Short-term efficacy of two breast pumps and impact on breastfeeding outcomes at 6 months in exclusively breastfeeding mothers: a randomised trial

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Abstract

The provision of breast pumps is a potential strategy to increase breastfeeding duration. This trial compared the effectiveness and acceptability of two breast pumps in mothers exclusively breastfeeding (EBF) their healthy term infant. It also tested whether provision of pumps versus vouchers of equivalent value influenced breastfeeding or attainment of mothers' goals at 3 and 6 months. Mothers were randomised at 3-4w post-partum (Beijing (n=30), Moscow (n=34), London (n=45), New York (n=3)) to group A (Philips single-electric pump, Natural bottle), B (Medela Swing single-electric pump, Calma bottle) or C (Control; vouchers). At 6w, group A and B mothers expressed for 10 minutes/breast; milk weight and provided opinions of pump/bottle. Feeding practices were assessed using questionnaires at 3 and 6mo. Milk weight/flow pattern did not differ between groups. Pump A scored significantly better for ease-of-use, cushion-feel, need-to-lean-forward, pleasant, comfort. At 3 and 6mo, %EBF or meeting their goal was not significantly different; (3mo 86, 85, 84%; 6mo 20, 15, 26%; meeting goal 24, 17, 27% for A, B C). Expressed breast milk (EBM) provision was higher in groups A and B (3mo 76, 76, 24% ($p<0.001$); 6mo 83, 87, 32% ($p<0.001$); and negatively predicted EBF at 6mo (OR no EBM 5.07 (95% CI 1.56-16.5)). The pumps were equally effective for milk expression at 6w. Pump provision did not significantly influence breastfeeding practices or attainment of goals but resulted in higher EBM provision, which was associated with lower EBF but not other breastfeeding categories at 6mo.

Key messages

- Two single-electric breast pumps with different design features showed similar efficacy but there were differences in mothers' opinions for pump characteristics
- Breastfeeding practices at 6 months did not differ significantly between mothers who were exclusively breastfeeding their term infant at 3-4 weeks and randomised to receive a breast pump versus vouchers to an equivalent value
- Women randomised to receive a pump were significantly more likely to express milk and feed it to their infant than those randomised to receive a voucher
- Feeding expressed breast milk at 3 or 6 months was associated with reduced exclusive breastfeeding at 6 months but did not predict the likelyhood of any breastfeeding at 6 months

Keywords: Breast pump, breastfeeding, efficacy, randomised trial, milk expression, expressed milk

Introduction

Breastfeeding is an important public health intervention, with benefits for infants and mothers (Victora CG et al., 2016), and the potential for significant economic savings from even modest increases in prevalence and duration (Rollins NC et al., 2016; Renfrew M et al., 2012). The World Health Organisation (WHO) recommends that mothers exclusively breastfeed (EBF) for the first six months of life (WHO, 2002)). However, many mothers do not achieve this and even when initiation rates are high the proportion still breastfeeding often falls steeply over the first weeks post-partum (Victora CG et al., 2016; RCPCH, 2017). Reasons why mothers do not follow or achieve breastfeeding recommendations are complex and differ among countries and regions, but include concern about the adequacy of milk production, family and work commitments, night-time waking and feeling uncomfortable breastfeeding in public (Victora CG et al., 2016; Rollins NC et al., 2016; RCPCH, 2017).

One possible strategy to improve the provision of breast milk could be the increased use of expressed breast milk (EBM), to be given to the infant when breastfeeding is not possible or convenient. The prevalence of milk expression is not well documented, but appears to vary between countries (Labiner-Wolfe J et al., 2008; Win NN et al., 2006; Weisband YL et al., 2017). Reasons for expressing milk in mothers who deliver a healthy term infant broadly reflect short-term issues such as difficulty establishing lactation or concerns about milk supply, and longer-term considerations including returning to work or 'keeping up the milk supply' (Win NN et al., 2006; Weisband YL et al., 2017). The impact of milk expression on breastfeeding outcomes is unclear. A systematic review of incentives to promote breastfeeding (Moran VH et al., 2015) identified seven studies, including 5 randomised trials, evaluating the effect of breast pump provision alone or with other incentives, and effects on breastfeeding outcomes were inconsistent. Other studies examined associations between breast pump use and breastfeeding outcomes (Win NN et al., 2006; Schwartz K et al., 2002; Bream E et al., 2017; Ahluwalia IB et al., 2000; Meehan K et al., 2008) with similarly mixed results, most likely reflecting differences in the study populations and underlying reasons for milk expression.

Several methods are available for milk expression, from hand expression to large dual-electric breast pumps. Breast pump technology was historically based largely on suction, which may be unphysiological (Burton P et al., 2013a). Advances in pump technology have included the introduction of massage cushions in the pump insert which aim to mimic the compressive action of the infant during breastfeeding; a strategy shown to be effective and appreciated by mothers expressing milk for both preterm (Fewtrell MS et al., 2001a; Burton P et al., 2013b) and term infants (Fewtrell MS et al., 2001b). Another development has been the introduction of two-phase patterns of milk expression, with 'let down' and 'expression' phases to mimic an infant breastfeeding (Kent JC et al., 2003). To our knowledge, whilst studies have examined the impact of breast pump design on short-term milk production and maternal preference, no study has yet tested whether the use or design of a pump influences breastfeeding duration or attainment of the mother's own goals.

This randomised trial had two main aims. Firstly, to compare the effectiveness and acceptability of two modern single electric breast pumps with different design features in mothers breastfeeding their healthy term infant; and secondly, to test whether the provision of these pumps versus provision of vouchers to an equivalent monetary value influenced the likelihood of the mother breastfeeding at 3 and 6 months and attaining her own breastfeeding goals.

Methods

Exclusively breastfeeding mothers were recruited 3-4 weeks post-partum from 4 sites (London (UK), Moscow (Russia), Beijing (China) and New York (US)). In the UK, mothers were recruited from local mother and baby groups, using flyers and via word of mouth while in the US, Russia and China they were recruited from maternity/baby clinics. Mothers were eligible if they; (i) had a healthy, term singleton infant (birthweight >2.5kg, ≥37 weeks gestation); (ii) were EBF and willing to be randomised to receive a pump or to continue breastfeeding without using a pump; (iii) were not using a pump regularly; (iv) could speak and write in English, Russian or Mandarin. Enrolment and randomisation were performed in the clinic or during a home visit. Mothers were randomised to one

of three groups: (1) Group A; Philips single electric Comfort breast pump with Natural bottle (Philips Consumer Lifestyle, Amsterdam, The Netherlands); (2) Group B; Medela Swing single electric pump with Calma bottle (Medela AG, Baar, Switzerland); (3) Group C; Babycare vouchers to the value of the breast pump/bottle combination. Pump A has a 5-petal massage cushion to reduce reliance on vacuum and compact expression funnel to minimise the need to lean forward; it also allows flexibility of suction and rate. Pump B has a two-phase expression system with a 'light and fast' initiation phase and a 'slower and deeper' extraction phase. A bottle and teat was included in the pack with the pump. The nurse explained to mothers in Groups A and B how to use and clean the pump, optimise milk expression and store breast milk safely. Apart from the physiological test at 5/6 weeks and familiarising themselves with the pump beforehand, it was entirely the mother's choice whether she expressed milk and/or used the study bottle. If a mother used another pump, she was asked to record this with the reason for her decision. Study literature was translated into Russian or Mandarin and back-translated by a second person to check for consistency of meaning.

Baseline data were collected on socio-economic status, pregnancy and delivery, infant health and feeding. Mothers were asked to indicate their personal goals for EBF and any breastfeeding in months, using questions from the Infant Feeding Practices Study (Centers for Disease Control & Prevention, 2009).

The study was registered with clinicaltrials.gov (NCT02128295; April 2014) and approved by the research ethics committee in each site (UK – UCL Research Ethics Committee, ref: 5645/001 12.8.14; USA – North Shore LIJ, Office of the Human Research Protection Program, ref: 14-325B 25.9.14; Russia – Local Ethics Committee, ref:35-04/15.04.14; China: Local Institutional Approval). All participants gave written informed consent.

The primary hypotheses were: that (i) milk weight produced at 1 minute intervals and total weight produced in 20 minutes at 5-6 weeks post-partum would be greater for mothers using pump A than

pump B; and (ii) mothers using pump A would award higher scores for a pump characteristics than those using pump B. The primary outcome measures were the weight of milk expressed in a 20 minute period at 5-6 weeks, and the mothers' opinions of the breast pump. Secondary hypotheses were: (i) a greater proportion of mothers using pump A would be EBF, partially breastfeeding and/or providing breast milk at 3 and 6 months, and would achieve their breastfeeding goals, compared to those using pump B; (ii) the proportion of mothers in group A who were breastfeeding and achieving their goals would not differ from a control group of mothers who did not receive a breast pump; (iii) mothers would give higher scores for characteristics of feeding bottle A than bottle B, if used. Secondary outcome measures were infant feeding practices reported at 3 and 6 months of age and opinions of the bottle if used. The hypotheses were based on the fact that Pump A combines two features previously shown to improve outcomes (a compression cushion and flexibility of speed and suction) whereas Pump B has one feature (flexibility of speed and suction); and on data from previous studies in which Pump A and bottle A received higher scores for certain characteristics (Fewtrell MS et al., 2001a; Burton P et al., 2013b; Fewtrell MS et al., 2001b); Fewtrell MS et al., 2012).

Measurement of primary outcome measures at 5-6 week visit

Mothers from groups A and B took part in the physiology study, conducted in the subject's home (UK and Russia) or clinic (US and China) as close to 11am as possible and, where feasible, at least 2 hours after the last feed. Mothers expressed milk for up to 20 minutes (10 mins/breast) and the weight of milk was recorded by the research nurse at 1 minute intervals, by placing a different bottle under the pump outflow for each 1 minute period. The time and side of the last breast feed was noted.

Mothers provided their opinion about the pump (comfort, ease of use, how pleasant to use, suction, speed of milk flow, assembly, cleaning, leakage and overall opinion) using a 10cm visual analogue scale (VAS).

Measurement of secondary outcome measures at 3 and 6 month follow-up

At 3 and 6 months, mothers completed questionnaires reporting infant feeding in the last 7 days. Questionnaires were sent to the mother in the week before their infant reached 3 or 6 months. Categories at 3 months were: EBF, mainly breastfeeding (BF) with <1 formula-feed (FF) per day, mainly BF with at least 1 FF per day, mainly FF with at least 1 BF per day, mainly FF with < 1 BF per day, exclusively FF. At 6 months, there were additional categories for BF or FF with solid foods or other drinks. Separate questions asked when solid foods and/or infant formula had first been given (<22 weeks, 22-24 weeks, 24-25 weeks, not started). Breast pump and bottle use in the past 7 days were recorded as: not used, once, twice, 3-5 times, 6-7 times. Opinions of the study pump and bottle (if used) were recorded as: strongly agree/agree; neither agree nor disagree; strongly disagree/disagree with a series of statements. This method was used rather than a VAS to facilitate completion online; SurveyMonkey was used in the UK, whilst questionnaires were sent by e-mail or post in the other centres. Mothers received a £15 (or equivalent) Babycare voucher on completion of the questionnaires.

Randomisation and blinding

The randomisation schedule was computer-generated in randomised blocks of 3 and 6, stratified by site and parity; assignments were prepared by a team member with no subject contact and kept in sealed, opaque envelopes. After confirming eligibility and obtaining written informed consent, the research nurse opened the next randomisation envelope in sequence, and provided the pump or vouchers according to the assigned group. It was not possible to blind mothers or research nurses to pump allocation, but data analyses for primary outcomes were performed blind to randomised group.

Statistics

A sample size of 64 per group for the primary analysis (comparison between randomised pump groups) at 6 weeks was estimated to provide 80% power to detect relevant differences in milk production and pump characteristics at $p<0.05$, based on a combination of data from previous studies (Fewtrell MS et al., 2001a; Fewtrell MS et al., 2001b) and consumer data, although none of the available data were directly applicable to the planned study as different breast pumps were used under different circumstances. To allow for drop-outs and subjects who did not comply with the protocol, we planned to recruit 228 subjects (76 per group) between the 4 participating centres (51 from Russia, 45 from China, 54 from the US, 78 from the UK).

Analyses were performed on an intention-to-treat basis. Comparisons between pump groups were made using t-test, Mann-Whitney test or chi-square test as appropriate. Comparisons of infant feeding practices between the 3 randomised groups were made by ANOVA with post-hoc pairwise testing (Dunnett test) if the ANOVA was significant, or where specified *a priori*. Data on the age at first introduction of solid foods and/or infant formula were recoded to a variable indicating EBF at 6 months (ie. no solids or formula) as yes/no. Data for milk production at 1 minute intervals were analysed by repeated measures ANOVA. Predictors of milk production during the physiological test were examined using general linear models, including parity, study site, randomised pump and time since the last breast-feed. Predictors of EBF and any BF at 6 months were examined using logistic regression. Analyses were performed using SPSS version 24.

Results

Study population

One hundred and seventy mothers were recruited from Beijing (n=45), Moscow (n=51), London (n=68) and New York (n=6) (**Figure 1**). The target sample size was not achieved in the US mainly due to mothers who either planned to use infant formula within the first few weeks or who did not

attend appointments; or the UK site where recruitment was slower than anticipated. 60 mothers were randomised to group A; 52 to group B; and 58 to group C, with no significant differences in baseline characteristics between groups (**Table 1**). However, differences in parity, maternal age, education, income and ethnicity were apparent among study sites (**Table S1**).

Primary outcome measures at 5-6 weeks

Physiology study

One hundred and seven mothers (57/60 group A, 50/52 group B) completed the physiology study with no significant difference in time since last breast-feed between groups. Milk weight at 1 minute intervals, the total milk expressed from either breast (**Table 2**) and the pattern of milk production (**Figure 2**) did not differ according to the pump used, with or without adjustment for study site (data not shown). Mothers in Russia and China had later peak milk production than UK mothers (**Figure S1**).

Opinions of breast pumps

One hundred and ten mothers (59 group A, 51 group B) completed the questionnaire. Pump A received significantly better (lower) scores for 'ease of use' (median 1.3 (25^{th}, 75^{th} centiles 0.7,2.0) v 1.9 (0.9,2.5), p=0.02), 'pleasant to use' (1.7 (0.9,2.7) v 2.3 (1.5, 4.0), p=0.02), 'feel of the pump insert' (1.95 (1.09, 3.07) v 2.71 (1.80, 4.39), p=0.02) and 'need to lean forward' (1.8 (0.8, 2.8) vs 6.1 (2.4, 8.7), p<0.001). The score for comfort was also lower (better) for pump A (1.4 (0.6, 2.3) v 2.0 (0.8, 3.2, p=0.051)). The pumps did not differ for overall opinion (1.6(0.8, 2.6) v 2.2(0.9, 3.5), p=0.06). The results were unchanged after adjusting for study site (data not shown).

Secondary outcome measures at 3 and 6 months

At 3 months, 84% (142/170) of mothers who returned the questionnaire, the majority of mothers reported EBF (86% group A, 85% group B, 84% group C). The majority of non-completers were from

the UK (25/28). Participation at 3 months did not differ between randomised groups. Mothers who completed the questionnaire were younger (31.5(4.3) versus 34.1(5.0) years), were less likely to have delivered by LSCS (17% v 36%, p=0.01) and less likely to have a family income > £45k pa (or local equivalent; 9% v 22%, p=0.014) than non-completers.

Eighty per cent (135/170) of mothers completed the questionnaire at 6 months; the majority of non-completers were from the UK (31/35). Participation at 6 months did not differ between randomised groups. Mothers who completed the questionnaire were more likely to have male infants (57% vs 43%, p<0.01), had fewer years in education (15.8 (3.5) yrs vs 17.7 (2.7) yrs, p=0.002), were less likely to have delivered by LSCS (16% v 34%, p=0.01) and less likely to have a family income > £45k pa (or local equivalent; 11% v 21%, p=0.008) than non-completers. Parity and birthweight did not differ. By 6 months, 3 group A mothers and 1 group B mother reported using a different breast pump on at least one occasion, while 6 group C mothers reported having used a pump.

At 6 months, 20%, 15% and 26% of mothers from groups A, B and C, respectively, reported EBF over the last 7 days, with no significant difference between groups (**Table 3*)***. The proportion of infants who were BF with the addition of solid foods (BFCF); was 68%, 59% and 85% for groups A, B and C (p=0.03; A v B, A v C not significant, B<C p<0.05). The proportion of mothers EBF or BF with either solids or up to one bottle of formula per day (BFCFF) was 75%, 67% and 85% for groups A, B and C (not significant); whilst the proportion of mothers reporting 'any breastfeeding' were 82%, 80% and 87%, respectively (not significant). Only 2 mothers were exclusively formula feeding and 15 (5 group B, 6 group A and 2 group C) were formula feeding with complementary feeding. The proportions who reported no use of solids or formula by 26 weeks were 16%, 18% and 26% for groups A, B and C (p=0.5). Discrepancies between this variable and 'EBF in the past 7 days' were observed where mothers reported EBF but also reported introducing solid foods by 26 weeks (2, 1 and 2 in groups A, B and C); or where they reported not EBF but also had not introduced solids or formula by 26 weeks

(2 group B, 2 group C). The latter discrepancy may be explained by the fact that a few mothers completed the questionnaire between 6 and 7 months so they may not have introduced solids or formula by 6 months despite no longer EBF when they completed the questionnaire. Excluding these 4 subjects, the EBF rate at 6 months was 20%, 16% and 27% for groups A, B and C, respectively (not significant). Assuming that these 4 subjects were EBF at 6 months, the rates were 20%, 21% and 31% for groups A, B and C, respectively (not significant). Rates of EBF at 6 months were not significantly different between the centres (**Table S1**).

Use of pumps and provision of EBM

At 3 months, 68% group A and 73% group B mothers were using their pump at least once a week, with 63% and 62% also using their study bottle. The proportion giving EBM to their infant did not differ between pump groups (76% group A, 76% group B, p=0.9); however, only 24% of control mothers had provided EBM at 3 months (p<0.001 for 3-way comparison) (**Table 3**). Significantly fewer mothers in Russia (37%) were giving their infants EBM compared to either mothers in the UK (71%) or China (71%), p<0.01.

At 6 months, there were no significant differences between groups in the proportions using their pump daily (group A 20% v group B 36%, p=0.09) or weekly (group A 62% v group B 77%, p=0.22); or in those using the study bottle. The proportion of mothers who had fed EBM to their infants was still significantly lower in group C (83% group A, 87% group B, 32% group C, p<0.001).

Attainment of breastfeeding goals at 6 months

At baseline, 127/165 (77%) mothers aimed to EBF for 6 months; this goal did not differ significantly by randomised group (80% group A, 73% group B, 78% control, p=0.62). Data for 5 mothers were excluded as they gave the same value for both duration of EBF and any breastfeeding or implausible values. Of 148 mothers who answered the further question: 'when do you plan to stop

breastfeeding your baby?', 82% said at or beyond 12 months.

One hundred and thirty two mothers provided data on breastfeeding goals and on infant feeding at 6 months. 100/132 (76%) aimed to EBF for 6 months. The proportion of mothers who attained their goal of EBF for 6 months was 24%, 17% and 27% for groups A, B and C respectively (not significant). Results for BFCF and BFCFF at 6 months were also not significantly different between groups (BFCF 63%, 69% and 89%; BFCFFF 71%, 79% and 88%). Conversely, 5/32 (16%) mothers who planned to EBF for < 6 months reported they were EBF at 6 months.

Opinions of bottles

41 group A and 52 group B mothers had used the study bottle and completed the 6 week questionnaire. Bottle A scored more highly (lower score) for cleaning (1.89 (25^{th}, 75^{th} centile 0.6, 2.3) v 2.0 (1.2, 3.4) p=0.04); leakage (1.0 (0.5, 2.2) v 2.5 (1.0, 4.6) p=0.001; shape of teat (2.6 (1.4, 3.9) v 3.8 (2.0, 5.1) p=0.01; and overall opinion (2.3 (0.9, 3.4) v 3.2 (1.8, 6.2) p=0.09). At 3 months, significantly more mothers using Bottle A agreed or strongly agreed that it was easy to clean compared to those using bottle B (88% v 54%, p = 0.001). At 6 months, more group A mothers agreed the bottle was easy to clean (97% v 70% group B, p=0.01) and that they liked the bottle (100% v 86%, p = 0.04).

Predictors of the amount of milk expressed in the physiology test

The total milk expressed was predicted by the time since the last feed (0.58g more per minute, p=0.002), parity (adjusted mean for primips 128.7g v multips 173.9g, p=0.002; and study site (China adjusted mean 120.8g, UK 140.3g, Russia 192.8g, p<0.001); but not by randomised pump group (group A 153.6g, group B 149.0g, p=0.7). The model predicted 40% of the variance in milk weight. Breast pump opinions scores were not significant predictors of milk production.

Predictors of EBF and any BF at 6 months

Parity, centre, randomised group, maternal age, years of maternal education, pump opinion scores, and use of EBM at 3 and 6 months were investigated as potential predictors of EBF or any BF at 6 months in 135 mothers for whom this outcome was available. Provision of EBM at either 3 or 6 months was the only significant predictor; mothers who reported giving EBM to their infant were significantly less likely to report EBF at 6 months (OR of EBF at 6 months if no EBM given by 3mo 4.03 (95% CI 1.23 to 13.2, Nagelkerke R^2 0.18) and if no EBM given by 6mo 5.07 (95% CI 1.56 to 16.5, Nagelkerke R^2 0.20). The effect remained after adjusting for the mother's initial goal for EBF. By contrast none of these factors, including provision of EBM, were significant predictors of other breastfeeding outcomes (any BF, BFCF or BFCFFF) at 6 months.

Discussion

The first aim of our study was to test the efficacy and acceptability of two single electric breast pumps with different design features. We found no difference in the total amount of milk expressed or pattern of milk flow at 5-6 weeks post-partum. More milk was expressed by multiparous women, and also when there was a longer time interval since the last feed, consistent with our previous study in term mothers (Fewtrell MS et al., 2001b). Interestingly, study site was also a significant predictor of the amount of milk expressed during the test, with Russian mothers expressing most milk and Chinese mothers the least, even after adjusting for parity. The explanation for this is unclear, although we cannot rule out differences in the way the physiology test was conducted in the different sites which may have influenced the time to milk ejection, despite our best efforts at training and standardisation of the process.

Mothers who used pump A awarded significantly more favourable scores for certain pump characteristics - ease of use, how pleasant the pump was to use, comfort, feel of the pump insert and the need to lean forward - compared to mothers who used pump B, similar to findings in

previous trials using manual or electric versions of these pumps in mothers of both preterm and term infants (Fewtrell MS et al., 2001; Burton P et al., 2013b; Fewtrell MS et al., 2001). In mothers expressing milk for their preterm infant we found that the score awarded for comfort of the pump on day 10 was a significant predictor of total milk volume expressed whilst the infant was hospitalised (Burton P et al., 2013b). However, in the current trial, opinions of the pump did not predict the amount of milk expressed, albeit on a single occasion at 5-6 weeks, nor breastfeeding practices at 6 months. Furthermore, use of the pumps did not differ between groups and similarly small numbers of mothers in each group changed to an alternative pump.

The second aim of our trial was to evaluate the impact of providing a breast pump on subsequent breastfeeding practices and the attainment of the mother's own goals. All mothers were EBF at the time of enrolment, and the rates of EBF plus other categories of breastfeeding at 3 and 6 months were higher for the study population than reported for the general population in each country. However, there was no significant difference in breastfeeding practices between the two pump groups and the control group who received vouchers. For each outcome, there was a trend towards higher values for the control group but this did not reach significance with the exception of BF with solid foods, where the rate was significantly higher for the control group compared to group B. At baseline, 77% of mothers stated their aim was to EBF for 6 months. This was achieved by 23%, whilst 73% were EBF with the addition of solid foods, with no difference between groups. Our findings suggest that the provision of a breast pump to mothers who have already established EBF neither increases nor decreases the likelihood of the mother breastfeeding at 6 months or, importantly, meeting her own breastfeeding goals. However, our study was not powered to detect differences in this outcome and a larger study would be required to exclude a smaller effect size.

Previous randomised trials investigating the effect of the provision of breast pumps on breastfeeding were conducted in the USA, and the results were inconclusive (Dungy CI et al., 1992; Bliss MC et al., 1997; Sciacca JP et al., 1995; Hayes DK et al., 2008; Rasmussen KM et al., 2011). The greatest positive impact of pump provision, as part of a discharge pack, was reported when the comparator was a pack containing infant formula which itself had a negative effect on breastfeeding (Dungy CI et al., 1992); although this effect was not seen in a larger RCT with similar interventions (Bliss MC et al., 1997). Sciacca et al (Sciacca JP et al., 1995) randomised 68 low income mothers to receive 'prizes', including pumps, versus usual care and low value gifts, and reported significantly higher proportions breastfeeding in the intervention group at 2, 6 and 12 weeks. Other trials compared electric versus manual pumps (Hayes DK et al., 2008), or the use of electric pumps, manual pumps or no pump in obese mothers (Rasmussen KM et al., 2011), and reported no effect on breastfeeding. None of these trials is directly comparable with ours, particularly since our intervention started once breastfeeding had been established rather than in the early post-partum period.

Although breastfeeding practices did not differ between groups, we found that the provision of a breast pump significantly increased the likelihood of the mother expressing and providing EBM to her infant at both 3 and 6 months, compared to mothers randomised to receive vouchers. Furthermore, after adjusting for potential confounders, the provision of EBM at both ages was associated with lower EBF at 6 months, although it had no impact on any other category of breastfeeding. The randomised groups did not differ in baseline characteristics or breastfeeding goals, suggesting that the availability of the pump in itself encouraged mothers to express and provide EBM. Both breast pumps came packaged with a bottle and teat and we cannot therefore determine which component of the intervention was responsible for the observed effect. However, we did not consider it practical to provide a breast pump without the bottle since this is attached to the pump during milk expression. Furthermore, since the majority of mothers use a bottle and teat to feed EBM to their term infant (UK Infant Feeding Survey, 2010), removing the teat from the pack was not considered to represent a 'real life' scenario.

Previous studies have reported on associations between milk expression and breastfeeding practices with mixed results, most likely reflecting differences in study populations. Win et al (Win NN et al., 2006) reported that Australian mothers who expressed were significantly less likely to stop breastfeeding before 6 months than those who had never expressed. Bream et al (Bream E et al., 2016) conducted a chart review in 487 predominantly African American women who were eligible to receive a free pump under the Affordable Care Act. EBF at 2 months was similar in mothers with or without a breast pump (19.4% v 16.3%), but breastfeeding was significantly lower (31.4 v 46.9%, p=0.004) and provision of EBM higher (16.6% v 8.2%, p=0.02) in women who used a pump. Pang et al (Pang WW et al., 2017) found no difference in the likelihood of full breastfeeding at 3 months between mothers who fed directly at the breast and those who combined direct breastfeeding with EBM, amongst 541 mothers in Singapore. Schwartz et al (Schwartz K et al., 2002) reported that milk expression before 3 weeks was a positive predictor of breastfeeding termination by 12 weeks in US mothers, whereas expression after 3 weeks was associated with a greater likelihood of continuation. These findings may relate to the different reasons for milk expression at different post-natal stages as highlighted by Weisband et al (Weisband YL et al., 2017), who performed a cross-sectional study before discharge from hospital in 100 US mothers planning to breastfeed for at least 6 months. 98% planned to use a pump and 29% had already started. Those who started early reported pumping to increase their milk supply or to overcome latching difficulties, whilst for the whole cohort the most common reason given was 'to keep up the milk supply'. Our study intentionally started once breastfeeding had been established to avoid any interference with this process, so it is most likely that our mothers were pumping to maintain their milk supply or to provide milk for use when they were absent, either related to work or for social reasons.

We also addressed the method used to administer EBM to the infant. Although some mothers prefer to feed EBM using a cup, the majority who provide EBM for their term infant choose to use a bottle; 92% in a 2010 UK survey (UK Infant Feeding Survey, 2010). We previously demonstrated that the design of a feeding bottle can significantly affect infant behaviour, including fussing (Fewtrell MS

et al., 2012) and colic (Lucas A et al., 1994; Lucas A & James-Roberts I, 1998), which might theoretically influence the likelihood of the mother continuing to provide EBM. However, whilst mothers in group A awarded significantly better scores for a number of characteristics at 6 weeks, 3 and 6 months, these differences did not influence the provision of EBM or the proportion of mothers using the bottle.

Strengths and limitations

The major strength of our study is its experimental design, and the inclusion of a control group who received a voucher of equivalent monetary value to the breast pumps, which allowed us to explore causal relationships between the intervention and breastfeeding outcomes, including maternal goals. Another strength is the inclusion of infants from four countries with significant cultural differences in infant feeding and care, including two where traditional confinement periods are commonly observed. Interestingly, despite differences in baseline characteristics, the findings for all outcomes with respect to randomised groups were similar across study sites, and adjusting primary and secondary outcome analyses for study site did not alter the results, suggesting they are generalizable to women who have established EBF at 3-4 weeks post-partum.

Our study also has a number of limitations. We did not adjust our sample size for multiple outcomes nor apply any statistical adjustment for multiple testing, and this should be considered when interpreting the findings, particularly as we did not meet our planned target. Our study population consisted of mothers who were EBF at enrolment and the findings cannot therefore be generalised to all mothers and infants in those settings, for example groups with low breastfeeding rates where provision of a pump early in the post-partum period might be considered as an incentive for breastfeeding. Interestingly, a recent study in the UK that explored the views of pregnant women, new mothers, their significant others and healthcare professionals about a range of potential incentives for increasing breastfeeding, reported that the provision of a free breast pump costing around £40 was considered the most acceptable option with 67.8% agreement (337/497) (Crossland

N et al., 2016). However, their qualitative research found mixed views around issues including the monetary value of pumps, sharing the load, perceived benefits, perceived risks and issues related to the timing of any intervention. We did not collect data on the mothers' reasons for expressing milk or their opinions about receiving a pump or vouchers, partly due to the language constraints. However, these are important issues to consider in future research as they may assist in better targeting the provision of breast pumps or other incentives to sub-groups who may benefit most.

We paid careful attention when translating study documents into Mandarin and Russian, in particular asking bilingual colleagues to check that the wording of the questionnaires conveyed the same intended meaning in both languages. However, it is impossible to rule out discrepancies. We carefully defined infant feeding categories in the questionnaires, but still found some inconsistencies in the responses, for example to the questions asking about EBF versus those asking if other fluids or solid foods had been introduced. However, these occurred in all 3 groups and we do not consider they would have systematically biased the findings. Furthermore, either excluding four subjects with a discrepancy in responses to the questions on EBF at 6 mo and the introduction of solid foods or formula before 6 months, or including them as EBF at 6 months, did not alter the findings.

Conclusion

In this multi-country trial, we found similar efficacy for two single-electric breast pumps with different design characteristics. Although one pump received better ratings for certain consumer characteristics, these did not predict the amount of milk expressed, use of the pump or breastfeeding practices. Provision of a breast pump to mothers who had already established EBF at 3-4 weeks post-partum did not significantly influence breastfeeding practices at 3 or 6 months. Mothers randomised to receive a pump were significantly more likely to express milk and to feed it to their infant and this was, in turn, associated with lower rates of EBF at 6 months, although there was no effect on other categories of breastfeeding. Future research should investigate the provision

of breast pumps on breastfeeding outcomes in a larger sample, and also in different populations, including mothers from groups where breastfeeding rates are particularly low, as well as exploring mothers' opinions and motivations and the use of breast pumps as an incentive to promote breastfeeding.

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Table 1: Baseline characteristics by randomised group

	All subjects	Group A	Group B	Group C
n	170	60	52	58
Birthweight (kg) (mean (SD))	3.47 (0.41)	3.45 (0.39)	3.43 (0.43)	3.52 (0.42)
Gender - Male	88	32	23	33
Female	82	28	29	25
Parity – Primip	105	37	33	35
Multip	65	23	19	23
Delivery – vaginal	136	51	43	42
LSCS	34	9	9	16
Time after delivery when infant put to the breast				
Within 30 mins	81	35	24	22
After 30 mins	89	25	28	36
Maternal data				
Age (years)	31.9 (4.5)	32.8(4.3)	31.5(4.5)	31.5(4.6)
Maternal education				
Years full-time	16.2 (3.4)	16.5(3.8)	16.1(2.9)	15.9(3.4)
Income pa1				
Low (<£20k)	40	13	14	13
Medium-low (<£30k)	44	15	10	19
Medium-high (<£45k)	32	12	11	9
High (>£45)	54	20	17	17
Maternal Ethnicity				
White British/Europ	86	36	27	24
Chinese	53	18	18	17
All other groups	24	6	6	12

Table 2. Milk weight (g) at 1 minute intervals during milk expression according to randomised breast pump (median (25^{th}, 75^{th} centile))

		Pump A		Pump B
	n		n	
Breast 1				
1 min	57	6.2 (3.1,10.5)	50	6.6 (3.7,14.7)
2 min	57	8.6 (4.5,14.4)	50	7.2 (4.4,13.9)
3 min	57	8.5 (4.8,14.9)	50	8.4 (4.7,14.6)
4 min	57	10.0 (4.5,15.0)	50	9.0 (4.1,13.6)
5 min	56	9.2 (4.7,14.8)	60	8.1 (5.5,13.0)
6 min	56	8.9 (4.3, 13.4)	50	9.2 (4.3,12.9)
7 min	56	8.6 (2.5,11.7)	49	7.9 (2.9,12.1)
8 min	56	5.9 (2.1,10.0)	49	6.0 (2.9,10.6)
9 min	55	4.3 (2.6,9.7)	48	4.2 (1.7,8.9)
10 min	55	5.0 (2.6,8,4)	48	5.1 (2.5,11.8)
Total side 1	***57***	***83.3 (47.5,115.2)***	***50***	***71.1 (46.9,124.6)***
Breast 2				
1 min	57	4.1 (2.5,9.6)	50	5.0 (2.5,9.1)
2 min	57	7.0 (3.4,10.5)	50	6.1 (3.3,10.1)
3 min	57	5.2 (2.1,11.2)	50	6.1 (3.3,11.1)
4 min	56	4.6 (2.2,10.7)	50	6.9 (3.7,11.8)
5 min	56	4.6 (1.7,10.3)	50	6.1 (2.9,9.7)
6 min	56	4.0 (0.8,9.6)	50	5.7 (2.3,9.7)
7 min	55	3.5 (0.7,9.2)	50	5.2 (2.2,9.2)
8 min	55	3.5 (0.6,8.6)	50	3.9 (1.8,7.3)
9 min	55	2.4 (0.7,6.0)	50	3.1 (1.9,6.4)
10 min	55	1.9 (0.7,5.1)	50	3.0 (1.3,4.6)
Total side 2	***57***	***43.6 (27.2,75.5)50***	***50.0 (39.2,72.5)***	

All comparisons p>0.05

Table 3. Breastfeeding practices at 3 and 6 months by randomised group (n(%))

	Group A	Group B	Group C	p (chi square)			
3 groups	A v B	A v C	B v C				
3 months (n=142)	**n=51**	**n=46**	**n=45**				
EBF	44 (86%)	39 (85%)	38 (84%)	0.96	1.0	1.0	1.0
Mainly BF (with 1FF)	46 (90%)	41 (86%)	40 (89%)	0.98	1.0	1.0	1.0
Provided EBM	37 (73%)	35 (76%)	11 (24%)	**<0.001**	0.82	**<0.001**	**<0.001**
6 months (n=135)	**n=50**	**n=39**	**n=46**				
EBF	10 (20%)	6 (15%)	12 (26%)	0.47	0.78	0.61	0.30
Mainly EBF (with 1FF)	13 (26%)	9 (23%)	12 (26%)	0.94	0.81	1.0	0.81
BFCF	34 (68%)	23 (59%)	39 (85%)	**0.03**	0.51	0.06	**0.013**
BFCFFF	37 (74%)	26 (67%)	39 (85%)	0.15	0.5	0.22	0.07
Any breastfeeding	41 (82%)	31 (80%)	40 (86%)	0.64			
Provided EBM	39 (83%)	34 (87%)	13 (32%)	**<0.001**	ns	**<0.001**	**<0.001**
Reported no introduction of solid foods or infant formula by 26 weeks	8 (16%)	7 (18%)	12 (26%)	0.5	1.0	0.32	0.40

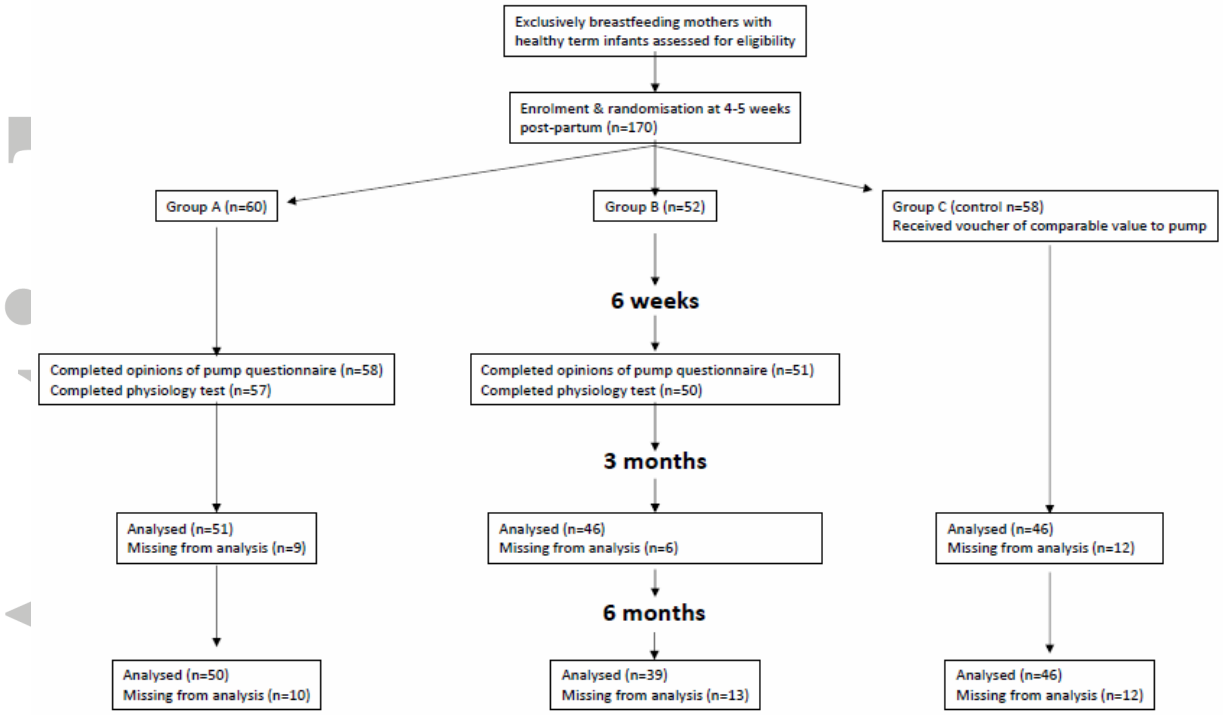
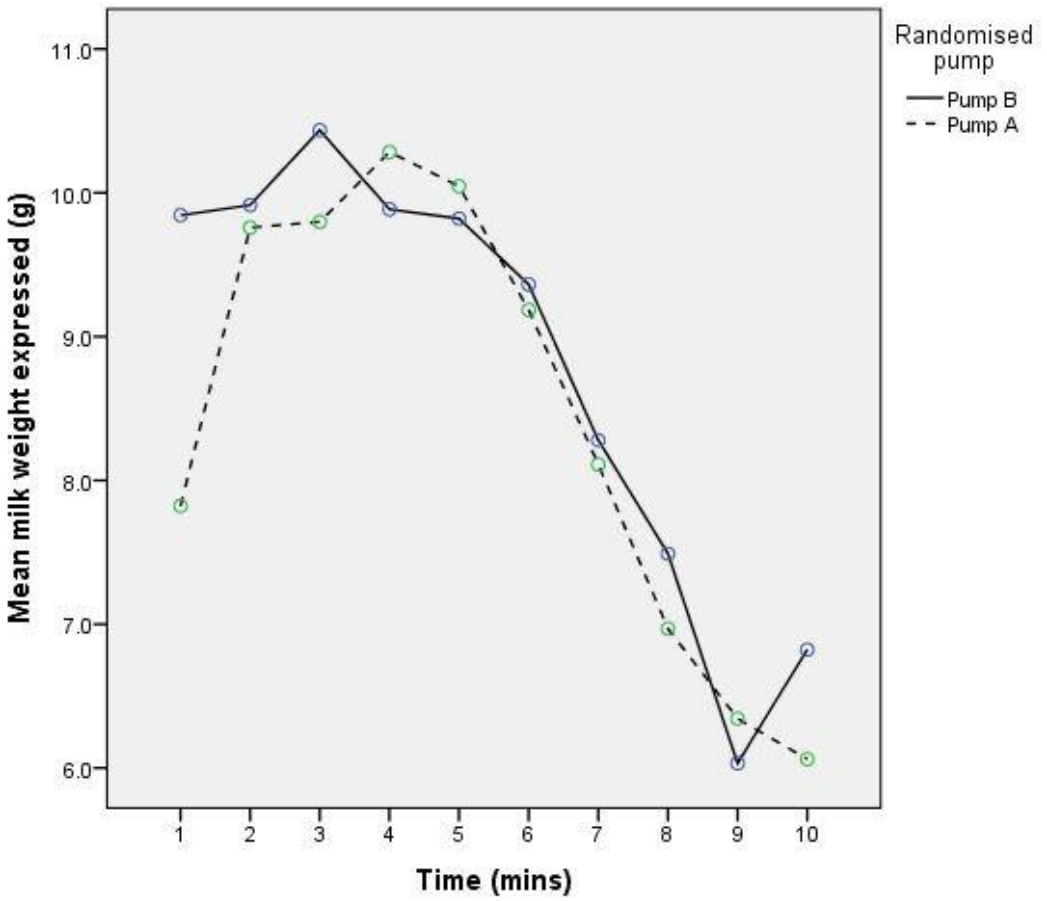


Figure 1. CONSORT Flow Diagram



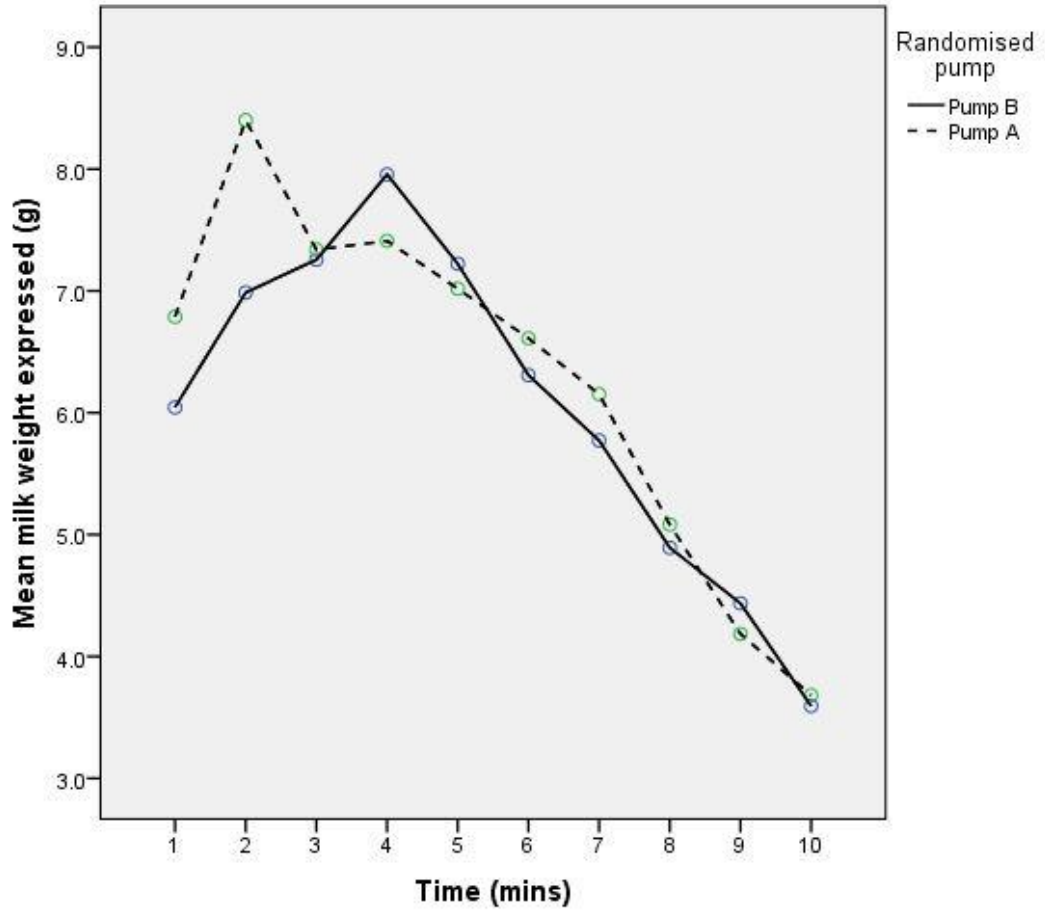


Figure 2. Mean milk weight at 1 minute intervals for Breast 1 and Breast 2 (estimated means from repeated measures ANOVA) expressed over 10 minutes according to randomised pump for whole cohort