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## Effectiveness of an educational intervention in primary care to maintain exclusive breast-feeding; cluster randomized clinical trial; prolact study

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**Background:** The World Health Organization recommends exclusive breast-feeding (EBF) until six months of life. In Spain the rates of EBF at six months are 28.5%. More evidence is needed on the effectiveness of group interventions to maintain EBF.

**Methods:** This study involves a community-based cluster randomized trial conducted at 10 Primary Healthcare Centres in the Community of Madrid (Spain). The project aims to evaluate the effectiveness of an educational group intervention performed by primary healthcare professionals in increasing the proportion of mother-infant pairs using exclusive breastfeeding at six months compared to routine practice. The number of patients required is 432 (216 in each arm). All mother-infant pairs using exclusive breastfeeding in the last 24 hours that seek care or information at healthcare centres are included to consecutive sampling, as long as the infant is not older than four weeks, and the mother gives consent to participate. The main response variable is mother-infant pairs using EBF at six months. All statistical tests are performed with intention-to-treat. The estimation is adjusted using an explanatory logistic regression model. A survival analysis is used to compare the two groups using the log-rank test to assess the effect of the intervention on the duration of breastfeeding. The control of potential confounding variables is performed through the construction of Cox regression models.

**Results:** 434 dyads were included, the mean age of the mother was 32.8 (5), 80% were Spanish nationality, 72.6% were active workers and vaginal delivery was 79.7%. Average weight at birth was 3.303 (0.391), median gestational age 39.5 (RIQ 39-40). 226 dyads were assigned to the intervention and 208 control groups. The 6-month LME was higher in the experimental group RR=2.37 (1.45-3.89) than the control group, RAR 0.13 (0.06-0.19), NNT 8.0.

**Discussion:** We must implement strategies with scientific to improve the percentage of exclusive breast-feeding at six months in our environment as established by the WHO. Group education is an instrument used by professionals in primary care that favors the acquisition of skills and modification of already-acquired behavior, all making it a potential method of choice to improve rates of exclusive breast-feeding in this period. The prolact intervention has been effective in primary care to maintain LME at six months.

Notes: