Impact of Food Supplementation during Lactation on Infant Breast-Milk Intake and on the Proportion of Infants Exclusively Breast-Fed[1,2]

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ABSTRACT To evaluate whether milk production can be improved by increasing food intake, a randomized, double-blind, supplementation trial was completed among 102 lactating Guatemalan women. The subjects were undernourished, as indicated by their low values for calf circumference (CC) and the small size of their infants at birth. A high-energy (2.14 MJ/d, HES) and a low-energy (0.50 MJ/d, LES) supplement were distributed 6 d/wk from wk 5 to 25 of lactation. Data were evaluated using repeated-measures analysis of variance on the increments from initial values for each outcome variable with one-tailed tests of statistical significance. The maternal energy intake increased 1.18 MJ/d ($P < 0.01$) more among the HES than the LES women. Benefit from supplementation was more evident among the more undernourished (CC ≤ median value, 29.5 cm) women. Among these 53 lower-CC women, infant milk and milk energy intakes were 10% higher (64 g/d and 14 MJ/d, respectively, at wk 25) in the HES than the LES group. After controlling for other determinants of infant milk and energy intakes in regression analyses, the significance of these differences increased to $P < 0.04$. However, there was no detectable effect on infant growth. Logistic regression analysis was used to show that HES women were significantly ($P < 0.05$) more likely than LES women to be exclusively breast-feeding their infants at wk 20, the time when the effect of supplementation was most evident. These findings establish that milk production and the duration of exclusive breast-feeding of undernourished women can be improved with the provision of supplemental food. J. Nutr. 128: 1692–1702, 1998.

KEY WORDS: • *lactation* • *malnutrition* • *food supplementation* • *breast-feeding human milk*

Despite its importance to public health, the question of whether poorly nourished lactating women improve their lactational performance if they increase their dietary intake has not been addressed adequately. Several studies in developing countries (Brown et al. 1986, Hanafy and Morsey 1972, Naing et al. 1980, van Steenbergen et al. 1983) have documented a positive relationship between maternal nutritional status during lactation and milk output, but others (Prentice et al. 1986, van Steenbergen et al. 1989, Villalpando et al. 1992) have not.

Studies in rats show that dams whose dietary intake is restricted before conception and also throughout the reproductive period to 75% of that consumed ad libitum by animals are able to buffer the effect of their own malnutrition on milk production, but those restricted to 50% of ad libitum intake are not (Young and Rasmussen 1985). A synthesis of data from additional studies with rats involving similar experimental treatments (Rasmussen, K. M., unpublished data) revealed a nonlinear positive relationship between maternal dietary intake or nutritional status and milk production, with a much steeper slope at low levels of maternal dietary intake than at higher levels. Inasmuch as rats and women differ in their energy requirements for lactation as well as in their available fat stores, it is likely that the degree of maternal malnutrition at which these slopes change will differ among species.

In their review of the relationship between maternal nutritional status and lactational performance, Brown and Dewey (1992) also concluded that the lack of association often observed could be because milk energy output is limited only below a critical but unknown point in maternal energy balance and among women with energy reserves below an unspecified minimal amount. Thus, supplementation programs to improve lactational performance may benefit only the infants of this subset of women. This proposed interaction between maternal energy reserves and energy intake in determining milk energy

[1] Presented in part at the meeting of the International Society for Research on Human Milk and Lactation, November 1990, Asilomar, CA (González-Cossío, T., Habicht, J.-P., Delgado, H. and Rasmussen, K.M. Impact of food supplementation to malnourished lactating women on the breast milk intake of their infants: a randomized double-blind study) and at the 75th annual meeting of the Federation of American Societies of Experimental Biology, April 1991, Atlanta, GA [González-Cossío, T., Habicht, J-P., Delgado, H. and Rasmussen, K.M. (1991) Food supplementation during lactation increases infant milk intake and the proportion of exclusive breastfeeding. FASEB J. 5: A917 (abs)].

[2] Supported by U.S. Agency for International Development Grant (0596-0115) to INCAP (Dr. Hernán Delgado).

[3] The costs of publication of this article were defrayed in part by the payment of page charges. This article must therefore be hereby marked "advertisement" in accordance with 18 USC section 1734 solely to indicate this fact.

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Manuscript received 20 April 1997. Initial review completed 6 July 1997. Revision accepted 16 June 1998.

output, along with other problems inherent in the designs of previous studies of supplementation among lactating women, may explain previous ambiguous findings in women.

Controversy has continued in part because the mechanistic hypotheses relating nutritional status to lactational performance are concerned with energy balance, which is difficult to measure well. However, most of the available data actually measure energy stores, as approximated by body mass index (BMI).[5] Unfortunately, BMI does not appear to be a good indicator of risk of poor milk production (reviewed in Prentice et al., 1994). In addition, using data from the trial described here, we (González-Cossío et al. 1994) have shown that BMI is a poor indicator of benefit from supplementation on lactational performance, whereas calf circumference (CC) is a good indicator for this purpose.

Studies that report a positive effect of increased food intake during lactation on milk output potentially have biases that offer alternative explanations for the observed effects. Such biases include lack of random assignment and lack of double-blindness (Girija et al. 1984b). Community trials (Chávez and Martínez 1980, Prentice et al. 1983) that report no net impact of supplementation on milk production also have these potential biases and, furthermore, do not account for the effects of direct, concurrent supplementation of infants, which reduces infant suckling.

The only published randomized supplementation trial was conducted among 21 markedly thin (BMI = 17.4 kg/m^2) lactating Burmese women who were between 1 and 4 mo postpartum (Naing and Oo 1987). They were supplemented with a meal offering an extra 3.77 MJ/d daily for 2 wk. At the end of the intervention, women who received the supplement had a significantly higher milk output (119 g/d) than the control women. The authors did not measure milk energy concentration or milk energy output and, given the inverse association often found between milk volume and its energy content (Nommsen et al. 1991, van Steenbergen et al. 1983, Villalpando et al. 1992), the net effect of supplementation on milk energy output in this trial is unknown.

Appropriate studies to test the biological hypothesis that lactational performance is responsive to improvements in dietary intakes must: i) be conducted among mothers with evidence of poor nutritional status, who have the potential to respond; ii) maximize maternal potential to respond by studying the effect when infant demand is high among intensively breast-feeding women; (iii) be randomized and double-blind to account for the probability of having unbalanced groups or measurement biases; and iv) document energy density of milk to determine if changes in milk volume are compensated for by changes in milk composition.

We present here the results of such a community-based food supplementation trial among undernourished lactating women. It includes a randomized double-blind design and was carried out over a 20-wk period during which peak milk production was expected to occur. The primary study hypothesis was that infants of undernourished women who received a high-energy supplement (HES) from 5 to 25 wk of lactation would ingest a larger amount of, and more energy from, breast milk than infants of similar women who received a low-energy supplement (LES). We also studied two further hypotheses: i) more infants will exclusively breast-feed in the group of mothers receiving the HES than in the group receiving the LES, and ii) mothers consuming the HES will weigh more through peak milk production than mothers consuming the LES. The expected direction of the impact of supplementation on the study outcomes was defined a priori. This included the prolongation of exclusive breast-feeding (Habicht and Behar 1974), an increased infant milk intake (volume and total energy) as well as a maternal weight protection. Infant growth was not expected to change enough to be identified as statistically significant by the sample size used in this study, which was chosen to detect changes in milk production.

[5] Abbreviations used: ANOVA, analysis of variance; BMI, body mass index; CC, calf circumference; HES, high-energy supplement; INCAP; Institute of Nutrition of Central America and Panama; LES, low-energy supplement; LSM, least squares means; RM-ANOVA, repeated-measures-ANOVA.

SUBJECTS AND METHODS

The study was a randomized double-blind food supplementation trial, stratified by maternal height to control for a potential association between height and breast milk production. Women who agreed to participate were categorized as being above or below the median height for undernourished women living in rural areas of Guatemala (Delgado and Flores 1988), and randomization was conducted separately within each maternal height group. The required sample size (n = 53/treatment group) was estimated (Snedecor and Cochran 1989) to identify a difference in infant milk intake of 120 g/d between supplement groups for an α level of 0.05 and a power of 90% for a one-tailed test, a standard deviation of 165 g/d (WHO 1985) around milk output, and an estimated drop-out rate of 40%. We calculate that this experiment had the power to identify a difference in infant weight gain between the groups of 278 g. However, this power was insufficient to declare as statistically significant the difference of 102 g in infant weight gain that would result (using data from Schroeder et al. 1995) from this expected difference in milk consumption.

Women were selected based on their CC during the third trimester of pregnancy or at delivery. This screening tool was used because a preliminary, hospital-based study (González-Cossío 1994) showed CC to be the best indicator to predict intrauterine growth-retardation in a similarly malnourished population. The cut-off point with the lowest number of false positive and negatives found in this hospital-based study was 29.1 cm, and this was used as the operational cut-off to select the study site.

Surveys of the 11 largest cities of Guatemala showed that Quetzaltenango and its surroundings were the areas with the largest number of women with CC ≤29.1 cm who could be reached for study. Quetzaltenango is in the highlands of western Guatemala and its population is mainly of Mayan origin. Most women in this region are bilingual, speaking a Mayan language and Spanish. To recruit the required number of mothers in the 5 mo available for this purpose, the screening cut-off point had to be raised from 29.1 to 30.4 cm midway through the experiment. Analyses in this paper are conducted between treatment groups and differentiate between mothers above and those at or below the baseline (5 wk) group median (29.5 cm) CC values.

The poorest sections of the study area were identified, and their health centers were visited to obtain information on the addresses and names of pregnant women. These women were visited, and then a house-by-house survey of the area was conducted to inquire about the presence of additional pregnant women. During the visits, maternal CC was measured, and women whose CC was below the cutoff point in use at that time were invited to participate. Eligible women were informed of their undernutrition, their risk of delivering a low birth weight infant, and of their need to increase their food intake at home to lower this risk. Informed consent was obtained after the nature of the study was explained to the mothers. The study protocol was approved by the human subjects committees of the Institute of Nutrition of Central America and Panama (INCAP) and Cornell University.

Treatment was randomized, stratified by maternal height, after the birth of the infant without screening for exclusive breast-feeding. No infant feeding bottles were available or used in the study community, and breast-feeding is prolonged. We assumed, therefore, that exclusive breast-feeding would be the norm in the first few months of life. Indeed, this is what was observed at 5 and 10 wk postpartum, when few mothers offered their infants foods other than human milk and

TABLE 1

Nutrient composition of the high-energy (HES) and low-energy (LES) supplements

Nutrient	HES	LES
Energy,[1] *MJ*	2.14	0.50
Protein, *g*	12.5	3.7
Carbohydrate, *g*	57.8	21.7
Fat, *g*	26.1	2.1
Vitamin A, *IU*	543	39.2
Niacin, *mg*	2.2	2.2
Folacin, *μg*	51.7	14.9
Iron, *mg*	2.4	1.9
Zinc, *mg*	1.5	1.5

[1] As derived from the following percentage of macronutrients: HES, protein, 9.8%; carbohydrate, 45.1%; fat, 45.9%. LES, protein, 12.3%, carbohydrate, 72%; fat, 15.6%.

then only irregularly and in insignificant (i.e., <0.026 ± 0.113 MJ/d) quantities.

The food supplementation consisted of two types of cookies, which were randomly assigned to the mothers. The acceptability of the cookies was tested in a 4-wk pilot study conducted among lactating mothers of a poor community similar to the intervention site. Women were offered either two high-energy cookies (HES), which together provided 2.14 MJ, or two low-energy cookies (LES), which provided 0.50 MJ (Table 1). [The ingredients in these cookies are listed in **Appendix A.**] Female community distributors delivered two cookies to the women's homes Monday through Saturday from wk 5 to wk 25 of lactation. Prorated per week, this energy consumption corresponded to 1.84 MJ/d for the HES and 0.43 MJ/d for the LES groups. Thus, the maximal expected difference in energy consumption between the groups from the supplement was 1.41 MJ/d. Because the HES was prepared with vitamin A-fortified white sugar and the LES was prepared with nonfortified brown sugar, there also was a difference in maternal vitamin A consumption attributable to the supplement (Table 1). Women who received the HES consumed 109% of the recommended vitamin A intake during lactation, whereas LES mothers only consumed 8% of the recommended vitamin A intake from the supplement. There were also small differences between the supplements in the amounts of protein (8.8 g) and folacin (36.8 μg) provided; however, the proportion of energy derived from protein was similar in both groups.

Mothers consumed the cookies at their homes in the presence of the distributors, who measured the amount eaten and collected the leftovers, which were weighed. To interfere minimally with usual food intake, distributors came at snack time. To blind the mothers to their supplementation group, cookies were packed in opaque plastic bags of four different colors, and different flavors were added to the formulas. Cookies for the HES group were somewhat larger (7 × 7 cm) than for the LES group (5 × 5 cm). Mothers in the two groups did not see each other's cookies because of the way that the cookies were distributed. The salient characteristics of the cookies that could be compared were taste and bag color, and these were distributed so as to obscure differences between the supplements.

There were two other interventions given to all participating mothers. First, women and infants had access to free medical attention Monday through Friday at the study clinic. Medicines were provided free as necessary. Second, participating women were counseled: (a) to breast-feed as often as the infant wanted to nurse; (b) to breast-feed during the day and at night (as is the usual practice); (c) to feed from both breasts for ≥8 min from each breast during each feeding episode, so that both breasts could be emptied; and (d) not to feed anything else (not even water) to the infant.

Infant growth was explained to the mothers at each contact and, at the last visit to the study clinic (wk 25 of lactation), they were advised about complementary feeding of their infants using locally available foods.

Data collection. Infant weight was obtained at birth. All baseline measurements were taken at wk 5 of lactation before supplementation started, and follow-up data were collected at wk 10, 20 and 25 of lactation. The baseline and three follow-up measurements were done at the study clinic. Measures included the amount of infant breast milk intake, maternal and infant anthropometry and general socioeconomic data; milk samples were obtained to estimate energy density. Information on maternal and infant dietary intake was collected both at the clinic and in the mothers' home.

Women spent 28 h at the study clinic for continuous observation and data collection. We provided alternative arrangements for the mothers' home-cooking, washing and care for older children. We also provided transportation and leisure sedentary activities for the women during their stay at the clinic.

Infant milk intake. The 24-h infant milk intake was measured by standard test-weighing procedures (Brown et al. 1982) using Toledo (Toledo Electronic Baby Weigh Scales, Model 1365; Toledo Scale Reliance Electric, Worthington, OH), Detecto (Detecto mechanical no-spring baby weigh scale; Detecto Scale Corporation, New York, NY.) or Health-O-Meter scales (Health-O-Meter Pediatric Scale, Model 322; Continental Scale, Bridgeview, IL). In previous tests, all three scales were equally precise and all three types were used. Infants nursed on demand day and night and wore disposable diapers. They were weighed in duplicate immediately before and after each nursing episode. Total milk intake was estimated by the sum of the differences in the infant weight before and after each nursing episode during a 24-h period. This underestimates true infant milk intake because insensible water loss was not measured, but it did not bias comparisons between treatment groups. Nevertheless, we report the summary findings from analyses corrected for insensible water loss using the method described by Dewey et al. (1991). Time of breast-feeding also was recorded. Any other foods or liquids the mother offered her child in the clinic also were documented. An infant having received no extra liquids or solids in the clinic was classified as exclusively breast-fed.

Anthropometric data. Maternal data included: weight, wearing a light bathrobe, measured with spring scales (Haneson Personal Scale; Haneson Scale of Sunbeam, Shubuta, MS), read to the nearest 100 g; height measured with wooden anthropometers (Constructed at INCAP (Guatemala City, Guatemala, Central America). It has two parts: a standing rigid wooden board with a plastic-covered fabric measuring tape glued onto it, and a sliding piece that rests against the mother's head for measuring height, or against the infant's feet for length.), read to the nearest mm; skinfold thicknesses at four different sites (biceps, triceps, subscapular and suprailiac) measured with calipers (Holtain skinfold calipers, Holtain, Crymych, Dyefed, U.K.), read to the nearest mm; and arm and CC measured with reinforced plastic-covered fabric measuring tapes (Butterfly, Shanghai, China.), read to the nearest mm.

Infant anthropometric data included birth weight measured with a portable spring hanging scale (Salter Infant Weight Scale, Model MP25; CMS Weighing Equipment, London, U.K.), read to the nearest 50 g. Subsequent infant weight was measured with the Toledo electric infant scale, read to the nearest 5 g, and used to calculate infant milk intake. Weight-for-age Z-scores were calculated using the ANTHRO routine (version 1.01) from the Centers for Disease Control (Atlanta, GA).

All these anthropometric data (except birth weight) were collected at the clinic by four female nurses who were blinded to the subjects' treatment group. They were standardized (Habicht 1974) twice, once at the beginning and again at the middle of the data-collection process. Technical errors were equal to or lower than those reported by Lohman et al. (1988).

Dietary data. Measurements of home dietary intake of mothers and their infants by 24-h recall (Sanjur 1982) were conducted within the same week as the clinic visits on three separate occasions—two weekdays and one weekend day. Portions of food available at the mothers home and at local markets were weighed to increase the precision of estimating the energy content of the diet from the recall data.

Daily supplement intake was estimated after subtracting the leftovers of the cookies from the fixed amount offered. The daily energy intake from supplement was calculated from the mean of the daily records of the measured amount ingested over each interval.

Total dietary intake was calculated by adding the supplement intake to the dietary recall data collected at the end of the interval. The increment in dietary intake at 10, 20 and 25 wk is the difference between the total dietary intake at those times and the baseline home dietary intake (5 wk).

Milk energy density. Milk energy density was estimated in samples drawn by breast pumps (mechanical pump: Happy Family Breast Pump, Happy Family Products, Los Angeles, CA, or Battery-operated pump: Chú-Chú Super Breast Pump, Jex, Osaka, Japan.). The left breast was emptied at the end of the 24 h of test-weighing the infants, 2 h after the last nursing episode. The reported milk intake and the estimated energy derived from it were adjusted to 24 h. This method was chosen to capture variation in energy density during the observation period and should provide an unbiased comparison between the treatment groups.

Milk samples were frozen in the field, transported to INCAP, thawed, homogenized by ultrasound and refrozen. Energy content was estimated in duplicate in lyophilized samples (with a known amount of added oil for combustion) by adiabatic bomb calorimetry (Gallenkamp Bomb Calorimeter, Model CB-370; Fisions Instrument Series, Crawley, Sussex, UK). This method may overestimate the absolute value of milk energy density and may increase variability around the true mean, but it does not bias comparisons between groups. Infant milk energy intake in 24 h was calculated by considering the infant milk intake (g) in 24 h and the energy value of his/her mother's milk.

Statistical methods. Data were analyzed with the SAS computer package (version 6.04 for personal computer). We used an "intent to treat" approach to data analysis and included all 102 mother-infant pairs who completed the intervention.

The initial characteristics of the women were compared across the two supplementation groups and also across the two CC groups. These two main effects and their interaction were assessed by analysis of variance (ANOVA) with two-tailed significance tests.

Maternal height was not associated with infant milk intake at any time. Therefore, contrary to our original intention, we evaluated the impact of supplementation without adjusting for maternal height.

To test the effect of supplementation on the continuous outcome variables, we used a split-plot, repeated-measures ANOVA (RM-ANOVA) (Kirk, 1968) on the increments from initial values to the three follow-up times. This RM-ANOVA takes into account the initial values of the variable, the average or changing effect of supplementation over time and any interaction between supplementation and maternal nutritional status (CC category). We expected the effect of supplementation to be positive for infant milk intake and milk energy intake, with the possibility that the impact of supplementation would become evident at different times. For instance, if the impact of supplementation is established at 10 wk and is constant thereafter, the RM-ANOVA would reveal an overall effect. If the impact increased from wk 10 to 25, then the RM-ANOVA would reveal a linear effect. A marked maximum or minimum at 20 wk would be revealed by a quadratic effect. The effects of supplementation and of initial maternal nutritional status (i.e., CC group) on the outcomes were evaluated with one-tailed tests of significance.

To test the effect of supplementation on the probability of exclusive breast-feeding at wk 20, we used logistic regression models that included indicator variables for supplementation and CC group. The results presented do not include an indicator variable for whether the woman was exclusively breast-feeding at 5 wk (analogous to the RM-ANOVA analyses on incremental values) because the results were the same when this was included or excluded.

We also examined the impact of supplementation with and without adjusting for potential confounding factors at the time of its greatest impact on the lower-CC mothers. To accomplish this, we used regression analysis and examined infant milk and milk energy intake at 25 wk and maternal weight at 20 wk. Because of missing data, these analyses included only 48 of the 53 lower-CC women and, therefore, the uncovaried results differ slightly from those reported for the whole sample. This one-tailed test in a subgroup at a single time is less powerful than RM-ANOVA, but it does not require the use of interaction terms for potential confounding factors. In addition, its meaning is unambiguous as to the timing and the groups being compared. Thus, this approach increases the plausibility of the locus of impact. If the estimates of impact are not confounded, plausibility is further increased above and beyond the unambiguous evidence of causality revealed by the statistical significance of the RM-ANOVA because of the randomized design. Similarly, we examined the effect of supplementation on exclusive breast-feeding at 20 wk in a logistic regression analysis with and without the confounding variables (described below) among the women with complete data for the variables examined (94 of the 102 women).

The potential confounding factors that we explored were chosen a priori based on a biological model of human lactation. They were: the infant's sex, initial weight and milk intake (volume and total energy); initial nursing frequency; and the mother's age, education, parity and initial home energy intake. Except as noted below, these factors were included in the regression model simultaneously. This procedure accounts for confounding variables even if they are not significantly related to the outcome. The disadvantage of this approach is a loss of power to identify the impact of supplementation relative to a more restrictive selection of potential confounding factors.

Although we considered nine potential confounding factors, only eight of these were included simultaneously. Infant milk volume and energy intake were examined separately because they were colinear ($r = 0.81$). To avoid overcontrol for factors that reflect the same concept (i.e., maternal nutritional status) as CC group and, therefore, might contribute to a response to supplementation, we did not include maternal weight, BMI, body fat, skinfold thickness or arm circumference.

The results of all analyses were declared to be statistically significant at $P < 0.05$ for main effects and $P < 0.10$ for interactions (Cohen, 1988).

RESULTS

Sample sizes and attrition. Of the 721 potential participants who were interviewed, 272 women had a CC under the selection cut-off value; 111 of these women agreed to participate and 102 completed the supplementation trial. Limited data were available on 161 of the nonparticipant women, and they were similar to those who completed the trial (data not shown).

Of the nine dropouts, three were in the HES/higher CC, four were in the HES/lower CC and two were in the LES/lower CC group. Five of the dropouts migrated out of the study area, two had infants who died during the study, one took a paid job and one rejected the HES treatment. Women who dropped out had similar mean weights and CC values to their remaining counterparts, but their dietary energy intakes, and their infants' initial milk consumption, weight and weight gain during the first 5 wk of life were substantially lower, although not significantly for lack of power (**Table 2**).

Initial characteristics. As expected from successful randomization to treatment group, the initial characteristics of the 102 women who completed the study did not differ ($P > 0.10$) by supplementation group assignment. The sole exception to this was maternal energy intake, which was lower for the HES than the LES group in the lower CC group than it was in the higher-CC group (interaction $P < 0.10$). Maternal weight, BMI and limb circumferences all differed significantly ($P < 0.02$) between the CC groups. In addition, birth weight was 216 g lower ($P < 0.05$) in the lower than in the higher CC group; by 5 wk this difference (251 g) remained but not significant.

Evaluation of the impact of supplementation. To illustrate the pattern of results, P values from the RM-ANOVA analyses are presented in **Table 3**. The supplementation effects are differentiated according to whether they benefitted both CC groups similarly (main effects) or whether one CC group benefitted more than the other (interaction effect). All statistically significant main effects resulted from responses to supplemen-

TABLE 2

Characteristics of the sample at 5 wk postpartum[1]

Characteristics of subjects	At or below median CC[2]				Above median CC		
	HES		LES		HES		LES
	Remained (n = 27)	Dropped out (n = 4)	Remained (n = 26)	Dropped out (n = 2)	Remained (n = 22)	Dropped out (n = 3)	Remained (n = 27)
Characteristics of mothers							
Weight,[c] *kg*	40.4 ± 3.2[2]	40.9 ± 2.6	41.7 ± 2.6	40.2 ± 2.9	44.5 ± 3.5	44.4 ± 2.5	44.5 ± 3.4
Height, *cm*	142.6 ± 4.7	147.0 ± 6.8	143.1 ± 3.8	140.5 ± 7.1	143.6 ± 4.5	146.4 ± 5.3	144.7 ± 6.2
BMI,[c] *kg/m³*	19.9 ± 1.4	18.9 ± 0.7	20.4 ± 1.3	20.4 ± 0.6	21.6 ± 1.7	20.8 ± 1.0	21.3 ± 1.3
AC,[c] *cm*	22.8 ± 1.7	22.2 ± 1.1	22.7 ± 1.3	22.9 ± 1.3	23.8 ± 1.5	24.0 ± 0.2	23.9 ± 6.2
CC,[c] *cm*	28.5 ± 0.9	28.5 ± 1.0	28.5 ± 1.0	29.0 ± 0.1	30.7 ± 0.9	30.9 ± 1.0	30.5 ± 0.6
TSF, *mm*	8.1 ± 1.8	8.6 ± 1.3	8.7 ± 1.5	8.2 ± 2.6	9.2 ± 2.4	9.1 ± 1.8	9.3 ± 1.9
Home energy intake,[s,i] *MJ/d*	10.6 ± 2.7	10.5 ± 1.9	11.9 ± 2.0	8.9 ± 0.3	11.5 ± 2.0	11.2 ± 4.2	11.2 ± 2.3
Ethnicity, % *indigenous*	65	100	73	100	82	100	67
Age, *y*	26.3 ± 7.0	20.8 ± 2.2	25.9 ± 6.4	38.0 ± 4.2	23.7 ± 5.0	20.7 ± 3.1	26.1 ± 6.8
Parity	3.4 ± 2.6	3.0	3.7 ± 2.0	7.0	3.6 ± 2.7	2.3 ± 0.6	4.1 ± 3.1
Education, % *<1 y/>6 y*	35/19	0/100 (n = 1)	31/23	100/0 (n = 1)	41/5	100/0 (n = 2)	30/19
Characteristics of infants							
Birth weight,[c] *kg*	2.76 ± 0.33	2.88 ± 0.25	2.72 ± 0.33	2.80 ± 0.28	3.02 ± 0.35	2.73 ± 0.35	2.91 ± 0.35
Gestational age, *d*	273 ± 16 (n = 17)	288 ± 25 (n = 2)	278 ± 28 (n = 15)	No data	269 ± 15 (n = 16)	292 (n = 1)	279 ± 20 (n = 27)
Sex, % *female*	52	75	46	0	59	66	41
Weight at 5 wk, *kg*	3.67 ± 0.60	3.48 ± 0.63	3.67 ± 0.54	3.42 ± 0.58	3.94 ± 0.54	3.45 ± 0.45	3.89 ± 0.53
Milk intake at 5 wk, *g/d*	661 ± 135	573 ± 355	665 ± 199	423 ± 157	719 ± 139	560 ± 33	687 ± 125
Milk energy intake at 5 wk, *MJ/d*	2.13 ± 0.51	1.81 ± 1.15	2.07 ± 0.64	1.21 ± 0.36	2.34 ± 0.52	1.86 ± 0.26	2.21 ± 0.52
Nursing frequency, *events/24 h*	13.3 ± 3.2	11.5 ± 3.1	14.3 ± 3.3	13.0 ± 1.4	13.6 ± 3.0	14.7 ± 0.6	13.9 ± 2.4

[1] Comparison of those who remained in the study (n = 102) with those who dropped out (n = 9) by supplementation and CC at or below and above median (29.5 cm) groups. Comparison of those who remained in the study (n = 102) with those who dropped out (n = 9) by supplementation and CC at or below and above median (29.5 cm) groups.

[2] Abbreviations used: CC, calf circumference; HES, high-energy supplement, LES, low-energy supplement; BMI, body mass index; AC, arm circumference; TSF, triceps skinfold thickness.

[3] Means ± SD.

Differences among the four groups (HES/LES, lower- and higher-CC) were statistically significant: [s]main effect of supplementation group assignment ($P < 0.05$), [c]main effect of CC group assignment ($P < 0.05$), [i]interaction ($P < 0.10$).

tation in the postulated direction, and all significant interactions resulted from a greater beneficial response by the lower compared to the higher CC group.

Increment in maternal energy intake. The effect of supplementation on maternal energy intake can be estimated directly from the average observed supplement intake at follow-up (Table 4, top) or from the average difference between total dietary intake (home dietary intake + supplement) during the supplementation period, compared with dietary intake (home dietary intake alone) initially (Table 4, bottom). HES women initially had a home energy intake 0.527 MJ lower than LES women, but as expected, the increments from baseline values were much larger. The average difference in total dietary intake between HES and LES mothers was 1.233 MJ/d ($P < 0.004$) compared to the 1.184 MJ/d ($P < 0.001$) average difference between HES and LES mothers in observed supplement intake.

Dietary substitution by the supplement cannot be estimated directly from the data available because dietary needs and intake change during lactation and because this experiment did not include an untreated control group. However, the 1.22 MJ/d difference between the LES and HES groups in the increment in total intake between the baseline and final dietary intake measurements approximated the 1.184 MJ/d difference in observed supplement intake. This suggests there was no differential substitution of the home diet by the supplement in the two dietary treatment groups.

Infant milk intake. Mean infant milk intake rose by 10% from 5 to 10 wk and at a lower rate thereafter, for a total increase of about 12% at 25 wk (Table 5). By 25 wk, the increase in infant milk intake was greater for the HES/lower-CC group (128 g/d) than for the other three groups (57–84 g/d). This greater increase was from the 7% lower initial values for both lower-CC groups, so that the final value (789 g/d) in the HES/lower-CC group was similar to those of the higher-CC groups (771–776 g/d). The values in these three groups differed from the LES/lower-CC group (720 g/d) at 25 wk. This lower maximal value for infant milk intake in LES/lower-CC group was reached by 10-wk postpartum. In contrast, infant milk intake in the other three groups rose to higher values before reaching a plateau. This difference among the groups after 10-wk postpartum resulted in a statistically significant ($P < 0.03$) linear interaction effect (Table 3).

After adjustment for the eight potential confounding factors (including initial milk energy intake), the estimated impact of

TABLE 3

Summary of one-tailed significance values for the effects of supplementation on the continuous outcome variables; results from RM-ANOVA[2] analyses of increments from initial values at 5 wk postpartum[1,2]

Statistical effect	Total maternal energy intake (supplement + home diet)	Infant milk intake variables: Volume ingested	Milk energy density	Milk energy consumed	Maternal weight	Infant growth (weight-for-age Z-score)
Overall effects[3]						
HES-LES main effect	<0.01	*	*	*	*	*
Interaction effect	*	*	*	<0.08	*	*
Linear effects[4]						
HES-LES main effect	*	*	*	*	*	*
Interaction effect	*	<0.03	*	*	*	*
Quadratic effects						
HES-LES main effect	*	*	*	*	<0.05	*
Interaction effect	*	*	*	*	*	*

1 Statistically significant *P* values are shown; significance defined as described in Subjects and Methods.
2 Abbreviations used: RM-ANOVA, repeated-measures analysis of variance; HES, high-energy supplement; LES, low-energy supplement.
3 Main effect: supplementation effect seen in both calf-circumference groups; interaction effect: supplementation effect that is seen more in one of the calf-circumference groups than the other.
4 Linear time trend: a different linear time trend between supplementation groups at 10, 20 and 25 wk; quadratic time trend: a difference in time trends between the 10–20 wk period and the 20–25 wk period that differs between supplementation groups.
* $P > 0.01$

supplementation on infant milk intake increased from 57 g/d ($P < 0.11$) to 76 g/d ($P < 0.03$). When this analysis was performed on values for milk intake that were corrected for insensible water loss, the impact of supplementation was 69 g/d ($P < 0.04$).

Milk energy density. Milk energy density decreased from 5 to 25 wk (Table 6). This decrease was much more regular than the increase in milk volume over this time period. There was no pattern of change in milk energy density values associated with the intervention or maternal CC group.

Infant milk energy intake. Infant energy intake from milk increased 10% in both supplementation groups during the first 5 wk of the intervention (Table 7). This mirrored the increase in milk ingested because milk energy density changed minimally compared to the change in volume. Thereafter, infant milk energy intake reached a plateau, which reflects the fact that the decrease in milk energy density counterbalanced the increases in milk volume that occurred during the same period. However, the behavior of the four supplementation/CC groups relative to each other was similar to that observed for infant milk intake: the greatest increase was among infants of the HES/lower-CC women. This resulted in a statistically significant ($P < 0.08$) interaction in the overall component of the RM-ANOVA (Table 3).

The greater rise in milk energy intake among the infants of the HES/lower-CC women overcame the lower initial values of the lower-CC groups (Table 6). This resulted in similar values among the HES/lower-CC group and the two higher-CC groups. As was the case with infant milk intake, values for milk energy intake among infants of the LES/lower-CC mothers were lower.

Statistical power to identify differences of the same propor-

TABLE 4

Effect of food supplementation on energy intake from supplement among women at or below and above median (29.5 cm) initial CC value[1]

Duration of lactation, *wk*	At or below median CC: HES (*n* = 26)	At or below median CC: LES (*n* = 25)	Above median CC: HES (*n* = 21)	Above median CC: LES (*n* = 25)
	MJ/d			
Observed supplement intake				
5–10	1.471 ± 0.022[2]	0.399 ± 0.022	1.460 ± 0.024	0.420 ± 0.022
10–20	1.770 ± 0.006	0.501 ± 0.006	1.757 ± 0.007	0.482 ± 0.006
20–25	1.733 ± 0.025	0.463 ± 0.026	1.665 ± 0.028	0.486 ± 0.026
Increment in total energy intake (home diet + supplement) from initial value (at 5 wk)*				
10	1.128 ± 0.403	0.437 ± 0.418	1.495 ± 0.456	0.498 ± 0.418
20	1.146 ± 0.422	0.132 ± 0.439	2.516 ± 0.479	0.763 ± 0.439
25	1.704 ± 0.551	−0.025 ± 0.562	1.630 ± 0.613	0.416 ± 0.562

1 Abbreviations used: CC, calf circumference; HES, high-energy supplement; LES, low-energy supplement.
2 Unadjusted means ± SD.
* Statistically significant differences among the groups are reported in Table 3.

TABLE 5

*Effect of food supplementation on infant milk intake among women at or below and above median (29.5 cm) initial CC[1] **

Stage of lactation, *wk*	At or below median CC		Above median CC	
	HES (n = 27)	LES (n = 26)	HES (n = 22)	LES (n = 27)
			g/d	
5	661 ± 135[2]	655 ± 198	719 ± 138	687 ± 125
10	749 ± 143	726 ± 153	789 ± 112	727 ± 113
20	776 ± 153	721 ± 166	804 ± 128	769 ± 128
25	789 ± 114	720 ± 165	776 ± 121	771 ± 117

1 Abbreviations used: CC, calf circumference; HES, high-energy supplement; LES, low-energy supplement.
2 Unadjusted means ± SD.
* Statistically significant differences among the groups are reported in Table 3.

tional magnitude was lower for infant milk energy intake than for infant milk intake. Nonetheless, after adjustment for the eight potential confounding factors (including initial milk energy intake), the impact of supplementation on infant milk energy intake in the lower-CC mothers at 25 wk increased from 0.16 MJ/d ($P < 0.21$) to 0.30 MJ/d ($P < 0.03$). When we corrected this analysis for insensible water loss, the impact of supplementation on milk energy intake was 0.27 MJ/d ($P < 0.04$).

Breastfeeding patterns. Overall, 96% of the study mothers were exclusively breast-feeding their infants when the study began (Fig. 1). At that time, only four mothers were offering small amounts of nonmilk liquids to their infants, and these four women were exclusively breast-feeding at 10-wk postpartum. There was no change to wk 20 of lactation in this high proportion among the HES mothers. In contrast, the proportion of exclusive breast-feeding fell among the LES mothers from 94% at wk 5 to 84% at wk 20. Supplementation significantly ($P < 0.04$) increased the probability of exclusive breast-feeding at wk 20. This effect was similar in both CC groups. The statistical significance of the impact of supplementation on exclusive breast-feeding was similar whether confounding was controled ($P < 0.028$) or not ($P < 0.024$).

From 20 to 25 wk, rates of exclusive breast-feeding fell in the two LES groups to about 68%. However, the two HES groups behaved differently; the HES/lower CC group continued to have a higher rate of breast-feeding (85%) than the LES groups, but the HES/higher CC group fell to 64%, similar to the LES groups.

Maternal weight. LES women were 920 g heavier at 5-wk postpartum than HES women, and remained heavier throughout the study (Table 8). Women in both supplementation groups gained modestly (150–200 g) during the period from 5 to 10 wk. Between 10 and 20 wk the LES group lost about three times more weight than the HES group (480 vs. 170 g, respectively). From 20 to 25 wk there was essentially no change (−20 g) in the HES group, compared to a 360 g gain in the LES group. The result was a nadir at 20 wk in the LES group, who weighed 330 g less than their initial weight. In contrast, there was no similar nadir in the HES group. This difference was significant (HES-LES quadratic time trend, $P < 0.05$) (Table 3). The ranking of the subgroups separated initially by these large differences did not change over the course of the study. Rather, it is the pattern of change within the subgroups that differed.

For the lower-CC mothers, the nadir in body weight of the women at 20 wk was 576 g below the initial weight. This was fivefold greater than for the higher-CC mothers, who were only 101 g below their initial weight at 20 wk. The 576 g loss in the LES/lower CC group contrasts with the 176 g gain in the HES/lower CC group. This net difference of 751 g is more than tenfold greater than the 63 g difference observed in the higher CC mothers, but the power of the study was not suffi-

TABLE 6

*Effect of food supplementation on milk energy density among women at or below and above median (29.5 cm) initial CC[1] **

Stage of lactation, *wk*	At or below median CC		Above median CC	
	HES (n = 27)	LES (n = 26)	HES (n = 22)	LES (n = 27)
			MJ/100 g	
5	0.325 ± 0.052[2,3]	0.324 ± 0.07[3]	0.326 ± 0.05	0.323 ± 0.05
10	0.326 ± 0.05[4]	0.312 ± 0.04[3]	0.313 ± 0.05	0.332 ± 0.05
20	0.320 ± 0.04[4]	0.314 ± 0.05	0.307 ± 0.09	0.318 ± 0.05[4]
25	0.308 ± 0.06	0.313 ± 0.09	0.289 ± 0.04	0.319 ± 0.06

1 Abbreviations used: CC, calf circumference; HES, high-energy supplement; LES, low-energy supplement.
2 Unadjusted means ± SD.
3 n = 25.
4 n = 26.
* Statistically significant differences among the groups are reported in Table 3.

TABLE 7

*Effect of food supplementation on infant milk energy intake among women at or below and above median (29.5 cm) initial CC[1] **

Stage of lactation, *wk*	At or below median CC		Above median CC	
	HES (n = 27)	LES (n = 26)	HES (n = 22)	LES (n = 27)
		MJ/d		
5	2.13 ± 0.51[2,3]	2.07 ± 0.64[3]	2.34 ± 0.52	2.21 ± 0.52
10	2.46 ± 0.56[4]	2.26 ± 0.63[3]	2.46 ± 0.50	2.41 ± 0.52
20	2.47 ± 0.53[4]	2.26 ± 0.64	2.47 ± 0.77	2.44 ± 0.56[4]
25	2.43 ± 0.57	2.20 ± 0.51	2.24 ± 0.47	2.46 ± 0.59

[1] Abbreviations used: CC, calf circumference; HES, high-energy supplement; LES, low-energy supplement.
[2] Unadjusted means ± SD.
[3] n = 25.
[4] n = 26.
* Statistically significant differences among the groups are reported in Table 3.

cient to identify this 751 g as significant (Table 3). This difference was not significant when tested in the lower-CC group alone or when the analyses were adjusted for potential confounding factors.

Infant weight Z-scores. At 5 wk of age infants of the lower-CC mothers were 1 Z-score lower than reference values (WHO, 1995). In comparison, infants of the higher-CC mothers were only about half a Z-score below reference values (Table 9). These differences in initial weight were statistically significant (Table 2, $P < 0.03$). As is characteristic of breast-fed infants, the Z-scores of infants in all groups improved between 5 and 10 wk after birth. Subsequently, the Z-scores of infants in all groups decreased. This decrease tended to be larger (0.18 Z-score, $P < 0.37$) in the infants of the higher-CC women than for those of the lower-CC women.

We expected a cumulative effect of supplementation on growth, especially as the infants nutrients needs continue to grow. Thus, it was not surprising to find no effect in the expected direction from wk 5 to 10. The effect of supplementation on infant growth from wk 5–25 in the lower-CC group was +0.110 Z-score compared with −0.04 Z-score in the higher-CC group. For lack of adequate sample size, this linear interaction was not statistically significant (P = 0.28).

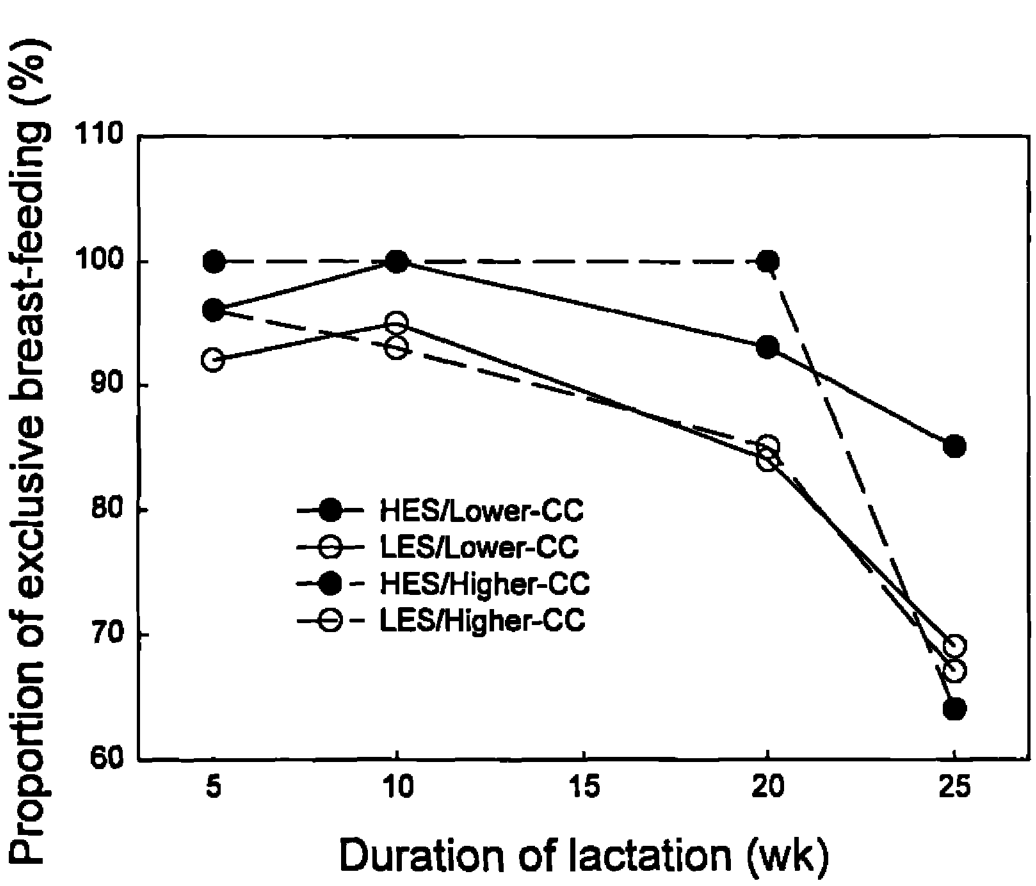

FIGURE 1 Effect of food supplementation on exclusive breast-feeding among lactating Guatemalan women at or below the median (29.5 cm) calf circumference (CC) compared to women above the median CC. Mean values ± SEM are illustrated. Abbreviations used: HES, high-energy supplement; LES, low-energy supplement. At wk 20, HES > LES ($P < 0.05$).

DISCUSSION

The results we report here are the first to demonstrate a positive effect of long-term food supplementation on lactational performance among undernourished women. These results are noteworthy because we used a design from which causal inference is possible. These results suggest that prior studies that employed designs that were not randomized and/or not double-blind may have failed to find an effect of food supplementation because of confounding or lack of potential to respond.

Impact of supplementation. The impact of supplementation on the 53 women in the lower-CC group was significant for infant milk intake and infant milk energy intake (a 10% difference for both) and was even more evident when adjusted for potential confounding by determinants of milk volume or energy content. The final result was that HES/lower-CC group resembled the two higher-CC groups at the end of the study even though it started out lower, while the LES/lower-CC group remained lower. Thus, the effect of supplementation was more evident at the levels of malnutrition for which the study was originally designed. In contrast, the impact of supplementation on the proportion of exclusive breast-feeding at 20 wk was evident in both the higher- and lower-CC groups. The significance of this effect also increased after adjustment for determinants of exclusive breast-feeding.

The impact of supplementation on maternal weight peaked at 20 wk, and was greater among the lower- than among the higher-CC women. The weight gain by the LES/lower-CC women in the last 5 wk of the study possibly resulted in part from lower infant milk intake during this period. The findings related to maternal weight change appear to be less robust than those related to lactational performance because of the lower statistical significance of these findings, which was not increased when adjusted for potential confounding factors. We found a difference in infant weight (+0.11 Z-score in the lower-CC group), which was not significant as a result of our inadequate sample size for testing the effect of supplementation in this particular outcome.

Certain features of the study design were important in achieving this impact. First, the subjects studied had the poten-

TABLE 8

*Effect of food supplementation on maternal weight among women at or below and above median (29.5 cm) initial CC[1] **

Stage of lactation, *wk*	At or below median CC		Above median CC	
	HES (*n* = 27)	LES (*n* = 26)	HES (*n* = 22)	LES (*n* = 27)
			kg	
5	40.4 ± 3.2[2]	41.7 ± 2.6	44.5 ± 3.5	44.4 ± 3.4
10	40.7 ± 3.3	41.6 ± 3.0	44.5 ± 4.1	45.0 ± 3.8
20	40.5 ± 2.7	41.1 ± 3.1	44.3 ± 3.8	44.4 ± 3.7
25	40.4 ± 3.3	41.7 ± 3.5	44.5 ± 4.3	44.6 ± 3.8

[1] Abbreviations used: CC, calf circumference; HES, high-energy supplement; LES, low-energy supplement.
[2] Unadjusted means ± SD.
* Statistically significant differences among the groups are reported in Table 3.

tial to respond to the intervention offered: they were breast-feeding intensively, were undernourished, and had been so historically. Second, the intervention successfully increased the energy intakes of the subjects.

Evidence of potential to respond to the intervention. Energy stress at the time of peak milk production is magnified if the infant breast-feeds intensively. Over 80% of the lower-CC women studied were fully breast-feeding, and the others added essentially no energy or nutrients to their infants diets.

Undernourished mothers were selected for inclusion in the study on the basis of their CC. Their weight-for-height was 90–95% of reference values (Jelliffe 1966), and 9% of them were classified as chronically energy-deficient (BMI <18.5 kg/m^2; James et al. 1988). On the average, their BMI values were low compared to lactating women from developing countries without current malnutrition (van Steenbergen et al. 1983, Villalpando et al. 1992). Their fat reserves were very low, lower than those expected from their moderately low BMI values. Their triceps' skinfolds thicknesses were 60% of the values of well-nourished reference women (data not shown) (Jelliffe 1966), and comparable to the malnourished lactating women from Bangladesh studied by Brown and colleagues (1986). Mothers in this Guatemalan sample were also stunted, which is probably the reflection of growth retardation during the first years of life (Martorell and Habicht 1986). Their average height was 143 cm, which is ≥5 cm shorter than Guatemalan women from the eastern part of the country (Lechtig et al. 1978). They were also very short when compared to lactating women from other developing countries, such as the Mexican Otomí women (145–148 cm, Villalpando et al. 1992); the Asian women from Bangladesh (148 cm, Brown et al. 1986), Burma (149 cm, Naing and Oo 1987), or Indonesia (151 cm, van Steenbergen et al. 1989), and much shorter than the African women from Gambia (158 cm, Prentice et al. 1983) or Kenya (156 cm, van Steenbergen et al. 1983).

Women whose CC value was below the median value of the mothers selected for this study, the more malnourished women, weighed less and had lower values for BMI, arm and CC, and triceps skinfolds thickness—but not height or percentage body fat—than the better-nourished women in the study. Also, infants born to the lower-CC women were 218 g lighter than those born to women with higher CC values, which reinforces the inference that the lower maternal anthropometric values reflected their poor current and past nutritional status. Women above the median CC also suffered from past and current malnutrition, as their suboptimal anthropometric measures show. However, they were less malnourished than the women below the median CC.

Evidence that the treatment increased net dietary intake. Supplementation was effective in improving maternal energy intake. HES women increased their total energy intake throughout the study period significantly more than LES women. There was no dietary substitution by the supplement. This increment in intake represents between 84 and 88% of the maximal difference in supplement offered between the two supplementation groups and >50% of the recommended energy increase during the first 6 mo of lactation (NRC 1989).

TABLE 9

Effect of food supplementation on infant weight among women at or below and above median (29.5 cm) initial CC[1]

Stage of lactation, *wk*	At or below median CC		Above median CC	
	HES (*n* = 27)	LES (*n* = 26)	HES (*n* = 22)	LES (*n* = 27)
			weight-for-age Z-score	
5	−0.913 ± 0.856[2]	−0.911 ± 0.780	−0.456 ± 0.796	−0.629 ± 0.731
10	−0.741 ± 0.777	−0.602 ± 0.750	−0.274 ± 0.778	−0.522 ± 0.684
20	−0.935 ± 0.795	−0.888 ± 0.769	−0.600 ± 0.872	−0.896 ± 0.752
25	−1.154 ± 0.843	−1.125 ± 0.731	−0.919 ± 0.967	−1.171 ± 0.735

[1] Abbreviations used: CC, calf circumference; HES, high-energy supplement; LES, low-energy supplement.
[2] Unadjusted means ± SD.

Vitamin A consumption also differed between the groups because of the two different kinds of sugar used in preparing the cookies, one of which was fortified with vitamin A. No biochemical data on vitamin A nutriture were collected, but no study subjects showed clinical signs of deficiency. Theoretically vitamin A deficiency could impair milk production through its impairment of protein synthesis (Liu and Roels 1980) but, to our knowledge, no studies have evaluated whether vitamin A deficiency impairs milk production in women. Furthermore, experimental vitamin A supplementation of ewes increased vitamin A concentration in milk but not milk volume (Donoghue 1988). Thus, we conclude that even though there were group differences in vitamin A consumption, the impact of supplementation on infant milk intake was due to the difference in energy intake and not to the difference in vitamin A consumption.

HES women also consumed more protein through the supplement than the LES women, so we cannot rule out the possibility that the impact of supplementation resulted to some extent from the difference in protein intake between the groups. However, our subjects consumed an energy-deficient diet, and we observed no evidence of protein deficiency. Thus, we conclude that, even with the differences between groups in the consumption of both vitamin A and protein, it is biologically more plausible that the impact of supplementation on infant milk intake resulted from the difference in maternal energy intake.

Exclusion of alternative hypotheses. Fewer than 10% of the women who initially agreed to participate in this trial failed to complete it. The women who dropped out were not evenly distributed among the treatment and CC groups. However, there was no important difference in the number of dropouts that might bias the results presented here.

The randomized double-blind design used in this study permits the inference that the observed impact of the supplementation on the outcomes studied was causal. The probability that the difference between treatment groups is not due to supplementation in a randomized trial is in the P values. Inasmuch as this experimental approach does not guarantee balancing all possible biases between the treatment groups (Snedecor and Cochran 1989), one may raise the plausibility even higher by ruling out the possibility that the observed differences between supplement groups were due to potential positive confounding factors. This was the case for both indicators of lactational performance.

The magnitude of the differences observed in the study may underestimate the full potential benefit of supplementation because the design did not include a no-treatment group. All women received some supplementation. Had there been a no-treatment group for comparison, benefits in milk output and maternal weight gain would have probably been larger.

Mechanisms of action. This study was designed to test a causal link between supplementation and lactational performance. It was not designed to elucidate the mechanisms of that link. Nevertheless, the findings support some speculation. First, the impact of supplementation on infant milk intake, which was evident at 10 wk, is likely to have been a direct effect of increased maternal dietary intake on lactation because all infants were ingesting essentially all their nutrients and energy from breast milk. Later, at 25 wk, the impact of supplementation on infant milk intake and milk energy intake probably was mediated by the differences between groups in exclusive breast-feeding that were observed at 20 wk.

These differences in exclusive breast-feeding at 20 wk could have been driven by the mothers' perception that her infant is not getting enough milk (Hillervik-Lindquist et al., 1991) or that her own health is at risk (Marquis et al. 1998) or both. Evidence that supports the first possibility is that the statistical significance of the logistic regression of supplementation on exclusive breast-feeding decreases from $P < 0.04$ to $P < 0.10$ when milk flow is introduced as a covariate (data not shown). For this purpose, milk flow was defined as the ratio of milk ingested in a suckling session to the duration of that session. Milk transfer rate was significantly ($P < 0.02$) related to exclusive breast-feeding in the regression analyses that included all women. The attenuation of the effect of supplementation on exclusive breast-feeding when milk transfer rate is introduced into the analysis did not occur when infant milk intake was included in the analysis as a covariate. This may possibly indicate that persistence in suckling serves as a clue that milk production is falling, even before this was evident in our measurements of daily milk intake.

In the more malnourished group, supplementation decreased frequency (HES, 11.7, and LES, 12.7 feeds/d, $P < 0.03$, one-tailed t test) and duration (HES, 16.8, and LES, 19.2 min/feed, $P < 0.10$) of suckling at 20 wk of lactation, concurrently with an increased probability of exclusive breast-feeding. Frequency and duration of breast-feeding no longer differed between treatment groups at wk 25 of lactation. All but one of the 102 study women remained amenorrheic at the end of the intervention. Given this improvement in breast-feeding behavior, there is little concern that our intervention would shorten the duration of postpartum amenorrhea in this population.

Conclusions and implications. The results reported here are significant for public health because they underscore the importance of coupling nutritional programs to malnourished lactating women with programs that promote exclusive breast-feeding at 4–6 mo of age. These results establish that undernourished lactating women can benefit from food supplementation: they lose less weight and produce more milk for their infants and they extend the period of exclusive breast-feeding. This protects infant health not only because a highly nutritious food continues to be provided but also because the serving of potentially contaminated weaning foods is avoided. Thus, this study shows that there is a clear opportunity to improve the lactational performance of malnourished mothers by appropriately designing and targeting nutritional programs.

ACKNOWLEDGMENTS

We thank the Division of Agricultural Sciences and Foods of INCAP, under the direction of dr. R. Bressani, for developing the recipes for the two kinds of cookies to Dr. Junio Robles for supervision in the field, to B. S. Humberto Méndez for aid in data management, and the mothers and infants of Xela for their participation.

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APPENDIX A

Ingredients in the high-energy (HES) and low-energy (LES) supplements

Ingredient	HES	LES
	g	
Wheat flour	22	11
Corn flour	—	3
Soy flour (hulled)	15	—
Soy flour (defatted and hulled)	—	1.2
Tortilla flour	16	—
Vegetable lard	17	1.3
Bran	—	7
Sugar	26	—
Brown sugar	—	7
Sesame seeds	9	1.1
Egg white	—	2
Baking powder	0.3	0.4
Guar gum	0.007	0.05
Yeast	3	1
Chocolate, vanilla flavor	<1, <1	0.1, 0.8
Licorice	—	0.03
Potassium sorbate	0.10	0.03
Coloring	0.06	0.01
Average weight of daily portion (2 cookies)	104	34