)	76.0 (272.9)	106.3 (601.6)	27.5 (-252.5, 122.0)
Expressed milk feeds in hospital [n (%)] ^b	12 (33)	5 (28)	7 (39)	0.60 (0.15, 2.45)
<i>Number expressed milk feeds [median (IQR)]^c</i>	2.5 (5.0)	2.0 (11.0)	3.0 (3.0)	-1.0 (-15.0, 2.0)
<i>Total volume expressed milk feeds (mL) [median (IQR)]^c</i>	34.0 (70.0)	33.0 (367.5)	35.0 (52.5)	2.0 (-607.0, 40.0)
Feeds at 1–2 weeks postpartum [n (%)] ^d				
<i>Only breastfeeding</i>	29 (83)	16 (89)	13 (76)	2.46 (.39, 15.63)
<i>Breastfeeding + formula</i>	6 (17)	2 (11)	4 (24)	.41 (.06, 2.58)
<i>Only formula</i>	0 (0)	0 (0)	0 (0)	n/a
Feeds at 3–4 months postpartum [n (%)] ^e				
<i>Only breastfeeding</i>	25 (74)	14 (78)	11 (69)	1.59 (.34, 7.37)

	Total (n = 36)	AME (n = 18)	Control (n = 18)	*uOR (95% CI) or Hodges-Lehmann median difference (95% CI)
<i>Breastfeeding + formula</i>	5 (15)	1 (6)	4 (25)	.18 (.02, 1.78)
<i>Only formula</i>	4 (12)	3 (17)	1 (6)	3.00 (.28,32.21)
BSES-SF scores [median (IQR)]				
<i>Postpartum hospitalization</i>	51.5 (16.5)	56 (13.5)	48.5 (17.8)	-7.0 (-14.0, 1.0)
<i>1–2 weeks postpartum^f</i>	58.0 (15.3)	59.0 (14.0)	54.0 (17.5)	-6.0 (-13.0, 1.0)
<i>3–4 months postpartum^g</i>	64.0 (14.5)	67.0 (4.0)	57.0 (11.0)	-8.0(-14.0, -2.0)
H & H Lactation Scale scores (perception of insufficient milk, continuous) [median (IQR)]				
<i>Postpartum hospitalization</i>	61.5 (11.3)	63.5 (13.3)	59.0 (14.3)	-5.0 (-11.0, 1.0)
<i>1–2 weeks postpartum^d</i>	65.0 (12.0)	67.0 (11.5)	63.0 (18.0)	-4.0 (-8.0, 0)
<i>3–4 months postpartum^h</i>	66.5 (7.0)	70.0 (1.0)	65.0 (8.0)	-5.0 (-6.0, -3.0)
Perception of insufficient milk (dichotomous) [n (%)]				
<i>Postpartum hospitalization</i>	15 (42)	4 (22)	11 (61)	.18 (.04, .78)
<i>1–2 weeks postpartum^d</i>	9 (26)	3 (17)	6 (35)	.37 (.08, 1.80)
<i>3–4 months postpartum^h</i>	3 (10)	1 (7)	2 (13)	.46 (.04, 5.75)
Delayed lactogenesis II [n (%)] ^e	15 (43)	8 (44)	7 (41)	1.03 (.27, 3.99)
<i>BSES-SF: Breastfeeding Self-Efficacy Scale Short Form, where higher score reflective of greater breastfeeding self-efficacy, range of possible scores 14–70; H & H Lactation Scale scores (PIBSS, MIBSS subscales), continuous-type measure of perceived insufficient milk, wherein lower scores represented lower breastfeeding satisfaction and lower confidence that one was making enough milk, range of possible scores 0–70; Perceived insufficient milk, dichotomous-type measure, as indicated by “no” or “unsure” response on survey item, “Do you feel you make enough breast milk to satisfy your baby?”</i>				
<i>*uOR: unadjusted odds ratio for AME group membership; Hodges-Lehmann median differences: estimated difference between continuous-type variable medians for AME and control groups</i>				

	Total (n = 36)	AME (n = 18)	Control (n = 18)	*uOR (95% CI) or Hodges-Lehmann median difference (95% CI)
^a 8 AME participants and 6 control participants whose infants received any formula in hospital; ^b Not specified if expressed milk feeds were antenatal or postpartum milk; ^c 5 AME participants and 7 control participants whose infants received any expressed milk in hospital; ^d data available for 17 control participants; ^e Data available for 16 control participants; ^f data available for 17 control participants and 17 AME participants who were breastfeeding; ^g data available for 13 control participants and 15 AME participants who were breastfeeding; ^h data available for 15 AME participants and 15 control participants who were breastfeeding				

Lactation Outcomes

During the postpartum hospitalization, all participants initiated direct breastfeeding, though more than half (n = 19/36; AME: n = 10, Control: n = 9) supplemented direct breastfeeding with their own expressed milk and/or formula. We did not identify consistent differences between AME and control groups in infant feeding patterns, including exclusive or any breastfeeding in hospital, at 1–2 weeks postpartum, or at 3–4 months postpartum (Table 3).

Both BSES-SF and H & H Lactation Scale scores trended higher (indicative of greater breastfeeding self-efficacy and higher satisfaction and confidence in milk supply, respectively) for those in the AME group versus the control group at each postpartum assessment point. These scores also generally increased over the postpartum course. For the dichotomous-type perceived insufficient milk assessment, more participants in the control group compared to the AME group endorsed uncertainty or affirmation that they were not making enough milk at each assessment point, with the largest difference during the postpartum hospitalization. While nearly half of the sample experienced delayed lactogenesis II (onset of copious milk production $\geq$ 4 days after birth), the rate of occurrence in both the AME and control groups was similar (Table 3).

Discussion

In this pilot randomized trial involving a sample of nulliparous birthing people in the U.S., we found that a structured AME protocol involving hand expression 1–2 times per day and weekly reinforcement visits with a lactation consultant beginning at 37 weeks of pregnancy was feasible. There was high compliance with daily AME, and most participants visualized and collected antenatal milk. We found no evidence of fetal, infant, or maternal harm associated with AME.

The average volume of milk expressed over the course of study participation and per AME episode was similar to that reported in the DAME Trial, a large randomized trial of AME among women with gestational or preexisting diabetes.²¹ Among 241 DAME participants with diabetes assigned to receive AME education, the median volume of milk expressed from 36 weeks of pregnancy to birth over a median

of 20 expressing episodes was 5.5mL.²¹ In our study, participants expressed a median of 5.8mL over 15.5 expressing episodes. In the pilot study to inform the DAME Trial, 26 women engaging in AME expressed a median of 39.6mL over 14 days and 24 expressing episodes (1.67mL per expressing episode).³⁷ This was a higher volume than we found in our study, with 0.22-0.88mL expressed per AME episode, dependent on gestational week. Similar to the slight increase in milk volume per expression episode we observed over progressive weeks of pregnancy, Rietveld (2011) also found increases over gestational weeks 35–38 among 11 participants with diabetes engaging in AME.³⁸

We found no evidence that AME was related to adverse safety outcomes, including NICU admissions, uterine hypercontractility, early onset of labor or younger gestational age at birth, lower infant birthweight, or higher rates of cesarean sections or vaginal births involving forceps or vacuum assist. The most common side effects or problems with AME in our sample were transient uterine contractility and increased fetal activity during or directly following AME. This aligns with the findings of the DAME trial; their study team conducted cardiotocography surveillance during expressing episodes, and they documented several occurrences of brief increased uterine activity during AME but no episodes of fetal tachysystole or uterine hyper-stimulation. They also found no differences in gestational age at birth, NICU admissions, Apgar scores, birthweight, or maternal onset of labor or delivery type between those assigned to AME and the control group. Pilot research conducted by the DAME researchers³⁷ and a retrospective cohort study involving 94 women with diabetes, all of whom had been advised to engage in AME beginning at 36 weeks of gestation (16 who engaged in AME),³⁹ found that AME was associated with younger gestational age at birth and increased rate of neonatal admission to special care units/NICUs. However, wide confidence intervals in both studies suggested that the observed differences may have occurred due to chance.⁴⁰

Our study was not powered to detect between group differences in lactation outcomes. Thus, the trends we observed with regard to higher postpartum breastfeeding self-efficacy and reduced perception of insufficient milk among AME participants may have been due to chance and/or more positive initial attitudes toward breastfeeding and higher breastfeeding self-efficacy within the AME group. Likewise, the small sample size and high rate of obstetric complications may have obscured or blunted any protective effect of AME on exclusive or any breastfeeding.

Our previously published qualitative research from participant interviews conducted at 1–2 weeks postpartum provides some contextualization of the lactation outcomes we observed.³⁶ Overwhelmingly, participants reported that AME enhanced their prenatal and postpartum confidence that they would be able to breastfeed and make sufficient milk. Other researchers have reported similar feedback from pregnant and lactating people who engaged in AME.^{16,37} However, participants in our study also reported inconsistent and sometimes unsupportive policies at the birth hospital for antenatal milk storage and provision. Several participants were discouraged from using their antenatal milk when supplementation of direct breastfeeding was advised. In addition, several AME participants experienced prolonged separation from their infant in the hospital due to birth complications and NICU admission. In these

cases, the total volume of antenatal milk available was not always sufficient to avoid formula use altogether, particularly as the birth hospital at that time did not have a feeding policy in place limiting supplemental feed volumes based on physiologic need.⁴¹

Larger studies outside of the U.S. have observed small effects of AME on reducing early formula use. In the DAME Trial, participants allocated to the AME arm had an adjusted relative risk of 1.15 (95% CI: 1.02–1.28) of exclusive breastmilk feeding for the first 24 hours after birth compared to the control group. More DAME participants assigned to AME were also exclusively breastfeeding during the birth hospitalization (57% vs. 49%) and at three months postpartum (60% vs. 55%), though these differences were not significant.²¹ Similar to the DAME Trial, in a retrospective cohort study conducted at a public hospital in North Queensland, Australia and involving 357 women with diabetes in pregnancy, 80 of whom expressed milk in pregnancy, infants whose mothers engaged in AME were significantly less likely to receive formula during the birth hospitalization versus infants whose mothers did not engage in AME (OR 0.12, 95% CI: 0.05–0.32).²⁴

Anecdotal observations suggest that AME may accelerate the transition to lactogenesis II after birth and contribute to more abundant initial postpartum milk volumes.³⁶ The physiologic basis for such an effect may involve critical period modulations around the time of birth that increase the number of prolactin receptors in breast tissue.^{42–44} Two randomized controlled trials conducted in India involving 180 and 200 pregnant women (both nulliparous and multiparous), respectively, found those assigned to a group advised to begin expressing milk after 37 weeks of gestation experienced shorter intervals to full lactation where no “top feed” was required versus a control group.^{20,23} We did not observe any signal in our data indicating more rapid onset of lactogenesis II among AME participants. It is possible that the high rate of birth complications, including preeclampsia, masked any potentiating effect of AME on lactogenesis-II.⁴⁵ Another consideration is that our sample consisted entirely of nulliparous individuals. On average, lactogenesis II occurs a half-day later and is more likely to be delayed in nulliparous-to-primiparous compared to multiparous individuals.^{46,47}

Any impact of AME on lactation outcomes is likely to be influenced by contextual factors, including timing and format of education. The DAME Trial and other studies on AME provided oral and/or written instructions on AME at study outset between 36 and 37 weeks of pregnancy.^{20,23,27} Casey et al. reported that all women in their retrospective cohort study in Australia were advised to begin AME at 34–36 weeks of pregnancy and were shown how to do AME by a midwife.²⁴ O’Sullivan et al. found that an online instructional video of AME evaluated among 95 pregnant, Australian women was effective in increasing participants’ knowledge and confidence in performing AME.⁴⁸ In regions where AME is not widely known or practiced, like the U.S., there may be a need to incorporate healthcare provider training and an evaluation of clinical/community infrastructures that may help to scaffold AME education. Our study used a “high touch” approach, where an IBCLC taught and reinforced AME in weekly face-to-face, one-on-one sessions, and we provided introductory education sessions to midwives at the recruitment site. Additional research is needed to examine the optimal format and “dose” of AME needed to achieve

measurable impact on lactation outcomes of interest, including proximal outcomes of breastfeeding self-efficacy and breastfeeding satisfaction, while accounting for scalability, costs, community needs, and cultural preferences. Our study team is currently conducting a large randomized trial of remote, telelactation-delivered AME education for nulliparous people in the U.S. with pre-pregnancy body mass indices ≥ 25 , who are at risk for adverse lactation outcomes. Details of the trial can be found at: <https://clinicaltrials.gov/ct2/show/NCT04258709>

In addition to the small sample size, there were several other limitations of this pilot trial. There was potential for bias in intervention delivery, in that the PI also functioned as the lactation consultant providing AME education. In addition, antenatal milk volumes were visually estimated by participants using a 5 mL anchor marking on the collection container; thus there was likely some degree of inaccuracy and imprecision in reported volumes. Finally, generalizability of findings is constrained by convenience sampling from a single midwifery practice, which resulted in a demographically homogeneous group of mostly white, college-educated participants.

Conclusions

This study provides the first evidence on the feasibility of AME among birthing people in the U.S. It is also the first investigation of AME among an exclusive group of nulliparous birthing people and those without diabetes. We found that weekly AME education and daily independent practice beginning at 37 weeks of pregnancy was feasible and safe. AME was also potentially beneficial in terms of increasing preparedness for breastfeeding and reducing reliance on formula when supplementation was advised or desired. Findings require replication within a powered sample and with other populations at risk for poor lactation outcomes.

List Of Abbreviations

AME
antenatal milk expression
NICU
neonatal intensive care unit

Declarations

Ethics approval and consent to participate: All participants provided written informed consent for study participation. The study was approved by the University of Pittsburgh Institutional Review Board.

Consent for publication: Not applicable

Availability of data and materials: The datasets generated during and/or analysed during the current study are not publicly available due to participants not consenting to this form of data sharing. However, data are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: JRD and KH conceived of the study idea and implementation details. MG recruited participants, conducted study visits, and assisted in data preparation and analysis. JRD and SS led data analysis. JRD wrote the initial manuscript draft. All authors read and approved the final manuscript.

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Figures

Figure 1

Consort flow diagram. *withdrawal also did not receive intervention, withdrawal occurred after postpartum hospital study visit

Figure 2

Box and whisker plot of average individual milk volume (mL) expressed per AME episode from gestational weeks 37 to 40. Horizontal lines in colored area represent medians across individual participant averages.