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Title	The dangers of only telling half the story. Review of "Effect of early limited formula on duration and exclusivity of breastfeeding in at-risk infants: an RCT", by Flaherman et al.
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Publication date	2013-09
Original Citation	Smith, H. A. and Murphy, M. (2013) "The dangers of only telling half the story". Review of "Effect of early limited formula on duration and exclusivity of breastfeeding in at-risk infants: an RCT", by Flaherman et al. Midirs Midwifery Digest, 23(3), pp. 379-381.
Type of publication	Article (non peer-reviewed)
Link to publisher's version	https://www.midirs.org/our-services/midwifery-digest-subscription/
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Download date	2026-11-05 13:08:16
Item downloaded from	https://hdl.handle.net/10468/2553

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Effect of early limited formula on duration and exclusivity of breastfeeding in at-risk infants: an RCT

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Background and objectives: Recent public health efforts focus on reducing formula use for breastfed infants during the birth hospitalization. No previous randomized trials report the effects of brief early formula use. The objective of the study was to determine if small formula volumes before the onset of mature milk production might reduce formula use at 1 week and improve breastfeeding at 3 months for newborns at risk for breastfeeding problems.

Methods: We randomly assigned 40 exclusively breastfeeding term infants, 24 to 48 hours old, who had lost ≥5% birth weight to early limited formula (ELF) intervention (10 mL formula by syringe after each breastfeeding and discontinued when mature milk production began) or control (continued exclusive breastfeeding). Our outcomes were breastfeeding and formula use at 1 week and 1, 2, and 3 months.

Results: Among infants randomly assigned to ELF during the birth hospitalization, 2 (10%) of 20 used formula at 1 week of age, compared with 9 (47%) of 19 control infants assigned during the birth hospitalization to continue exclusive breastfeeding ($P = .01$). At 3 months, 15 (79%) of 19 infants assigned to ELF during the birth hospitalization were breastfeeding exclusively, compared with 8 (42%) of 19 controls ($P = .02$).

Conclusions: Early limited formula may reduce longer-term formula use at 1 week and increase breastfeeding at 3 months for some infants. ELF may be a successful temporary coping strategy for mothers to support breastfeeding newborns with early weight loss. ELF has the potential for increasing rates of longer-term breastfeeding without supplementation based on findings from this RCT.

KEY LINE BOX

What's known on this subject: Public health policy focuses on reducing formula use for breastfed infants during the birth hospitalization. Observational evidence supports this approach, but no previous studies have examined the effect of early use of small volumes of formula on eventual breastfeeding duration.

What this study adds: Use of limited volumes of formula during the birth hospitalization may improve breastfeeding duration for newborns with high early weight loss. Reducing the use of formula during the birth hospitalization could be detrimental for some subpopulations

of healthy term newborns.

KEY LINE BOX END

Flaherman VJ, Aby J, Burgos AE et al. Pediatrics, 2013; vol 131, no 6, pp1059–1065.

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TINT TEXT BOX

Reviewed by Hazel A Smith and Margaret Murphy

The dangers of only telling half the story

The objective of Flaherman *et al*'s (2013) randomised controlled trial (RCT) was to study whether small volumes of formula supplementation, given to babies who had lost more than 5% of their birth weight in the first 24–48 hours following birth, would reduce the subsequent use of formula at one week and promote exclusive breastfeeding at one, two and three months.

All 40 mothers enrolled in the study had a supervised breastfeeding session with a '*study doctor or nurse*'. Twenty mothers in the intervention group were shown how to give their babies 10 ml of formula by syringe after each breastfeed; this was to continue until the mothers produced mature milk. The 20 babies in the control group were given no supplementation but in a 15 minute session, mothers were shown how to sooth their infants. Immediately after this session, women completed a verbal questionnaire to assess breastfeeding efficacy and '*maternal pain'*. A research assistant then contacted women daily to assess '*compliance with randomization group and assess when mature milk production began*' (Flaherman *et al* 2013:1061). The mothers were then contacted by telephone at one week to identify formula use and at one, two and three months to disclose whether they were exclusively breastfeeding their babies.

The following quote by Moher *et al* (2010) is from the CONSORT (Consolidated Standards of Reporting Trials) 2010 guidelines:

'*Well designed and properly executed randomised controlled trials (RCTs) provide the most reliable evidence on the efficacy of healthcare interventions, but trials with inadequate methods are associated with bias….Biased results from poorly designed and reported trials can mislead decision making in health care at all levels, from treatment decisions for a patient to formulation of national health policies.*'

(Moher *et al* 2010:1)

Although Flaherman and colleagues (2013) use the CONSORT flow diagram in their paper they unfortunately do not follow CONSORT guidance on RCT validity. The validity of an RCT starts at the conception of the study. The research question needs to be very clearly defined and there needs to be a specific and clear outcome that will be measured in a standard manner.

Flaherman *et al* (2013) fail to define their outcome of exclusive breastfeeding or how it was measured. The reported findings are difficult to understand as the rates of exclusive breastfeeding **increase** in the intervention group as the infants get older. The World Health Organization (WHO) (2013) states that exclusive breastfeeding is: '*…defined as no other food or drink, not even water, except breast milk*', yet Flaherman *et al* (2013) report that at one month 70% were exclusively breastfeeding, at two months this rate had increased to 80% and by three months 79% of infants in the intervention group were exclusively breastfeeding. These reported rates of exclusive breastfeeding are not possible, as defined by the WHO guidelines outlined above, and therefore there are concerns about the validity of the study. It is not known if the results were caused by incorrectly identifying who was exclusively breastfeeding or if the study did not standardise how it was collecting its data, both of which could result in misclassification. In light of this, we suggest that the whole data set needs to be looked at and reanalysed.

The authors also report on the volume of formula consumed by both groups of babies in the first week of life, yet it is not clear how this was measured or recorded. By the authors' own admission, the size of the sample of the RCT was not selected for power but for feasibility, so the possibility of any significant result being achieved through chance cannot be ruled out.

It is not recorded what type of antenatal education the women in the study had (was it from a midwife or International Board Certified Lactation Consultant?); how long each of the mothers intended to breastfeed; whether the women had any prior breastfeeding experience (positive or otherwise); what type (if any) of postnatal care these mothers received; or whether their babies were born in Baby Friendly accredited hospitals. All of these factors have been shown to have an effect on initiation and duration of breastfeeding.

The authors were interested in studying whether the intervention made a difference to exclusive breastfeeding in the first three months of life, they report that, '*Most (62%) mothers planned to breastfeed exclusively and there was no group difference*' (Flaherman *et al* 2013:1061). This definition of '*most*' is of concern as it means that 38% of 40 women did NOT intend to breastfeed exclusively. There is no discussion of how this factor may have

affected outcomes, given the small numbers of participants. This again raises questions about the design of the study and validity of the findings.

The rates of breastfeeding for both the control and intervention groups are higher than the national average. It would have been beneficial if the authors had assessed whether taking part in the intervention group resulted in the mothers breastfeeding for longer than they intended, compared to the control group.

The intervention is early limited formula (ELF) at the end of each breastfeed but the authors fail to explain how they determined that 10ml of Nutramigen is a limited amount of formula. To our knowledge, there is no study which has examined how to quantify the volume of any formula supplementation given to breastfed babies. It is concerning that an RCT implemented an intervention with no apparent scientific base.

The authors do not address any potential harm that could arise from this intervention. Interestingly, they state, '*To avoid exposing newborns to intact cow's milk protein, we chose an extensively hydrolysed formula*' (Flaherman *et al* 2013:1060). There is no explanation of how the authors decided that a non-standard formula, which is not routinely available in maternity settings, was a better option than the formula that was given to non-study participants in the same setting.

The authors identified that the reason for the RCT was to address maternal concern over milk supply. Maternal concerns are not usually addressed by supplementation but by support and education from experienced maternity staff who can help them to recognise their baby's cues for hunger and satisfaction. By giving a breastfed baby supplementation, maternal concerns are only reinforced.

This RCT showed that there was no significant difference between the groups in maternal breastfeeding self-efficacy scores at one week of age, so the study failed to address what it had identified as the most common cause of early breastfeeding cessation – maternal concern with milk supply. The authors found that, '*No formula at 1 week of age was the strongest predictor of exclusive breastfeeding at 3 months of age in this study*' (2013:1063). This would suggest that the predictors for giving formula supplementation in the first week need to be investigated and it is these predictors that should drive intervention.

As researchers in the area of breastfeeding, we are concerned that supplementation of breastfed infants may be viewed as an innocuous practice and adopted by practitioners. Given the profound benefits of exclusive breastfeeding to the health of infants globally, our efforts would be better directed towards supporting women to achieve exclusive breastfeeding, rather than eroding their confidence in their milk supply in the early days. We believe that the

authors may have lost the wisdom and knowledge about the behaviour patterns of breastfed infants and might be looking for problems where there may be none.

References

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TINT TEXT END

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