


Research Article Summary

Start Assignment

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1. Find a recent peer-reviewed journal article presenting a research project you (clinical research or health services research or translational research).
 2. Download the PDF of the article and upload it in the assignment.
 3. Using MS Word, and following the one-page template shown in Appendix 1, Chapter 1 (pp.12-13) produce a one-page outline of the article. Pages are Attached
 4. In addition, write a couple sentences summarizing the results and capturing your main thought about this article.
 5. Upload the MS Word file.

APPENDIX 1

Outline of a Study

This is the one-page study plan of a project carried out by Valerie Flaherman, MD, MPH, begun while she was a general pediatrics fellow at UCSF. Most beginning investigators find observational studies easier to pull off, but in this case a randomized clinical trial of modest size and scope was feasible, the only design that could adequately address the research question, and ultimately successful—see publication by Flaherman et al (1) for the findings, which, if confirmed, could alter policy on how best to initiate breast feeding.

■ TITLE: EFFECT OF EARLY LIMITED FORMULA USE ON BREASTFEEDING

Research question:

Among term newborns who have lost $\geq 5\%$ of their birth weight before 36 hours of age, does feeding 10 cc of formula by syringe after each breastfeeding before the onset of mature milk production increase the likelihood of subsequent successful breastfeeding?

Significance:

1. Breast milk volume is low until mature milk production begins 2–5 days after birth.
2. Some mothers become worried if the onset of mature milk production is late and their baby loses a lot of weight, leading them to abandon breastfeeding within the first week. A strategy that increased the proportion of mothers who succeed in breastfeeding would have many health and psycho-social benefits to mother and child.
3. Observational studies have found that formula feeding in the first few days after birth is associated with decreased breastfeeding duration. Although this could be due to confounding by indication (see Chapter 9), the finding has led to WHO and CDC guidelines aimed at reducing the use of formula during the birth hospitalization.
4. However, a small amount of formula combined with breastfeeding and counseling might make the early breastfeeding experience more positive and increase the likelihood of success. A clinical trial is needed to assess possible benefits and harms of this strategy.

Study design:

Unblinded randomized control trial with blinded outcome ascertainment

Subjects:

- **Entry criteria:** Healthy term newborns 24–48 hours old who have lost $\geq 5\%$ of their birth weight in the first 36 hours after birth
- **Sampling design:** Consecutive sample of consenting patients in two Northern California academic medical centers

Predictor variable, randomly assigned but not blinded:

- **Control:** Parents are taught infant soothing techniques.
- **Intervention:** Parents are taught to syringe-feed 10 cc of formula after each breastfeeding until the onset of mature milk production.

Outcome variables, blindly ascertained:

1. Any formula feeding at 1 week and 1, 2, and 3 months
2. Any breastfeeding at 1 week and 1, 2, and 3 months
3. Weight nadir

Primary null hypothesis:

Early limited formula does not affect the proportion of women who are breastfeeding their baby at 3 months.

REFERENCE

1. Flaherman VJ, Aby J, Burgos AE, et al. Effect of early limited formula on duration and exclusivity of breastfeeding in at-risk infants: an RCT. *Pediatrics*, in press.