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Provision of lipid-based nutrient supplements to Honduran children increases their dietary macro- and micronutrient intake without displacing other foods

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Abstract

Inadequate energy intake and poor diet quality are important causes of chronic child undernutrition. Strategies for improving diet quality using lipid-based nutrient supplements (LNS) are currently being tested in several countries. To date, information on children's dietary intakes during LNS use is available only from Africa. In this study, we collected 24-hour dietary recalls at baseline, 3, 6, 9, and 12 months on Honduran children (n=298) participating in a cluster-randomized trial of LNS. Generalized estimating equations were used to examine differences in number of servings of 12 food groups in the LNS and control arms and multilevel mixed effects models were used to compare macro- and micronutrient intakes. Models accounted for clustering and adjusted for child's age, season, and breastfeeding status. Mean daily servings of 12 food groups did not differ by study arm at baseline and remained similar throughout the study with the exception of groups that were partially or entirely supplied by LNS (nuts and nut butters, fats, and sweets). Baseline intakes of energy, fat, carbohydrates, protein, folate and vitamin A, but not vitamin B12, iron, and zinc, were lower in the LNS than control arm. The change in all macro- and micronutrients from baseline to each study visit was larger for the LNS arm than the control, except for carbohydrates from baseline to 9 months. These findings indicate that LNS improved the macro- and micronutrient intakes of young non-malnourished Honduran children without replacing other foods in their diet.

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CONTRIBUTIONS

AMSR, GR, and MEB designed and conducted the study and provided guidance and comments on the manuscript. VLF performed the analysis and drafted the manuscript.

CONFLICT OF INTEREST STATEMENT

The authors report no conflicts of interest.

Keywords

lipid-based nutrient supplements; dietary intake; food groups; infant and child nutrition; cluster randomized controlled trial; Honduras

INTRODUCTION

Globally, 165 million children < 5 years of age are stunted, indicating that they are chronically undernourished (de Onis et al., 2012). Seven million of these reside in Latin America or the Caribbean. Chronic undernutrition has multiple causes, including inadequate energy intake and poor diet quality (Black et al., 2013). In many low-income communities, even when caloric intake is sufficient, consumption of micronutrients and essential fatty acids is lower than recommended (Gibson and Hotz, 2000, Dewey and Brown, 2003, Huffman et al., 2011). This has prompted interest in the use of lipid-based products as a vehicle for important nutrients that could help to prevent undernutrition in infants and young children (Dewey and Arimond, 2012, Arimond et al., 2013).

Lipid-based nutrient supplements (LNS) are most commonly composed of peanut butter, vegetable oil, sugar, and vitamin/mineral mix with or without milk powder. They can be provided to infants and young children in medium quantities (~45-90 grams/day) for the prevention of stunting or wasting or in smaller quantities (~20 grams/day) for home fortification (Arimond et al., 2013). LNS have proven to be effective for the treatment of severe and moderate acute malnutrition (Manary et al., 2004, Ciliberto et al., 2005, Matilsky et al., 2009, LaGrone et al., 2010). When given to children > 6 months of age, they produced modest gains in weight and linear growth and prevented severe stunting, using varying quantities of LNS (20-50 g) and duration of supplementation (3-12 months) (Phuka et al., 2008, Thakwalakwa et al., 2010, Thakwalakwa et al., 2012, Adu-Afarwuah et al., 2007, Iannotti et al., 2014). LNS increased concentrations of hemoglobin in African children (Kuusipalo et al., 2006, Adu-Afarwuah et al., 2008) and vitamin B12 and folate in the present study in Honduran children (Siega-Riz et al., 2014). Observational and quantitative studies in Africa indicate that LNS are consumed in addition to usual foods and increase macro and micronutrient intakes (Maleta et al., 2004, Adu-Afarwuah et al., 2007, Flax et al., 2008, Hemsworth et al., 2013, Thakwalakwa et al., 2014), but it should be noted that some of these studies assumed participants consumed LNS as intended and measured overall dietary intake without quantifying the amount of LNS eaten. Food cultures, diet quality, and levels of food insecurity vary greatly between and within countries and regions, making it important to understand how products, such as LNS, affect dietary intakes in different locations. To our knowledge, dietary intakes of children receiving LNS in Latin America have not been reported previously.

The main aim of the present analysis was to examine the influence of LNS on food group consumption to determine if LNS added to the diet or displaced usual foods in Honduran children, aged 6-18 months at baseline, participating in cluster-randomized supplementary feeding trial. We also tested differences in dietary intakes of macro- and micronutrients in

children receiving LNS or no LNS. Analyses were performed based on intent-to-treat and on an alternate definition of LNS compliance.

METHODS

Study Population

We conducted a cluster-randomized controlled trial among young children and their caregivers living in three municipalities of the department of Intibucá in Honduras. Details of the study design and the primary study outcomes have been described elsewhere (Siegariz et al., 2014). Briefly, a total of 18 communities were matched into pairs by region and based on several poverty indicators. One cluster within each pair was randomized to the intervention or control group. Children were eligible to participate in the study if they were 6-18 months at the time of recruitment, had a caregiver > 16 years of age, were free of medical conditions, had weight-for-height z-score ≥ -2 SD, and had no known peanut allergy.

Study Protocol

Participants in both the intervention and control groups received food vouchers for local staples and a monthly nutrition education intervention for 12 months. Food vouchers were redeemable for rice, beans, corn, vegetables and fruits at local stores. The total value was based on the number of family members and provided about \$2.50 per person/month.

The intervention group also received *Plumpy'doz* (a type of LNS produced by Nutriset (Malaunay, France)) during the same period. The quantity of LNS caregivers were advised to feed the children in the intervention group was age-dependent. The dosage of LNS was 46.3 g/day (3 teaspoons 3 times/day for a total of 9 teaspoons/day) for infants 6-11 months of age and 70 g/day (4.5 teaspoons day 3 times/day for a total of 13.5 teaspoons/day) for children 12-30 months of age.

The study began in March 2009 and concluded in April 2010. Study interventions were provided for 12 months and data were collected during monthly visits to each community. Study personnel were not blinded to study arm assignment. Dietary assessments were completed at baseline and then monthly using a 24-hour recall instrument and utensils (i.e., cups, plates, bowls, spoons) purchased at local stores. Interviewers did not probe specifically about LNS consumption and recorded only information on the portion consumed; no data on left-overs of LNS were obtained. Dietary data from the baseline, 3, 6, 9 and 12 month visit were entered into the Minnesota Nutrition Data System for Research (NDSR, 2010) to calculate quantities of nutrients and daily servings of food groups consumed. Data on LNS use and acceptability were collected from mothers in the intervention groups during monthly study visits. They were asked if they had mixed LNS with other food or drinks and, if so, they described the combinations.

Institutional review boards at the University of North Carolina at Chapel Hill and in Honduras approved the study protocol. Informed consent was obtained from caregivers for child participation. The trial was registered at clinicaltrials.gov ().

Variable definition

Macronutrients analyzed included total energy (kcal), fat (g), carbohydrates (g) and protein (g), while micronutrients included vitamin A retinol equivalents (μg), vitamin B12 (μg), folate (μg), iron (mg), and zinc (mg). Using detailed food group data from NDSR, 12 aggregate food groups were created, which are described in Table 1. Serving sizes in NDSR are based on the 2000 Dietary Guidelines for Americans and do not vary by age (USDA Agricultural Research Service Dietary Guidelines Advisory Committee, 2000).

Statistical Analysis

Descriptive statistics were calculated as means, medians, and proportions. Because macro and micronutrients did not follow Gaussian distributions, geometric mean values and 95% confidence intervals are presented and all values were log transformed for further analysis. Generalized estimating equations (GEE) were used to examine differences in the number of servings of each food group consumed by intervention and control groups accounting for clustering at the village level and adjusting for child's age, season, and breastfeeding status (yes/no). Multilevel mixed effects linear regression models for each macro and micronutrient were used to compare intervention and control groups accounting for clustering at the village level and adjusting for child's age, season, and breastfeeding status. Breastfeeding was common in both study groups at baseline (84% in both groups), but starting from 6 months more children in the control than the LNS group were still breastfed (Siega-Riz et al., 2014). The main analysis was conducted based on intent-to-treat. As previously reported, approximately 70% of children assigned to the LNS group consumed any LNS; mean LNS intake ranged from 35-50 g and few children (2-9%) in the intervention arm consumed the recommended amount of LNS for their age (46/70 g) (Siega-Riz et al., 2014). Consequently, we conducted sensitivity analyses using an alternate definition of LNS adherence defined as consumption during the previous 24 hours of 20 g of LNS by children 6-11 months of age and 40 g of LNS by children 12 months of age. This definition was based on the quantities of LNS provided to children in other studies (Arimond et al., 2013, Adu-Afarwuah et al., 2007, Thakwalakwa et al., 2010, Thakwalakwa et al., 2012). For the sensitivity analysis, we used the same type of modeling, adjusting for clustering and controlling for the same variables, as in the main analysis. Tests were performed with $P < 0.05$ to denote significance.

RESULTS

A total of 332 children were screened, 301 were eligible, and 300 were enrolled. Two children were found to be ineligible after enrollment, giving a total sample of 298 (LNS, $n=160$; Control, $n=138$). The characteristics of each study arm were previously described (Siega-Riz et al., 2014). Briefly, at baseline, enrolled children were 11 months of age on average and had mean weight-for-age, length-for-age, and weight-for-length Z -scores in the normal range. The majority of child caregivers were their mothers, who had a primary level of education, were not employed, and had given birth to 3-4 children. No significant differences were observed in baseline maternal or child characteristics that might influence dietary patterns (not shown). Overall, alternate LNS compliance (20/40 g) was 25%, ranging from 22-29% across visits during the intervention period. Approximately 30% of mothers in the intervention group reported mixing LNS with other food or drinks. The majority mixed

LNS with milk, while a small proportion mixed it with water, *atol*, chocolate, juice, or bean purée.

The most frequently consumed food items in this population were rice, tortillas, eggs, potatoes, non-citrus fruits, and infant formula. Examining consumption of servings within food groups, non-citrus fruits accounted for the majority of daily servings of fruit eaten (ranging from a mean of 0.67 ± 0.85 to 1.43 ± 1.72 servings). Very small mean daily servings of citrus juices and fruits were given initially and increased with time. Daily servings of citrus juices ranged from 0.05 ± 0.20 to 0.52 ± 0.79 and citrus fruits from 0.07 ± 0.26 to 0.57 ± 0.94 . In the vegetable group, white potatoes accounted for the majority of daily servings throughout the study (ranging from 0.16 ± 0.40 to 0.50 ± 0.80 servings), while other vegetables (0.04 ± 0.08 to 0.43 ± 0.66) and tomatoes (0.03 ± 0.09 to 0.18 ± 0.26) were initially eaten by few participants, with daily servings slowly increasing over time. In the grain group, throughout the study, rice was the most commonly consumed item (0.44 ± 0.90 to 0.89 ± 0.79 servings), followed by tortillas (0.34 ± 0.46 to 0.65 ± 0.41 servings) and cookies (0.13 ± 0.31 to 0.60 ± 0.69 servings). In the meat and eggs group, mean daily servings of eggs were the highest throughout the study (0.20 ± 0.32 to 0.64 ± 0.52). Poultry was also relatively common (0.05 ± 0.21 to 0.44 ± 0.86), but other forms of meat were served infrequently. Mean daily servings of dairy were initially very small and increased with time [non-human milk (0.13 ± 0.47 to 0.27 ± 0.71) and cheese (0.03 ± 0.10 to 0.24 ± 0.44)]. Mean daily servings of infant formula ranged from 0.88 ± 1.84 to 1.06 ± 2.12 . By far the most common sweet was sugar and the most common beverage was plain water followed by unsweetened coffee and smaller servings of sweetened fruit juices. More daily servings of sugar and water were consumed by participants in the LNS than the control arm (sugar – control 1.67 ± 6.61 to 3.30 ± 3.86 , LNS 1.03 ± 2.93 to 5.65 ± 6.25 ; water – control 0.80 ± 0.63 to 1.21 ± 0.74 , LNS 0.65 ± 0.51 to 1.66 ± 0.89). Shortening (0.40 ± 0.94 to 1.11 ± 2.27 servings) and margarine (0.23 ± 0.77 to 0.60 ± 1.82 servings) were the most common fats; the LNS group also consumed 1-2 daily servings of oil as part of the supplement. Nuts were rarely consumed in this study population, except when provided through the study intervention as LNS.

At baseline, there were no significant differences in the mean number of servings of most food groups consumed in the control and LNS arms, except for legumes, with the control consuming more servings than the LNS arm (Table 2). The change in mean servings of fruit, vegetables, legumes, and miscellaneous food groups from baseline to all other time points did not differ by study arm. The study arms differed mainly in servings of food groups that were partially or entirely supplied by LNS (nuts and nut butters, fat, and sweets); the LNS arm consumed more servings of these food groups than the control from 3-12 months. The same patterns were detected in sensitivity analysis using the alternate LNS compliance definition (20/40 g/day). A few other differences between the arms were observed at specific time points. The mean change in servings of grains from baseline to 3 months, meat and eggs from baseline to 6 months, and beverages from baseline to 6, 9, and 12 months was larger in the LNS than the control group. The mean change in servings of dairy and infant formula from baseline to 12 months was lower in the LNS group compared to the control.

Baseline intakes of all macronutrients (energy, fat, carbohydrates, and protein) were higher in the control than the LNS group (Table 3). The change from baseline to each study visit

was larger for LNS than control for all macronutrients and at all time points, except for carbohydrates from baseline to 9 months. Baseline micronutrient intakes were significantly higher in the control than the LNS arm for vitamin A and folate (Table 4). The change in all micronutrient intakes from baseline to all study visits was significantly larger for LNS than control. Changes in macro- and micronutrients from baseline were larger in the LNS than the control group in sensitivity analyses using the 20/40 g/day LNS adherence definition. Increases in nutrient intakes were observed over the entire course of the study for both the LNS and control arms.

DISCUSSION

Honduras is one of the countries in Latin America and the Caribbean where chronic undernutrition continues to be a major problem, with stunting affecting 30% of children < 5 years of age (Lutter et al., 2011). While there are many factors that contribute to stunting, inadequate diet quality is one key element. It is often difficult for families in low-income countries to provide nutrient-rich foods, such as animal source foods, to their children (Dewey and Brown, 2003). Preventive LNS interventions, like we tested in this study, are intended to help overcome deficits in nutrient intakes, but dietary intakes of children consuming LNS were previously documented only in Africa. In this cluster-randomized trial, LNS added to the diet of Honduran children by increasing the number of servings of nuts and nut butters, fats, and sweets. Consumption of LNS did not decrease servings of other food groups, indicating that it did not replace usual complementary foods. This finding is similar to results from Malawi showing that the amount of energy from staple foods and other food groups was the same before and during LNS consumption (Maleta et al., 2004). Likewise, studies in Ghana and Malawi showed that nutrient intakes did not differ between study arms when only non-supplementary foods were considered (Adu-Afarwuah et al., 2007, Thakwalakwa et al., 2014). Together, these studies contribute to the growing evidence that LNS, given in medium and small quantities, do not replace complementary foods in settings where diet quality is poor.

Given the high content of fat and sugar in LNS, it is somewhat surprising that the supplement did not replace some of the servings of fat and sugar in the diet, but added to them. As the LNS in this study produced no significant growth response, which could account for the higher intakes, we suspect that children may have developed preferences for these types of tastes. Children are predisposed to sweet food and drinks by innate preference and through repeated exposure (Ventura and Mennella, 2011). Mothers notice their children's food preferences and respond by serving them foods they like to eat (Birch and Fisher, 1998). The sweet taste of LNS was highlighted in a study in Malawi as a factor that made it easy to feed to children (Flax et al., 2009). In that study, mothers also reported needing to add sugar to plain maize porridge because their children had adapted to the taste of LNS and would no longer eat it unsweetened. Further research is needed to understand the long-term effects of LNS, with its high fat and sugar content, on eating patterns and health during adolescence and young adulthood, especially given the influence of early nutrition on health later in life (Adair, 2014).

In the present study, supplementation with LNS led to consistently higher mean intakes of macro- and micronutrients in young non-malnourished Honduran children. This finding is consistent with studies in Malawi and Ghana that showed higher intakes of energy (Maleta et al., 2004, Adu-Afarwuah et al., 2007, Hemsworth et al., 2013), protein, iron, zinc, and vitamin A in children receiving LNS (Thakwalakwa et al., 2014). Increases in dietary intakes of vitamin B12, folate, and vitamin A documented in this study were also detected in hematologic indicators of micronutrient status (Siega-Riz et al., 2014). However, increases in iron and zinc intakes in the LNS arm did not translate into differences between study arms in the corresponding biomarkers. This finding points to the need to ensure that iron in LNS is adequately bioavailable and to consider how anti-nutrients, such as phytates, in the diet influence absorption. Studies in Benin suggest that adding phytase and ascorbic acid together with LNS to cereal-based porridge could be an appropriate strategy for increasing iron absorption from LNS (Cercamondi et al., 2013). Absorption of zinc from the diet is also affected by phytate content and other fortification studies have noted the difficulty in changing serum zinc status through dietary intervention (Brown et al., 2007, Gibson et al., 2011).

Energy intakes from complementary food among children in this study were low at baseline and high on the final study visit. Low complementary food intake at baseline could indicate high breastmilk intake, which is consistent with delays in the introduction of complementary food noted among some Honduran infants (Secretaria de Salud [Honduras] et al., 2013). Reported low energy intakes at baseline are unlikely to be related to under-reporting because 24-hour dietary recalls tend to produce over-estimates of child intakes rather than under-estimates (Burrows et al., 2010, Thakwalakwa et al., 2011). High energy intakes reported at the end of the study align with the high proportion of children (~70%) who were weaned before the last study visit and are close to the recommended daily energy intake for this age group (Food and Agriculture Organization, 2001).

This study had two main limitations. First, breastmilk intake was not quantified. While we cannot rule out displacement of breastmilk by LNS, we controlled for breastfeeding status in the analysis, and previous studies found that LNS does not influence the quantity of breastmilk consumed by breastfed children (Galpin et al., 2007, Owino et al., 2011, Kumwenda et al., 2014). It is possible that LNS displacement of breastmilk intake is more common in children who consume large doses of LNS (e.g., 46/70 g/day). However, few children in this study consumed the recommended doses, which may explain, in part, why we saw no displacement of other foods by LNS. Second, adherence to the prescribed LNS regimen was poor. Consumption of smaller than recommended doses of LNS makes this study more generalizable to other interventions using similar doses, while failure of some children to consume any LNS limits generalizability. Like the present study, the trial conducted by Maleta et al. (2004) reported poor adherence to consumption of the recommended medium-size daily quantity of LNS. Both of these studies suggest that even when smaller quantities of LNS are consumed, they improve diet quality and increase intake of problem micronutrients. They also point in the direction currently being pursued in some trials to provide a smaller daily quantity of LNS, which can still provide essential nutrients and is more likely than larger doses to be consumed in its entirety (Arimond et al., 2013).

In conclusion, this study showed that small to medium quantities of LNS increased the dietary intakes of macro- and micronutrients in young Honduran children without replacing foods that were usually consumed. Further work is needed to ensure that increased dietary intakes of iron and zinc from LNS are adequately absorbed. Continued low food variety, even when participants were given family food vouchers and LNS, suggests that multi-pronged strategies are necessary for improving the diets of young children in resource-poor settings.

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KEY MESSAGES

- This study provides the first evidence from Latin America that LNS can be integrated into diets in this geographic area.
- LNS provided to young Honduran children improved the quality of their diet by increasing intake of macro and micronutrients.
- LNS did not displace consumption of other foods.

Table 1:

Food groups used in the analysis of dietary intakes of children in Honduras

Food group	Types of foods included
Fruits	Citrus and non-citrus fruits and juices and avocados
Vegetables	Dark green, deep yellow, starchy and other vegetables plus vegetable juices
Legumes	Beans
Grains	Whole and refined grains in the form of flour or rice, bread, tortillas, crackers, pasta, ready-to-eat cereal, cakes, cookies, snack chips, and baby food grain mixtures
Meat	All sources of animal protein, such as beef, pork, chicken, fish, and eggs
Nuts and nut butters	Nuts and LNS
Dairy	Non-human milk, yogurt, cheese, and cream
Infant formula	Human milk substitutes
Fat	Margarine, oil, shortening, butter, and other animal fat
Sweets	Sugar, honey, jam, and candy
Beverages	Sweetened and unsweetened soft drinks, tea, coffee, and water
Miscellaneous	Gravy, sauces, condiments, and soup broth

Table 2:

Percent of participants consuming food groups and servings consumed during 12 months of follow-up in children assigned to LNS or control (intent to treat)

Food group	Baseline		3 months		6 months		9 months		12 months	
	Control (n=138)	LNS (n=160)	Control (n=128)	LNS (n=149)	Control (n=127)	LNS (n=150)	Control (n=122)	LNS (n=128)	Control (n=111)	LNS (n=129)
Fruit										
% consuming	68	58	88	86	79	73	95	87	92	90
Median (IQR) /	0.73 (0.00, 2.51)	0.25 (0.00, 2.51)	1.05 (0.46, 1.91)	0.86 (0.39, 1.88)	1.07 (0.37, 2.13)	0.81 (0.00, 1.88)	1.76 (0.86, 2.72)	1.41 (0.70, 2.56)	2.37 (1.50, 4.26)	2.50 (1.33, 4.57)
Mean ± SD /	1.51 ± 2.17	1.44 ± 2.23	1.36 ± 1.23	1.32 ± 1.37	1.43 ± 1.39	1.18 ± 1.25	2.12 ± 1.67	1.79 ± 1.62	3.06 ± 2.30	3.13 ± 2.46
Difference between arms ²	-	-0.05	-	0.01	-	-0.21	-	-0.34	-	0.16
Vegetables										
% consuming	93	94	98	97	100	99	98	100	97	100
Median (IQR) /	0.14 (0.02, 0.39)	0.06 (0.01, 0.27)	0.23 (0.13, 0.65)	0.26 (0.11, 0.55)	0.44 (0.18, 0.90)	0.45 (0.17, 0.98)	0.95 (0.44, 1.77)	0.80 (0.39, 1.31)	0.88 (0.53, 1.80)	0.94 (0.56, 1.57)
Mean ± SD /	0.32 ± 0.58	0.20 ± 0.33	0.46 ± 0.51	0.57 ± 0.83	0.69 ± 0.82	0.84 ± 1.14	1.21 ± 1.01	1.07 ± 1.01	1.31 ± 1.48	1.32 ± 1.34
Difference between arms ²	-	-0.12	-	0.22	-	0.25	-	-0.08	-	0.10
Grains										
% consuming	93	94	98	98	100	99	99	100	100	100
Median (IQR) /	0.76 (0.34, 1.63)	0.55 (0.23, 1.11)	0.94 (0.60, 1.56)	1.13 (0.56, 2.10)	1.62 (0.93, 2.39)	1.21 (0.72, 1.93)	1.72 (1.19, 2.79)	1.59 (1.02, 2.36)	2.07 (1.85, 2.32)	2.20 (1.48, 3.01)
Mean ± SD /	1.19 ± 1.28	0.85 ± 1.01	1.34 ± 1.60	1.64 ± 1.70	2.10 ± 1.36	1.66 ± 1.59	2.02 ± 1.19	1.83 ± 1.23	2.41 ± 1.25	2.51 ± 1.79
Difference between arms ²	-	-0.32	-	0.62**	-	-0.12	-	0.03	-	0.39
Meat & eggs										
% consuming	73	71	76	79	85	85	87	91	91	94
Median (IQR) /	0.22 (0.00, 0.60)	0.12 (0.00, 0.38)	0.30 (0.00, 0.54)	0.31 (0.02, 0.76)	0.68 (0.25, 1.19)	0.71 (0.20, 1.40)	0.96 (0.37, 2.14)	0.77 (0.22, 1.77)	1.12 (0.74, 2.05)	1.44 (0.74, 2.33)
Mean ± SD /	0.42 ± 0.56	0.28 ± 0.37	0.44 ± 0.55	0.52 ± 0.63	0.94 ± 1.06	1.17 ± 1.70	1.32 ± 1.29	1.28 ± 1.71	1.51 ± 1.34	1.64 ± 1.31
Difference between arms ²	-	-0.14	-	0.23	-	0.35*	-	0.02	-	0.23
Dairy										
% consuming	63	54	80	92	83	96	82	92	87	93

Food group	Baseline		3 months		6 months		9 months		12 months	
	Control (n=138)	LNS (n=160)	Control (n=128)	LNS (n=149)	Control (n=127)	LNS (n=150)	Control (n=122)	LNS (n=128)	Control (n=111)	LNS (n=129)
Median (IQR) /	0.03 (0.00, 0.19)	0.01 (0.00, 0.13)	0.24 (0.05, 0.50)	0.25 (0.12, 0.50)	0.39 (0.13, 1.13)	0.38 (0.19, 0.70)	0.50 (0.11, 1.00)	0.40 (0.19, 0.91)	0.92 (0.36, 1.52)	0.62 (0.23, 1.17)
Mean ± SD /	0.29 ± 0.90	0.21 ± 0.67	0.46 ± 0.67	0.43 ± 0.68	0.81 ± 1.15	0.69 ± 1.10	0.75 ± 1.21	0.58 ± 0.56	1.13 ± 1.30	0.82 ± 0.78
Difference between arms ²	-	-0.08	-	0.02	-	-0.07	-	-0.15	-	-0.29 *
Infant formula										
% consuming	96	95	94	91	87	82	82	67	72	55
Median (IQR) /	0.06 (0.05, 0.10)	0.07 (0.04, 0.11)	0.05 (0.04, 0.08)	0.05 (0.03, 0.14)	0.05 (0.03, 0.09)	0.05 (0.03, 1.80)	0.05 (0.03, 0.28)	0.04 (0.00, 0.43)	0.04 (0.00, 1.42)	0.02 (0.00, 0.05)
Mean ± SD /	0.93 ± 2.58	0.90 ± 1.91	0.94 ± 2.03	1.11 ± 2.27	0.87 ± 1.98	1.22 ± 2.22	0.85 ± 1.81	0.92 ± 1.87	1.16 ± 2.05	0.75 ± 1.80
Difference between arms ²	-	-0.07	-	0.13	-	0.23	-	-0.20	-	-0.51 *
Legumes										
% consuming	86	86	93	91	97	96	68	66	68	68
Median (IQR) /	0.21 (0.06, 0.50)	0.13 (0.03, 0.34)	0.33 (0.16, 0.52)	0.22 (0.11, 0.40)	0.51 (0.22, 0.84)	0.35 (0.21, 0.65)	0.30 (0.00, 0.60)	0.17 (0.00, 0.33)	0.23 (0.00, 0.60)	0.20 (0.34, 0.39)
Mean ± SD /	0.35 ± 0.42	0.24 ± 0.28	0.44 ± 0.47	0.30 ± 0.28	0.61 ± 0.48	0.49 ± 0.40	0.37 ± 0.37	0.25 ± 0.27	0.40 ± 0.45	0.34 ± 0.39
Difference between arms ²	-	-0.11 *	-	-0.03	-	-0.01	-	-0.02	-	0.04
Nuts & Nut butters										
% consuming	2	1	2	74	2	73	1	75	1	70
Median (IQR) /	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.40 (0.00, 0.61)	0.00 (0.00, 0.00)	0.54 (0.00, 0.84)	0.00 (0.00, 0.00)	0.55 (0.00, 0.87)	0.00 (0.00, 0.00)	0.66 (0.00, 0.87)
Mean ± SD /	0.09 ± 0.75	0.03 ± 0.28	0.04 ± 0.25	0.38 ± 0.40	0.03 ± 0.31	0.58 ± 0.57	0.00 ± 0.04	0.54 ± 0.49	0.02 ± 0.19	0.53 ± 0.42
Difference between arms ²	-	-0.06	-	0.41 ***	-	0.60 ***	-	0.59 ***	-	0.57 ***
Fat										
% consuming	83	82	92	96	93	97	97	100	97	98
Median (IQR) /	0.28 (0.04, 0.90)	0.12 (0.02, 0.40)	0.44 (0.15, 0.88)	2.13 (0.75, 3.40)	0.65 (0.24, 1.53)	2.77 (1.56, 4.18)	1.13 (0.52, 2.09)	3.01 (1.49, 4.36)	1.05 (0.53, 2.13)	3.56 (1.88, 4.65)
Mean ± SD /	0.90 ± 1.59	0.55 ± 1.49	1.05 ± 2.58	2.75 ± 3.28	1.73 ± 3.52	3.87 ± 4.24	1.62 ± 1.75	3.68 ± 4.36	1.71 ± 2.08	3.31 ± 1.98
Difference between arms ²	-	-0.33	-	2.00 ***	-	2.44 ***	-	2.28 ***	-	1.79 ***
Sweets										
% consuming	64	54	60	95	65	89	70	96	69	91

Food group	Baseline		3 months		6 months		9 months		12 months	
	Control (n=138)	LNS (n=160)	Control (n=128)	LNS (n=149)	Control (n=127)	LNS (n=150)	Control (n=122)	LNS (n=128)	Control (n=111)	LNS (n=129)
Median (IQR) /	0.46 (0.00, 1.20)	0.26 (0.00, 0.93)	0.78 (0.00, 2.60)	2.47 (1.32, 4.38)	0.86 (0.00, 3.40)	3.31 (1.65, 5.82)	0.93 (0.00, 2.42)	3.55 (2.04, 4.78)	2.41 (0.00, 5.49)	4.00 (2.27, 6.71)
Mean ± SD /	1.67 ± 6.61	1.03 ± 2.94	2.29 ± 4.72	4.03 ± 5.02	2.53 ± 4.51	4.74 ± 5.36	2.04 ± 3.67	4.32 ± 4.35	3.33 ± 3.86	5.72 ± 6.30
Difference between arms ²	-	-0.62	-	2.38**	-	2.75***	-	2.62**	-	2.91***
Beverages										
% consuming	99	97	100	98	100	100	99	100	99	100
Median (IQR) /	0.99 (0.61, 1.53)	0.85 (0.48, 1.43)	1.22 (0.75, 1.70)	1.10 (0.75, 1.56)	1.55 (1.03, 2.23)	1.78 (1.13, 2.26)	1.51 (1.03, 2.12)	1.91 (1.43, 2.71)	1.49 (0.99, 2.25)	2.21 (1.61, 2.69)
Mean ± SD /	1.12 ± 0.73	0.99 ± 0.72	1.31 ± 0.73	1.26 ± 0.80	1.64 ± 0.83	1.80 ± 1.01	1.63 ± 0.83	2.05 ± 0.92	1.67 ± 1.07	2.21 ± 1.03
Difference between arms ²	-	-0.11	-	0.07	-	0.26*	-	0.47***	-	0.66***
Miscellaneous										
% consuming	78	71	93	89	90	88	96	99	96	100
Median (IQR) /	0.05 (0.00, 0.14)	0.02 (0.00, 0.09)	0.09 (0.05, 0.18)	0.07 (0.04, 0.15)	0.15 (0.07, 0.29)	0.14 (0.06, 0.27)	0.26 (0.14, 0.38)	0.17 (0.12, 0.25)	0.26 (0.15, 0.41)	0.26 (0.17, 0.36)
Mean ± SD /	0.11 ± 0.16	0.07 ± 0.15	0.15 ± 0.18	0.12 ± 0.16	0.23 ± 0.32	0.27 ± 0.49	0.32 ± 0.29	0.22 ± 0.21	0.32 ± 0.24	0.29 ± 0.22
Difference between arms ²	-	-0.03	-	0.00	-	0.07	-	-0.07	-	0.00

Values are percent, median (IQR) and mean ± SD.

¹ Medians and means are unadjusted.

² At baseline, difference represents the difference between control and LNS. At other time points, differences represent the difference in the mean change in control and LNS from baseline. Differences and p-values are from longitudinal GEE models accounting for clustering at the village level and controlling for age, breastfeeding status, and season.

* P<0.05,

** P<0.01,

*** P<0.001

Table 3: Geometric mean and adequacy of macronutrient intake during 12 months of follow-up in children assigned to LNS or control (intent to treat)

Macronutrient	Baseline		3 months		6 months		9 months		12 months	
	Control (n=138)	LNS (n=160)	Control (n=128)	LNS (n=149)	Control (n=127)	LNS (n=150)	Control (n=122)	LNS (n=128)	Control (n=111)	LNS (n=129)
Energy (kcal)										
Geometric mean	311.2 (256.1, 378.1)	238.8 (198.9, 286.7)	461.4 (403.3, 527.8)	594.5 (515.4, 685.8)	681.5 (613.1, 757.4)	788.5 (704.0, 883.1)	754.0 (683.9, 831.4)	833.9 (762.5, 911.9)	963.6 (883.4, 1050.9)	1080.9 (1001.8, 1166.3)
Difference in mean log energy [†]	-	-0.23*	-	0.50***	-	0.38***	-	0.28**	-	0.34**
Total fat (g)										
Geometric mean	9.2 (7.5, 11.4)	6.8 (5.7, 8.2)	14.3 (12.2, 16.7)	22.9 (19.7, 26.7)	22.5 (19.8, 25.5)	31.8 (27.8, 36.3)	25.2 (22.4, 28.4)	34.4 (30.9, 38.2)	31.3 (28.1, 35.0)	40.4 (36.9, 44.1)
Difference in mean log fat [†]	-	-0.28*	-	0.74***	-	0.61***	-	0.50***	-	0.50***
Total carbohydrates (g)										
Geometric mean	47.6 (39.0, 58.1)	37.2 (30.6, 45.3)	71.1 (62.2, 81.4)	82.2 (71.0, 95.3)	99.2 (89.6, 109.9)	102.2 (91.6, 113.9)	110.5 (100.4, 121.6)	108.3 (98.9, 118.6)	141.8 (129.6, 155.2)	148.9 (136.8, 162.0)
Difference in mean log carbs [†]	-	-0.21*	-	0.37**	-	0.24*	-	0.15	-	0.26*
Total protein (g)										
Geometric mean	8.1 (6.5, 10.1)	6.0 (4.9, 7.3)	12.8 (11.0, 14.9)	15.6 (13.4, 18.2)	21.7 (19.4, 24.4)	24.4 (21.6, 27.6)	23.0 (20.5, 25.9)	24.0 (21.7, 26.5)	29.5 (26.7, 32.7)	31.7 (28.9, 34.7)
Difference in mean log protein [†]	-	-0.27*	-	0.47***	-	0.39***	-	0.25*	-	0.30*

Values are geometric means (95% confidence intervals) and proportions.

[†]Differences in mean values and P-values for the differences were obtained from longitudinal mixed models accounting for clustering at the village and individual levels and controlling for age, breastfeeding status, and season. P-values at baseline indicate the difference between study arms at that time point. P-values for later visits compare the difference between study arms in change from baseline to that time point.

* P<0.05,

** P<0.01,

*** P<0.001

Table 4: Geometric mean and adequacy of micronutrient intake during 12 months of follow-up in children assigned to LNS or control (intent to treat)

Macronutrient	Baseline		3 months		6 months		9 months		12 months	
	Control (n=138)	LNS (n=160)	Control (n=128)	LNS (n=149)	Control (n=127)	LNS (n=150)	Control (n=122)	LNS (n=128)	Control (n=111)	LNS (n=129)
Total Vitamin A (IU)										
Geometric mean	569.4 (438.6, 739.1)	427.1 (324.2, 562.8)	740.5 (602.5, 910.1)	1326.9 (1101.9, 1597.8)	942.4 (773.2, 1148.5)	1729.5 (1470.8, 2033.8)	1205.4 (1032.6, 1407.1)	2007.5 (1759.5, 2290.5)	2052.3 (1684.1, 2500.9)	2626.8 (2335.0, 2955.1)
Difference in mean log vit A /	-	-0.28 *	-	0.84 ***	-	0.86 ***	-	0.71 ***	-	0.52 **
Total Vitamin B12 (µg)										
Geometric mean	0.2 (0.2, 0.3)	0.1 (0.1, 0.2)	0.4 (0.3, 0.5)	0.8 (0.6, 1.0)	0.8 (0.6, 0.9)	1.3 (1.1, 1.6)	0.9 (0.7, 1.1)	1.3 (1.1, 1.5)	1.3 (1.1, 1.5)	1.7 (1.5, 1.9)
Difference in mean log B12 /	-	-0.30	-	1.01 ***	-	0.80 ***	-	0.57 **	-	0.45 *
Folate (µg)										
Geometric mean	63.4 (50.8, 79.1)	45.9 (37.0, 57.0)	99.7 (85.6, 116.2)	159.2 (134.2, 188.9)	145.2 (130.1, 162.2)	238.9 (211.2, 270.3)	151.1 (136.6, 167.1)	237.1 (213.4, 267.4)	186.1 (167.9, 206.4)	283.9 (256.9, 313.7)
Difference in mean log folate /	-	-0.30 *	-	0.78 ***	-	0.79 ***	-	0.69 ***	-	0.72 ***
Iron (mg)										
Geometric mean	2.0 (1.6, 2.6)	1.5 (1.2, 1.9)	3.3 (2.8, 4.0)	7.0 (5.7, 8.6)	5.0 (4.4, 5.7)	10.6 (9.2, 12.2)	5.2 (4.5, 5.9)	10.0 (8.7, 11.4)	6.3 (5.6, 7.2)	11.3 (10.0, 12.8)
Difference in mean log iron /	-	-0.27	-	1.02 ***	-	1.00 ***	-	0.86 ***	-	0.83 ***
Zinc (mg)										
Geometric mean	1.2 (1.0, 1.5)	0.9 (0.8, 1.1)	1.9 (1.6, 2.2)	5.2 (4.3, 6.3)	3.0 (2.7, 3.4)	8.1 (6.9, 9.5)	3.2 (2.8, 3.6)	7.8 (6.7, 9.1)	4.0 (3.6, 4.5)	8.6 (7.4, 9.9)
Difference in mean log zinc /	-	-0.24	-	1.23 ***	-	1.20 ***	-	1.05 ***	-	0.96 ***

Values are geometric means (95% confidence intervals) and proportions.

/ Differences in mean values and P-values for the differences were obtained from longitudinal mixed models accounting for clustering at the village and individual levels and controlling for age, breastfeeding status, and season. P-values at baseline indicate the difference between study arms at that time point. P-values for later visits compare the difference between study arms in change from baseline to that time point.

* P<0.05,

** P<0.01,

*** P<0.001