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RESEARCH

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Safety of antenatal breastmilk expression from week 34 of pregnancy: a randomized controlled pilot study (The Express-MOM study)

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Abstract

Background Mother's own milk (MOM) is important as the first nutrition for preterm infants, but mothers often struggle to initiate milk production right after preterm birth. If antenatal breastmilk expression (aBME) does not induce preterm labor when performed before term age, it could promote nutrition with MOM right after preterm birth. In this pilot study, we aimed to investigate whether aBME induces preterm labor among healthy nulliparous women from week 34 of pregnancy, to examine if aBME promotes the availability of MOM right after birth and affects breastfeeding outcomes.

Methods Women were randomized to aBME (10 min 2 × daily) from week 34 of pregnancy until birth or to the control group. Both groups had a breastfeeding consultation between week 33 and 34 of pregnancy and were followed until eight weeks after birth. The primary outcome was gestational age (GA) at birth. Secondary outcomes were the availability of MOM and exclusive breastfeeding rates from 24 h to eight weeks after birth. Ranksum test and a posterior plot for the probability of non-inferiority were applied to the primary outcome. The availability of MOM is reported as medians and IQR. Breastfeeding outcomes were analyzed with mixed effects logistic regression.

Results One hundred forty-four pregnant women were eligible for participation, 51 were excluded, and 33 declined participation/did not answer inclusion phone calls. 60 women were included and randomized. Primary outcome data were available in 55 women (28 in intervention, 27 in control). We found no difference in GA at birth between the two groups: median (IQR), 40 + 1(39 + 5:41 + 2) in intervention vs. 40 + 2 (39 + 4:41 + 1) in control, $p = 0.98$. Antenatal expressed MOM was available at birth in most women in the intervention group (23/28, 82%), with a median of 52 mL during pregnancy. There was no statistically significant difference in breastfeeding outcomes. No adverse events were reported.

Conclusions aBME performed by healthy nulliparous women from gestational week 34 did not induce preterm labor. In most women in the intervention group, MOM was available right after birth. The study results provide the basis for a trial among women at high risk for preterm birth.

Trial Registration.

clinicaltrials.gov (NCT05516199).

Keywords Antenatal breastmilk expression, Mother's own milk, Preterm birth, Breastfeeding

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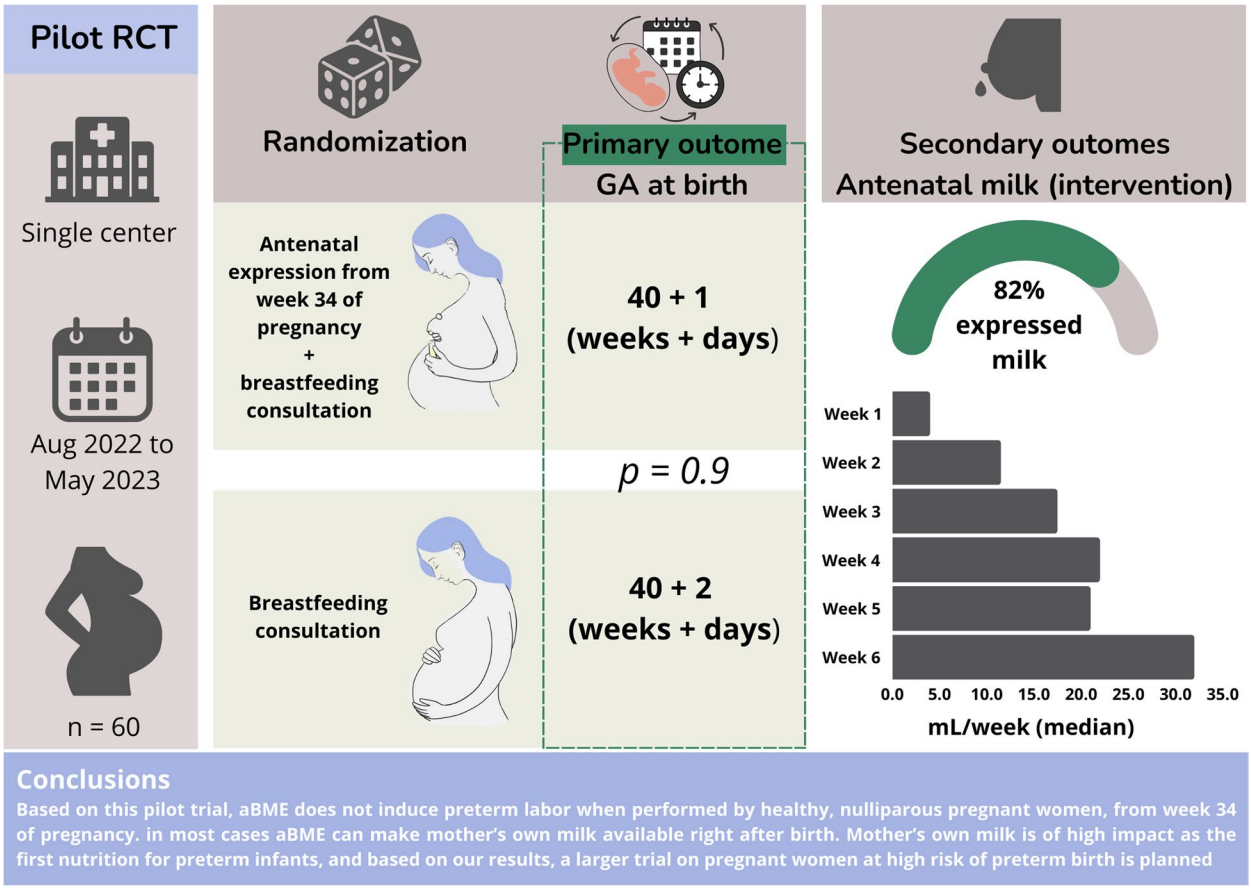
Graphical Abstract



Background

The World Health Organization recommends feeding with mother's own milk (MOM) immediately after preterm birth (PTB). Furthermore, they emphasize the importance of the bioactive components present in MOM compared to donor human milk (DHM) and infant formula [1]. The DHM is from a later stage of lactation, and during processing, a significant part of the bioactive components are lost [2]. The bioactive components, especially abundant in colostrum, provide protection against infections [3], maturate the intestines, and promote neurodevelopment [4]. However, many mothers struggle to initiate milk production right after PTB [5], due to several factors including delay in expressing colostrum and delayed onset of secretory activation [6, 7]. Therefore, DHM or infant formula is the primary source of nutrition for preterm infants in the first days of life.

There has been a rising interest in antenatal breastmilk expression (aBME), primarily investigated in pregnant women with diabetes [8], who, like mothers of preterm infants, are at risk of delayed secretory activation and low milk production [9, 10]. However, it has been of concern that increasing oxytocin levels during aBME could induce PTB [11]. Three recent randomized controlled trials (RCT) have investigated aBME, both by hand [12, 13] and by using electrical breast pumps [14]. None of the studies found associations with spontaneous birth at lower gestational age (GA). However, all studies were performed at or close to term. Only a few old case reports on aBME performed before term age exist [8], but these studies are case-based, methodologically heterogeneous, and do not report GA at birth. To our knowledge, no RCT has examined aBME before term age. If MOM could be available right after PTB, it would significantly advance the nutritional treatment of preterm infants, potentially offering

a positive impact on both short- and long-term health outcomes.

On this background, we hypothesized that aBME is safe to perform before term age in healthy pregnant women and can provide MOM to the infant immediately after birth.

Methods

Trial design

This is a single-center, unblinded randomized controlled pilot trial. The Research Ethical Committee of the University of Southern Denmark approved the study (22/2533). The study gained approval from the Data Protection Agency of the Region of Southern Denmark (21/59493). The study protocol and statistical analysis plan were registered on clinicaltrials.gov (NCT05516199).

Participants

Pregnant women eligible for participation were healthy, ≥ 18-year-old nulliparous women with a singleton pregnancy, planning to exclusively breastfeed, give birth at Odense University Hospital, and had a pre-pregnancy BMI ≤ 27 kg/m^2. Exclusion criteria were major chronic diseases (physical and/or mental), pregnancy-related conditions that could influence the time of birth (pre-eclampsia, gestational diabetes, polyhydramnios, preterm pre-labor rupture of membranes, previous cervical conization), suspicion of fetal compromise (IUGR, known fetal anomaly that could influence breastfeeding), placenta previa, breast surgery or medications which prohibited breastfeeding.

Enrolment and randomization

Pregnant women were recruited through social media and the outpatient/midwife clinics. Women interested in participating completed an online contact form and received written information about the trial by email. This was followed by a phone call from the first or second author within 2–3 days. A signed written consent was obtained through a secure digital identification platform in the REDCap database [15] and stored securely in the OPEN server (www.open.rsyd.dk), Region of Southern Denmark. The participating women were randomly assigned with a 1:1 allocation to intervention or control in block sizes of two and four, by a computerized random sequence generator in the REDCap database. Neither women, personnel, nor investigators were blinded due to the behavioral nature of the intervention and safety considerations.

Intervention

Both groups received an individual breastfeeding consultation with an experienced midwife (second author) between pregnancy week 33 and 34 in addition to standard care. The women's partners were encouraged to join the consultation. The intervention group also received instruction on hand expression techniques and proper breastmilk collection and storage. They were encouraged to perform aBME 5 min at each breast, twice daily starting from GA 34 + 0. A cardiotocography (CTG) was performed before, during, and after the first antenatal hand expression to assess fetal well-being and uterine contractions. The women were provided with written instructions on handexpression and milk storage, colostrum collectors (Haakaa, Auckland, New Zealand), and were instructed to bring any expressed milk to the hospital when in labor. They were provided with a paper schedule for daily registration of expressions and the results were reported weekly via an application incorporated in the database. They were advised to promptly contact the obstetric emergency department if experiencing continuous excessive painful contractions, vaginal bleeding, or decreased fetal movements.

Outcomes

The primary outcome was GA at birth. Secondary outcomes were the availability of antenatal milk assessed by mL of milk per week, if any, and the total number of expressions per week. Other outcomes were proportions of infants fed exclusively with MOM the first 24 h postpartum, and breastfeeding rates evaluated at 1, 2, 4, 6, and 8 weeks after birth.

Data collection

Maternal baseline data were obtained during the breastfeeding consultation. Obstetric and infant data were extracted from medical files. Weekly REDCap-administered questionnaires via the MyCap application were completed via smartphones from intervention start until eight weeks postpartum. The intervention group was addressed with aBME-related questions before birth (whether they had performed aBME (yes/no), number of expressions per week, milk volume, if any), while both groups answered questions on breastfeeding after birth (yes/no, exclusively/partially, or full formula feeding).

Sample size

The sample size was estimated based on pilot data proceeding the DAME-study [12]. Only a few prospective studies were available at the time of protocol writing, and therefore, no credible power calculation could be made. As a result, we estimated that enrolling 30 participants

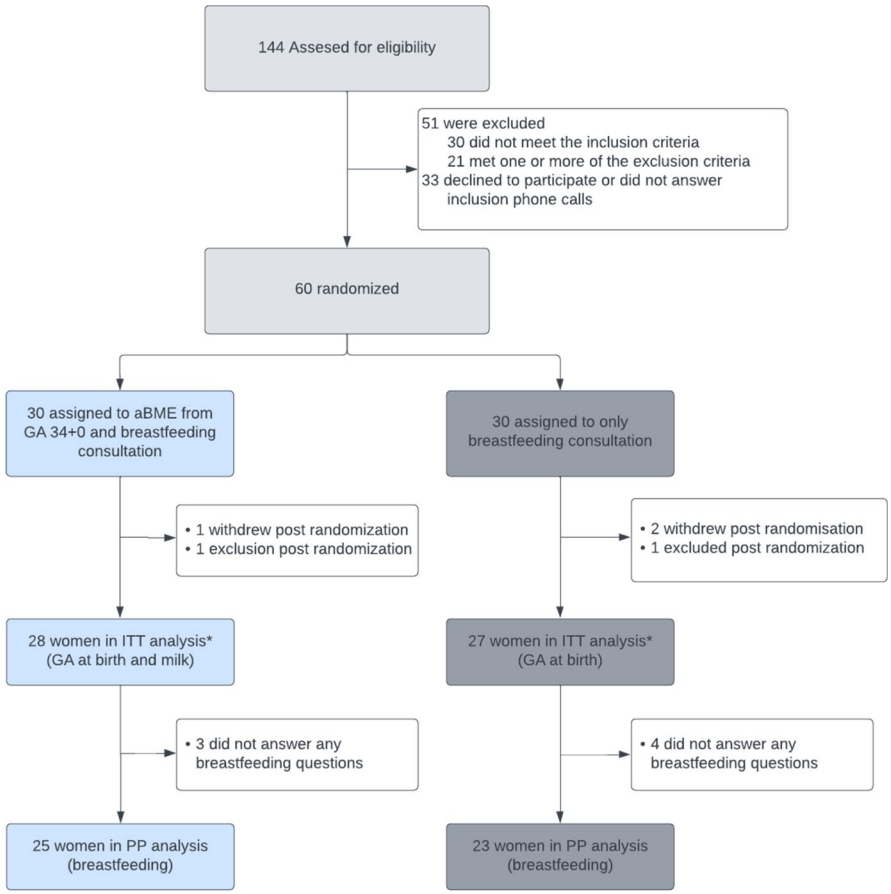


Fig. 1 Participant flowchart

in each group for the pilot trial was both realistic and feasible.

Statistics

Continuous data are summarized as mean or median. Categorical data are presented as counts (n) and percentages (%). Due to the non-normality of GA at birth, median and interquartile range (IQR) and a non-parametric test (Ranksum test) are applied to this variable. A modified Intention-To-Treat (ITT) analysis is applied including only participants who began aBME or attended breastfeeding consultations as the ITT population. A posterior plot for the probability of non-inferiority is produced by Bayesian binomial regression, with a symmetric weakly informative for the primary outcome [16]. Adverse events are reported for the intervention group as numbers (n) and percentages (%). Weekly expressions and weekly volumes of expressed milk (mL) in the intervention group are reported as medians and IQR. Breastfeeding outcomes are analyzed using mixed effects logistic regression (with restricted maximum likelihood), considering the mother by a random intercept. Analyses were performed using Stata Statistical Software, Release 18 (StataCorp, Texas, USA). (OSC).

Results

Between August 31, 2022 and May 24, 2023, 144 women were assessed for eligibility (Fig. 1). Of those, 51 were excluded: 30 did not comply with the inclusion criteria (multiparous ($n=8$), from other regions ($n=6$), pre-pregnancy BMI > 27 kg/m^2 ($n=16$)), and 21 meet one or more of the exclusion criteria (major chronic diseases ($n=5$), pregnancy-related complications ($n=1$), medication that prohibited breastfeeding ($n=1$), previous cervical conization ($n=3$), previous breast surgery ($n=3$) were > week 34 of pregnancy ($n=5$), or < week 20 of pregnancy ($n=3$). Six declined participation, and 27 did not answer the phone calls. In total, 60 women were randomized. Prior to intervention start, two women were excluded: one from the intervention group due to cervical ripening and one from the control group for not attending the breastfeeding consultation. Additionally, three withdrew

Table 1 Maternal and birth characteristics

	aBME from week 34 + breastfeeding consultation (*n* = 28)	**Only breastfeeding consultation (*n* = 27)**	***p-value***
Maternal characteristics			
Demographics			
• Maternal age at inclusion, years (median, IQR)	28 (2.5)	29 (3)	*0.9*
• Educational level (n, %)			
- High	15 (54%)	17 (63%)	*0.7*
- Intermediate	13 (46%)	10 (37%)	*0.48*
- Low	0%	0%	*N/A*
• Marital status			
- Cohabitated with a partner (n, %)	28 (100%)	27 (100%)	*NA*
Clinical characteristics			
• Pre-pregnancy BMI (median, IQR)	23 (5)	23 (4)	*0.4*
• Smoking, yes (%)	0%	0%	*NA*
Breastfeeding consultation			
• Other breastfeeding consultation, yes (n, %)	20 (71%)	20 (74%)	*0.2*
- Private breastfeeding consultant	5 (18%)	1 (4%)	*0.09*
- Public birth/child preparation	15 (54%)	19 (71%)	*0.12*
• Breastfeed as a child (n, %)			
- Yes, or partially	26 (93%)	25 (93%)	*0.97*
• Partner participating in breastfeeding consultation, yes (n, %)	24 (86%)	13 (48%)	***0.003***
Birth characteristics*			
Onset of labor			
• Spontaneously (n, %)	18 (64%)	22 (81%)	*0.15*
• Induction (n, %)	9 (32%)	3 (11%)	*0.06*
• Elective caesarean section (n, %)	1 (3%)	2 (7%)	*0.53*
Delivery mode			
• Vaginal (n, %)	22 (78%)	20 (74%)	*0.78*
• Caesarean section (n, %)			
Category 1	2 (7%)	0 (0%)	*0.15*
Category 2	3 (11%)	1 (4%)	*0.31*
Category 3	0 (0%)	5 (18)	***0.01***
Elective	1 (4%)	1 (4%)	*0.98*
Infant			
• Birth weight, g (median, IQR)	3550 g (475)	3530 (540)	*0.35*
• Birth length, cm (median, IQR)	52 (3)	52 (2)	*0.31*
• Head circumference, cm (median, IQR)	35 (3)	35(2)	*0.43*
• APGAR			
- 1 min (< 5)	2 (7%)	3 (11%)	*0.61*
- 5 min (< 5)	1 (4%)	1 (4%)	*NA*
• Intravenous fluids (yes) (%)	1 (4%)	1 (4%)	*NA*

* *aBME* antenatal breastmilk expression, *CTG* Cardiotocography

* Two women in the control group initially planned to give birth by elective cesarean section, but one was converted to an emergency cesarean section. Hence the difference between onset of labour and delivery mode

consent before the intervention started: one from the control group, who chose to start hand expression, and two due to time constraints. These five are not included in the Intention-to-Treat (ITT) analysis ($n = 55$). Three in the intervention group and four in the control group did not respond to any breastfeeding questions after birth. These are included in birth and 24-h outcomes, but excluded from the breastfeeding analyses ($n = 48$).

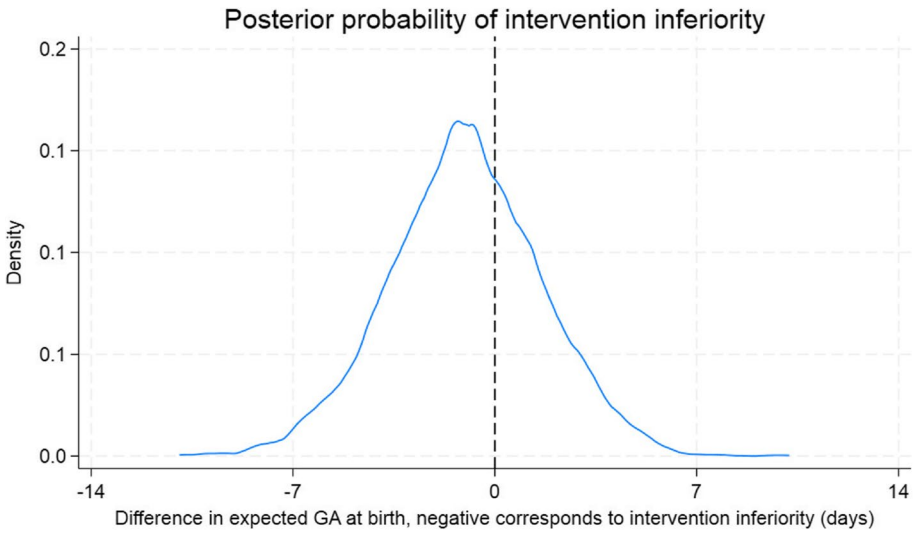


Fig. 2 Posterior plot for the probability of non-inferiority of aBME from week34

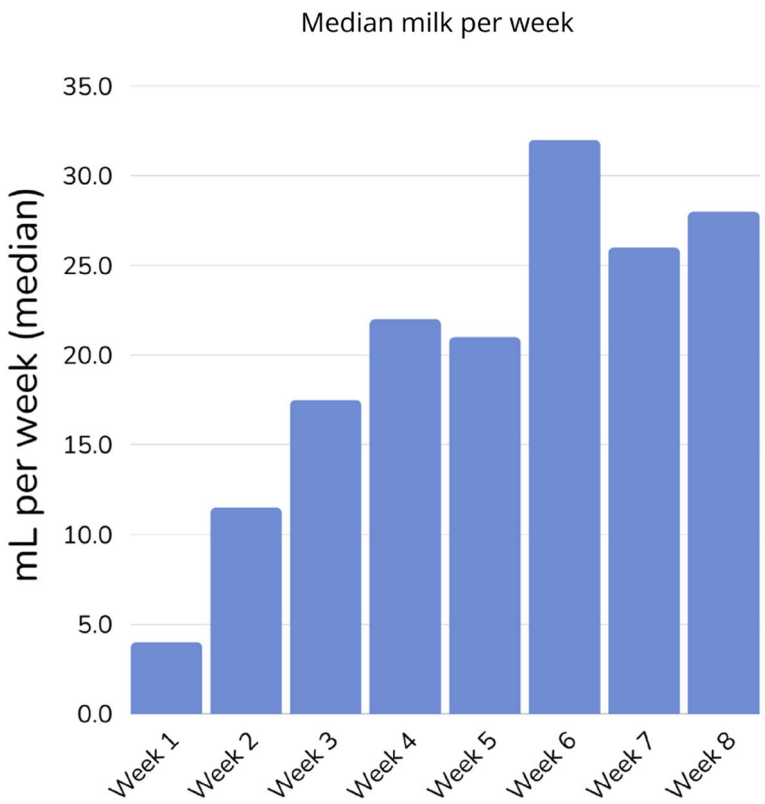


Fig. 3 Median volume of antenatal milk expressed per week. Week 1 indicates the first week from GA 34 + 0, week 2 is GA 35 + 0 and so on

Baseline characteristics

The women were comparable in demographical and clinical characteristics (Table 1). Significantly more partners to women in the intervention group participated in the breastfeeding consultation (24 (85.71%) 95%CI (72.75:98.68) vs. 13 (48.15%) 95% (29.30:66.99), $p = 0.003$). The groups were similar regarding other breastfeeding consultations (private or public), and whether they had been breastfed themselves. All women in the intervention group had normal CTG before, during, and after the

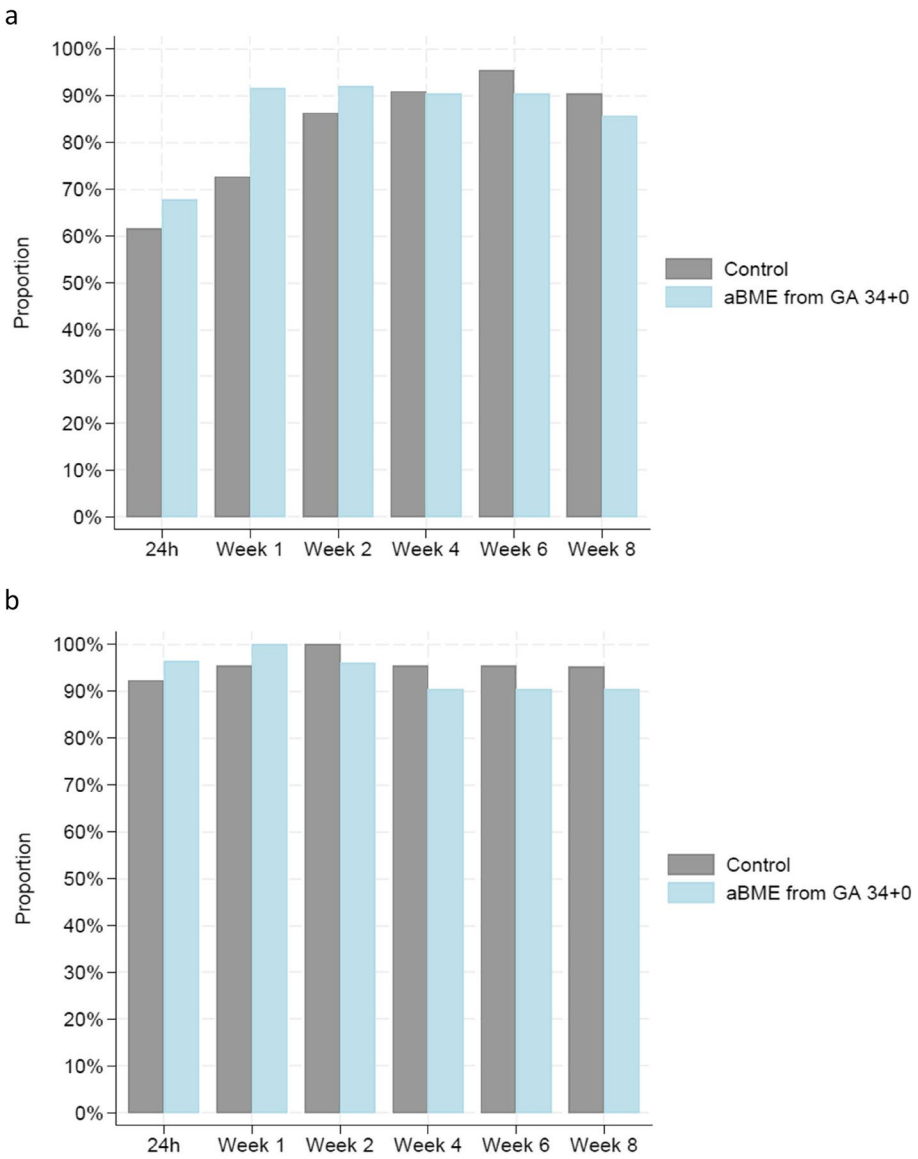


Fig. 4 Breastfeeding outcomes from 24 h until eight weeks after birth. **a** Proportion of exclusive breastfeeding in the two groups at different time plots after birth. **b** Proportion of any breastfeeding (exclusively or partially) in the two groups at different time plots after birth

first hand expression and could start aBME from week 34 of pregnancy.

Delivery and neonatal outcomes

There was no difference in GA at birth between the two groups (median (IQR), 40+1(39+5 to 41+2) in intervention vs. 40+2 (39+4 to 41+1) in control, $p=0.98$). (Fig. 2). The onset of labor and delivery mode were similar (Table 1), except that more women in the control group had a category 3 cesarean section (0 (0%) vs. 3 (18.51%), $p=0.001$). The infants were comparable in all anthropometric parameters at birth. (Table 1).

The posterior probability of intervention inferiority plot (Fig. 2) indicated a very limited probability of a GA negative difference of more than a few days, if at all, with a probability of less than 2% for a difference of more than 7 days.

Antenatal breastmilk expression

The median expressing episodes per week was 12 times (IQR (8)). Most of the women (82%) reported to have performed aBME at least 7 times per week, and 53% reported to have expressed 12 times or more per week during the intervention period. In total, 23/28 (82%) in

the intervention group did express milk before birth. The median volume of milk expressed and stored during pregnancy was 52 mL milk with a considerable variation from few droplets of milk to 477 mL (Fig. 3). A Spearman's correlation was estimated to determine the relationship between the number of expression episodes and milk volumes. There was a statistically significant positive correlation between the number of expression episodes and mL milk, but only 40% of the variation can be explained by the number of aBME attempts (0.39 (0.22–0.56), $p < 0.002$). The median expressing episodes pr. week for the women who did not express any milk was 5.5 times.

Adverse events

No women reported bleeding, contractions, or uterus pain in relation to hand expression. One woman reported increased Braxton Hicks contractions three days after she started hand expression, although these were not directly related to the expression episodes. She paused the intervention and was examined with ultrasound scanning of the cervix and CTG. No pathology was found, and she restarted hand expression. The Braxton Hicks contractions stopped spontaneously, and she gave birth at term age. Two women in the intervention group gave birth before term age in GA 36 + 1 and 35 + 4 due to placental abruption (not related to hand expression episodes) and chorioamnionitis, respectively.

Breastfeeding

Exclusive MOM and breastfeeding

There was no statistically significant difference between the two groups regarding feeding exclusively with MOM during the first 24 h after birth (OR 1.4 95%CI (0.20:10.42), $p = 0.73$). Almost all the women initiated breastfeeding to any extent during the first 24 h (27/28 (96%) in the intervention group vs. 24/27 (93%) in the control group) (Fig. 4b). The proportions of exclusively breastfed infants in the two groups at different time points are illustrated in Fig. 4a. There were higher odds of exclusive breastfeeding in the intervention group (OR 12.46. (0.70:22.74), $p = 0.08$) one week after birth, but this was not statistically significant. We found no difference in the odds for exclusive breastfeeding between the two groups at two weeks (OR 4, 95%CI (0.19:78.44), $p = 0.38$), four weeks (OR 1.3, 95%CI (0.056:32.47), $p = 0.85$), six weeks (OR 0.5, 95%CI (0.016:17.61), $p = 0.72$) or eight weeks (OR 0.5, 95%CI (0.029:9.39), $p = 0.65$) after birth.

Any breastfeeding

We found no difference between the groups in any breastfeeding vs. no breastfeeding at any time during follow-up (Fig. 4b).

Discussion

Summary of results

This pilot trial is the first randomized study to investigate aBME in pregnant women before term age, focusing primarily on safety with a potential risk of PTB. No difference in GA at birth between groups was found, and no adverse events related to aBME were observed, indicating that aBME before term is safe. Notably, 82% of the women in the intervention group did express milk during pregnancy, although the volumes varied widely. MOM was available for the infants, but no statistically significant difference in exclusive MOM feeding in the first 24 h after birth was found.

Induction of labor

The primary concern regarding aBME before term age is that increasing maternal oxytocin levels could induce preterm contractions and thereby PTB, because synthetic oxytocin is used to induce labor [17]. Although the exact physiological mechanisms of labor are not completely understood, the time of oxytocin exposure, endocrinological changes, and anatomic factors seem important as well [18]. A Cochrane review evaluated aBME as a way of inducing cervical ripening and contractions [11]. The review comprised six trials with 719 women, all beyond week 37 of pregnancy. They reported that more women in the aBME group were in labor compared to oxytocin or no intervention, why they suggested aBME as a potential method for labor induction. This conflicts with our results. It is crucial to highlight that aBME was done for one to three hours daily in all included trials, diverging from our approach of 5 min per breast twice daily.

Notably, the results of the review were not significant if the women had an unfavorable cervix. A finding supported by a review of maternal plasma levels of oxytocin during childbirth, which indicates that oxytocin spikes during labor did not correlate with uterine contractions, suggesting additional mechanisms for the control of contractions [19]. Moreover, the uterine oxytocin receptor expression evolves throughout pregnancy, with a rapid upregulation in late pregnancy, accompanied by a diminished inhibitory effect of relaxin, estrogen, and progesterone [20]. Among breastfeeding women, oxytocin increases within one minute after breast stimulation and returns to baseline six minutes after the end of stimulation [21]. While unexplored among pregnant

women performing aBME, one could hypothesize that hand expression for ten minutes may also only lead to a temporary oxytocin exposure, insufficient to induce contractions independently. Furthermore, oxytocin levels increase during sexual intercourse, which is considered safe during pregnancy [22]. Importantly, our study revealed no impact on GA, which is similar to the findings by Forster and colleagues [12].

Milk production

Colostrum production after birth varies between women, but a median of 30 mL/day in early lactation has been reported [23]. In our study, 82% could express milk, whereas Estafanous et al. found that 62% could express milk [14]. Milk volumes collected during the intervention period were reported by Forster et al. (median 5.5 mL) [12], Estafanous et al. (median 6.8 mL) [14], and Demirci et al. (median 5.8 mL) [13]. They all found lower milk volumes compared to our results (median 52 mL milk). This may be explained by high compliance in our trial, as 82% of women reported practicing aBME at least seven times weekly. Furthermore, they performed aBME for a longer period compared to other studies. Similar to Demirci et al. [13], we found an increasing volume throughout pregnancy. Whether this is due to a true increase in colostrum production, a manifestation of gaining expertise with the techniques, increased comfort with expressing (manuscript in preparation from this study), or a combination thereof, is unknown and cannot be drawn from this study. In this study, we did not analyze the antenatally expressed colostrum, and to our knowledge, no current studies have analyzed the composition of antenatally expressed colostrum. Therefore, we do not know if it resembles the same favorable composition as colostrum expressed after birth. This is important to investigate in future studies.

Breastfeeding outcomes

Breastfeeding is the most frequently reported outcome on aBME [8]. The prevailing trend indicates that aBME not significantly influences breastfeeding outcomes [14, 24–26]. The understanding that secretory activation is primarily triggered by decreasing progesterone levels after placental delivery rather than an increase in oxytocin substantiates this alignment. In contrast, one study by Lamba et al. [27], report significantly improved early lactation outcomes among women performing aBME, measured by the time for secretory activation. However, the intervention and participants are not described in detail, and the outcomes are not clearly defined. A study investigated aBME from term age among women, comparable to our study population [13]. They found that exclusive breastfeeding rates were lowest in the initial postpartum days, but peaked one to two weeks after birth. Our findings similarly indicate higher odds of exclusive breastfeeding in the intervention group one week after birth. Nevertheless, both studies have small samples and are not powered to detect differences in breastfeeding outcomes. In Denmark, we have high breastfeeding rates in the first weeks after birth [28], and thus, it would require many participants to detect a possible difference. In 2023, a study protocol for investigating aBME in women with pre-pregnancy BMI > 25 kg/m^2 was published, hypothesizing higher rates of exclusive breastfeeding within the first two weeks postpartum in the aBME group [29]. Additionally, they introduce exploratory outcomes, including breastfeeding 6 and 12 months postpartum, marking it as the first study to undertake long-term breastfeeding evaluation after aBME.

Strengths and limitations

This study has strengths and limitations. For safety reasons, we recruited only low-risk pregnancies, creating a highly homogeneous cohort. While not representative of the general population, this homogeneity minimizes confounding factors. The use of a weekly mobile application for questionnaires minimized recall bias and likely improved adherence to the intervention. The participants demonstrated high compliance and adherence to the intervention, which was crucial for deriving meaningful conclusions, emphasizing the internal validity of the study.

A limitation is the inability to conduct a reliable power calculation given the absence of prior research at lower gestational weeks. Both groups received identical breastfeeding consultations, with an expectation of easier breastfeeding establishment conveyed to all participants. The inability to blind participants and personnel introduces a potential performance bias, as expectations may have influenced reported outcomes in the intervention group.

Perspectives

The new guidelines for the nutrition of preterm infants from the European Society of Pediatric Gastroenterology, Hepatology, and Nutrition support the very early initiation of enteral feeds with mother's own colostrum [30]. A recent meta-analysis on mother's own colostrum administered immediately after PTB showed protection against necrotizing enterocolitis, late-onset sepsis, feeding intolerance, and even death [31]. Applying the principles of aBME to mothers at risk of PTB holds the potential to revolutionize the nutritional treatment of preterm infants. However, this target group differs significantly from the women in this trial, and the pathophysiology of conditions predisposing to PTB remains unclear [32, 33].

The underlying pathophysiology could affect outcomes, including labor, the amount of milk available before birth, and breastfeeding. Therefore, a statistically robust trial is essential to evaluate aBME in pregnant women with a high risk of PTB.

Conclusions

Based on this pilot trial, aBME does not induce preterm labor when performed by healthy, nulliparous pregnant women, from week 34 of pregnancy. We also conclude that aBME in most cases can make MOM available right after birth. MOM is of high impact as the first nutrition for preterm infants, and based on our results, a larger trial on pregnant women at high risk of preterm birth is planned.

Abbreviations

MOM	Mother's own milk
DHM	Donor human milk
PTB	Preterm birth
GA	Gestational age
aBME	Antenatal breastmilk expression
RCT	Randomized controlled trial

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Authors' contributions

M.B.S.: Concept and design, writing the protocol and statistical analysis plan, acquisition, analysis, and interpretation of data, and drafting the manuscript S.B:B.: Concept and design, acquisition of data and revising the manuscript S.M.: Supervising the statistical analysis plan, interpretation of data, and revising the manuscript K.G.H.: Concept, revising the manuscript C.A.V.: Concept and design, revising the protocol and the manuscript G.Z.: Concept and design, interpretation of the data, and revising protocol, statistical analysis plan and the manuscript. All authors approved the final version of the manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The Research Ethical Committee of the University of Southern Denmark approved the study (22/2533). The study gained approval from the Data Protection Agency of the Region of Southern Denmark (21/59493). All participants signed written consent before participation in the study.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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