Maternal & Child Nutrition

DOI: 10.1111/j.1740-8709.2010.00286.x

Original Article

Acceptability of lipid-based nutrient supplements (LNS) among Ghanaian infants and pregnant or lactating women

Seth Adu-Afarwuah*, Anna Lartey*, Mamane Zeilani† and Kathryn G. Dewey‡

**Department of Nutrition and Food Science, University of Ghana, Legon, Accra, Ghana, †Nutriset SAS, Malaunay, France, and ‡Program in International and Community Nutrition, University of California, Davis, California, USA*

Abstract

Inadequate micronutrient intake during pregnancy, lactation and infancy is a major problem in many developing countries. Lipid-based nutrient supplements (LNS) can improve micronutrient status, growth and development of infants, and also have potential to improve nutritional status of pregnant and lactating women. The objective of the study was to test the acceptability of LNS designed for infants (LNS-20gM) and pregnant or lactating women (LNS-P&L). Participants were infants ($n = 22$, mean age = 8 months) and pregnant or lactating women ($n = 24$) attending routine services at a hospital in Ghana. Infants consumed 45 g of a test meal consisting of one part LNS-20gM and three parts fermented maize porridge, while women consumed 50 g of a similar test meal containing LNS-P&L instead. Participants also used their respective LNS at home for 14 days. Primary outcome was the proportion of the test meal consumed. On average, infants consumed 76.2% of the test meal [95% (confidence interval) CI: 65.7, 86.7], while women consumed 87.1% (95% CI: 82.6, 91.6). During the 14-day period, median daily consumption of LNS-20gM was 19.3 g, very close to the recommended 20 g d^{-1}, while that of LNS-P&L was one sachet, as recommended. We conclude that LNS-20gM and LNS-P&L were well accepted.

Keywords: lipid-based nutrient supplements, acceptability, test feeding, fermented maize porridge, multiple micronutrient supplement, home fortification.

Correspondence: Prof. Anna Lartey, Department of Nutrition & Food Science, University of Ghana, Legon, Box LG 134, Legon Accra, Ghana. E-mail: aalartey@ug.edu.gh

Introduction

Inadequate micronutrient intake during pregnancy, lactation and infancy is a major problem in many developing countries. In Ghana, the Demographic and Health Survey of 2008 showed that an estimated 70% of pregnant women and over 80% of children between 6 and 12 months of age were anaemic, and this is believed to be mainly due to inadequate iron intake. It is likely that the intakes of other key nutrients such as essential fatty acids (EFAs), zinc and vitamin A in these vulnerable groups are also low, given the low intakes of animal source foods especially among children (Colecraft *et al*. 2006).

Addressing micronutrient deficiency in developing countries remains a challenge. For pregnant women, the World Health Organization (WHO) recommendation of routine iron and folic acid supplementation has been adopted by many countries, but adherence is often poor because of the side effects of the iron supplements (Galloway & McGuire 1994). National food fortification programs exist in many countries, but the level of fortification is often too low, particularly for children (Brown *et al*. 1998), and the limited

consumption of the fortified products by many households (due to inadequate access) tends to reduce their effectiveness. Local complementary foods are often thin gruels of low energy and nutrient densities, and because they are almost entirely of plant sources, they also have low nutrient bioavailability (Gibson *et al*. 1998).

We have pioneered a food-based approach to combating micronutrient deficiencies using lipid-based nutrient supplements (LNS). LNS include the family of multiple micronutrient (MMN)-fortified semi-solid pastes usually prepared from vegetable oil, groundnut paste, milk, sugar and different concentrations of micronutrients depending on the type of product and the specific nutritional conditions in the target population. When mixed with food, LNS improves the energy and nutrient content of the food because of its high nutrient and energy density. Used in the home, it permits targeting to the individuals for whom it is intended. From previous studies in Ghana (Adu-Afarwuah *et al*. 2007) and Malawi (Phuka *et al*. 2008, 2009), LNS has significant positive effects on infant growth, development and micronutrient status, and has potential to improve the nutritional status of pregnant and lactating women, and thereby enhance their children's nutritional status as well.

The type of LNS for infants called Nutributter (Nutriset SAS, Malaunay, France), which was used in our previous study in Ghana (Adu-Afarwuah *et al*. 2008) and was well accepted, was made from a mixture of oils that included rapeseed oil and had a sugar content similar to that of Plumpy'nut™ (Nutriset SAS). We recently modified the formulation of Nutributter by: (1) using soybean oil instead; (2) including a few more nutrients, e.g. vitamin E and K and increasing the levels of others, e.g. Zn and Ca; and (3) reducing the sugar content by 50%. We called the modified Nutributter LNS-20gM. Further, we formulated an LNS product for pregnant or lactating women, which we called LNS-P&L. The objective of this study was to assess the acceptability of LNS-20gM and LNS-P&L. The study was a necessary step before conducting an efficacy trial with the two products, which is currently underway (ClinicalTrials.gov Identifier: NCT00970866).

Subjects and methods

Overview and design

The LNS-P&L and LNS-20gM were manufactured by Nutriset SAS (Malaunay, France), which also produced the Nutributter. The products were then shipped by air to Ghana for the study. LNS P&L was packaged in 20 g sachets, while LNS-20gM and Nutributter were in plastic cups with lids, each with a net weight of 140 g.

The nutrient compositions of LNS-P&L and LNS-20gM, as well as Nutributter, are presented in Table 1. These concentrations are those of the products as a whole (per daily dose), which include contributions from the ingredients as well as the MMN premix. LNS-P&L was modelled on the United Nations International Multiple Micronutrient Preparation (UNIMMAP) for pregnant and lactating women (UNICEF/World Health Organization/United Nations University 1999) and similar products used in Guinea Bissau (Kaestel *et al*. 2005). It provided approximately one recommended daily allowance (RDA) (pregnancy) of four vitamins (A, D, folic acid, pantothenic acid) and one mineral (Mn), and two RDAs of seven vitamins (C, B1, B2, B3, B6, B12, E) and three minerals (Zn, Cu, Se). The vitamin K and I concentrations are based on current WHO recommendations, while Fe is kept at a level considered sufficient for both pregnancy and lactation.

Key messages

- Lipid-based nutrient supplements (LNS) formulated for infants and pregnant or lactating women were well accepted in an acceptability trial in Ghana.
- When using LNS for home fortification, women can mix it with any food they prefer, and therefore there is flexibility in consuming the supplement.
- Use of LNS for home fortification can be made simpler by packaging the supplement in convenient daily doses.

Table 1. Composition of LNS-20gM and LNS-P&L per 20 g portion*

Nutrient	LNS-20gM	LNS-P&L	Nutributter
Ration (g day^{-1})	20	20	20
Total energy (kcal)	118	118	108
Protein (g)	2.6	2.6	2.6
Fat (g)	9.6	10	7.1
Linoleic acid (g)	4.46	4.59	1.29
α-Linolenic acid (g)	0.58	0.59	0.29
Vitamin A (μg RE)	400	800	400
Vitamin C (mg)	30	100	30
Vitamin B_1 (mg)	0.3	2.8	0.3
Vitamin B_2 (mg)	0.4	2.8	0.4
Niacin (mg)	4	36	4
Folic acid (μg)	80	400	80
Pantothenic acid (mg)	1.8	7	1.8
Vitamin B_6 (mg)	0.3	3.8	0.3
Vitamin B_{12} (μg)	0.5	5.2	0.5
Vitamin D (IU)	200	400	–
Vitamin E (mg)	6	20	–
Vitamin K (μg)	30	45	–
Iron (mg)*	6	20	9
Zinc (mg)	8	30	4
Cu (mg)	0.34	4	0.2
Calcium (mg)	280	280	100
Phosphorus (mg)	190	190	82
Potassium (mg)	200	200	152
Magnesium (mg)	40	65	16
Selenium (μg)	20	130	10
Iodine (μg)	90	250	90
Manganese (mg)	1.2	2.6	0.08
Phytate (mg)	23.4	24.7	82

*Nutrient concentrations are those of the products as a whole, which include contributions from the ingredients as well as from the multiple micronutrient premix. LNS-20gM provided approximately the Recommended Nutrient Intakes (RNI) for 19 vitamins and minerals for infants 7–12 months of age. Fe was kept at 55% of the RNI because of concerns about increasing the risk of malaria. Zn is >100% of RNI because of the possibility of low zinc absorption from the supplement as it is usually mixed with maize-based complementary foods high in phytate. LNS-P&L was based mainly on the United Nations International Multiple Micronutrient Preparation formulation developed by UNICEF/World Health Organization (WHO)/United Nations University and adapted for studies in Guinea Bissau, and provided approximately one recommended daily allowance (RDA) of four vitamins (A, D, folic acid, pantothenic acid) and one mineral (Mn), and two RDAs of seven vitamins (C, B1, B2, B3, B6, B12, E) and three minerals (Zn, Cu, Se). Vitamin K and I in LNS-P&L are based on current WHO recommendations, while Fe is kept at a level considered adequate for both pregnancy and lactation. Amounts of P, K and Mg in LNS-P&L and LNS-20gM, and of Ca in LNS-P&L, are the maximum that could be included because of technical constraints.

We modified the original formulation of Nutributter when developing LNS-20gM primarily because the rapeseed oil in Nutributter is not readily available in most countries, whereas the soybean oil used in LNS-20gM is available in many developing countries. The LNS-20gM provided approximately the Recommended Nutrient Intake (RNI) for 19 vitamins and minerals for infants 7–12 months of age. Fe was kept at 55% of the RNI because of concerns about increasing the risk of malaria (World Health Organization 2006). Compared with Nutributter, LNS-20gM has higher concentrations of EFAs (linoleic and α-linolenic acids), because the intakes of EFAs from complementary foods in Ghana may be low, as observed elsewhere in West Africa (Bond *et al*. 2005). LNS-20gM has twice as much Zn as Nutributter because our previous study (Adu-Afarwuah *et al*. 2008) showed no effect of Nutributter on plasma zinc concentration, possibly because of low zinc absorption from the supplement as it was usually mixed with maize-based complementary foods high in phytate. The amounts of P, K and Mg in LNS-P&L and LNS-20gM, and of Ca in LNS-P&L are the maximum that could be included in the supplements due to technical constraints with adding amounts equivalent to the RNI.

We carried out the study with LNS-P&L and LNS-20gM in two parts. Part 1 was a test feeding trial in which we mixed each supplement with fermented maize porridge (called *koko* in Ghana) and asked study participants to taste the mixture. We did not directly compare either of the two supplements with Nutributter, but we included a tasting of Nutributter on the third day of the test feeding trial to verify that the original formulation was well accepted in this study population, as it was in our previous study (Adu-Afarwuah *et al*. 2008).

In Part 2 of the study, all participants in the Part 1 trials received a 2-week supply of LNS-20gM or LNS-P&L, which they consumed in their homes for 14 days under real-life conditions. The daily dose of LNS-20gM was 20 g, and for LNS-P&L it was one sachet (which was also 20 g). This Part 2 of the study was not for testing a specific hypothesis, but simply for assessing how the supplements were used, as well as users' reactions to the supplements.

Sample size was based on the desire to test the hypothesis that mean consumption in Part 1 would be at least 50% of the amount offered. We assumed that the standard deviation (SD) of consumption would be 30% of the amount offered. The sample size of 18 would therefore allow us to reject the null hypothesis with 90% power if the true mean were at least 75%. Assuming 10% attrition, we needed at least 20 infants for the LNS-20gM trial, and at least 20 pregnant and lactating women for the LNS-P&L trial.

Study area and participants

The study was conducted in June 2009 in Agomanya in the Eastern Region of Ghana. As in other parts of the country, the main food fed to infants is *koko*, which is also widely eaten by adults. Participants for the LNS-20gM testing were healthy infants who attended a routine growth monitoring and promotion (GMP) session at the St. Martin de Porre's Catholic Hospital on 1 June 2009. Those for the LNS-P&L testing were pregnant or lactating women who made routine antenatal clinic visits (pregnant women) or brought their infants for GMP sessions (lactating women) at the same hospital between 9 June and 10 June 2009.

For infants, inclusion criteria were: (1) 6–12 months of age; (2) currently receiving breast milk; and (3) had consumed complementary foods for at least 30 days. For women, the criteria were: (1) at least 18 years of age; and (2) confirmed to be pregnant or breastfeeding. Exclusion criteria for infants and women (after initial consent) were: (1) known intolerance to milk or peanut; or (2) illness requiring referral. Ethical approval for the study was obtained from the Institutional Review Boards of the University of California, Davis, USA and the Noguchi Memorial Institute for Medical Research, University of Ghana. Written consent to take part in the study was obtained from each participant or mother (in the case of infants).

Recruitment and procedures

On the day of the growth monitoring or antenatal session, nurses in charge of the session, assisted by a trained field worker, referred to the study enrolment team every infant aged 6–12 months or woman no less than 18 years who showed up for the session. The enrolment team then verified the age of the subject followed by the other inclusion criteria using the Child Health Card (infants) or Antenatal Card (pregnant women). Referred subjects who met all inclusion criteria were given details of the study and were invited to participate. After consent, trained field workers completed a screening questionnaire to determine if a potential subject had to be excluded because of illness or intolerance to milk or groundnuts. The nurses were told to stop referring infants and women after the target sample size had been achieved. Subjects who remained eligible after the screening were asked to report at the project feeding centre (set up at the hospital) the next day to begin the Part 1 trial.

Part 1 trial: LNS-20gM

Infants were brought to the test-feeding centre each morning for 3 consecutive days to consume a test meal of *koko* mixed with LNS-20gM (day 1 and day 2) or Nutributter (day 3). With ingredients purchased from the local market, the *koko* was prepared each morning by our field workers and carried in a thermos flask to the feeding centre. Each day, we recorded the time mothers arrived at the feeding centre with their infants and information about infants' most recent food (including breast milk) intake and morbidity during the past 24 h. We ensured that infants were offered the test meal at least 1 h after they were last fed. Each mother was given 50 g of *koko* mixed with supplement (LNS-20gM or Nutributter) in the ratio of 3:1 (which is nearly equivalent to mothers mixing two teaspoons of the supplement weighing about 10 g to 2–3 tablespoons of porridge measuring 30–40 mL for the child) and asked to first taste 1 teaspoon (~5 g) of the food. The remaining mixture measuring about 45 g was fed to the infant by the mother, after it was re-weighed. The amount of the test meal consumed within 15 min, or up to the time the child stopped eating and at least twice refused the mother's attempt to re-feed, was recorded. The emotional

state of the infant during the feeding was also recorded. Using a 5-point hedonic scale in which each point (1 = Dislike a lot, 2 = Dislike a little, 3 = Neither like nor dislike, 4 = Like a little, 5 = Like a lot) was depicted by a facial drawing, we asked mothers to rate the food's colour, odour, taste and overall liking. We considered the first day of the tasting as a practice day to allow mothers to familiarize themselves with the test procedures. Therefore, the tasting data recorded on that day were not included in the analysis.

Part 1 trial: LNS-P&L

Women reported at the test-feeding centre each morning for 3 consecutive days. Each day, information about morbidity during the past 24 h was recorded. Then, each woman was offered 50 g of *koko* mixed with LNS-P&L (days 1 and 2) or Nutributter (day 3) prepared as above, and the amount of the food she consumed within 15 min, or up to the time she said she would not eat any more, was recorded. Women were asked to rate the colour, odour, taste and overall liking of the food using a 5-point hedonic scale as above. As with the infants, the first of the 3 days (day 1) was used as a practice day, so the food tasting data recorded on that day were not included in the analysis.

Part 2 trial: LNS-20gM and LNS-P&L for use at home

After each of the Part 1 trials, all participants were supplied with the respective supplements (infants = LNS-20gM, women = LNS-P&L) for home fortification of their foods for 14 days. With a daily dose of 20 g, each child was expected to consume two of the LNS-20gM cups, but we gave each child 3 cups so that there would be enough for the child in case some other individuals within or outside the family wanted to taste the supplement. To feed the LNS-20gM to infants, mothers were told to add 2 flat teaspoons (~ 10 g, taken from the cup) to infants' prepared food two times a day (total 20 g or 4 teaspoons a day). To ensure that infants consumed the entire portion taken, mothers were instructed to add the supplement to 2–3 tablespoons of food and feed it to the child before feeding the rest of the food. Mothers were provided with teaspoons to help them to estimate the daily dose, after field workers had demonstrated to them how to use the teaspoons.

As the LNS-P&L was already provided in 20-g sachets, and the daily dose for women was 20 g, pregnant or lactating women were instructed to add the content of one sachet to their prepared food each day, specifically, half a sachet to be added to each of two meals daily. Each woman was given 16 sachets (although we expected them to consume 14), for the same reason as above for the infants. Subjects (pregnant or lactating women) or their mothers (infants) were told to store the supplements at room temperature and to not cook food any further after adding the supplement.

At the end of the 2-week period, field workers estimated the total amount of supplement consumed by counting the number of leftover sachets (in the case of pregnant or lactating women) or by weighing leftovers in the cups (in the case of infants). Subjects or their mothers were asked to estimate how much (in terms of teaspoons or sachets) of the supplement, if any, was consumed by someone else. When some of the supplement had been consumed by someone else, this was subtracted from the total amount consumed to obtain the actual amount consumed by the study participant. In an exit interview based on a questionnaire format, we asked study participants (or in the case of infants, their mothers) open-ended questions that included whether supplements were usually eaten alone or mixed with foods, what types of foods the supplements were usually mixed with, what reactions (like or dislike) women or mothers had to the supplements, and willingness to use such supplements in the future if they were available.

Data analysis

We performed data analysis using SAS version 8.1 (SAS Institute, Cary, NC). Background characteristics of participants including report of morbidity symptoms prior to the Part 1 test feeding were evaluated by using descriptive statistics. For the Part 1 test feeding (day 2 and day 3 of trial), we calculated the mean ± SD of the proportion of the test meal

consumed, and determined the 95% confidence interval (CI) of the mean. We had decided a *priori* that if the lower end of the 95% CI for LNS-20gM or LNS-P&L was greater than 50%, we would consider the food (and thereby LNS-20gM or LNS-P&L) acceptable. We used two-tailed paired Student's t-tests (SAS Proc Mixed) to detect differences in continuous variables between day 2 (LNS-P&L or LNS-20gM) and day 3 (Nutributter), and chi-squared tests (SAS Proc Freq) for proportions. Data from the hedonic scale questions were presented as median (min, max), while differences in the hedonic responses between day 2 (LNS-P&L or LNS-20gM) and day 3 (Nutributter) were analysed using the non-parametric Wilcoxon signed rank sum test, as the hedonic responses were considered to be ordinal.

For the exit interview at the end of the 2-week home-use period, we summarized the different practices women adopted while consuming the supplement (LNS-P&L) or feeding the supplement (LNS-20gM) to their infants. We calculated the median (min, max) of the weight or number of sachets of supplement consumed per day during the 14-day period, as these intakes were skewed to the right. As done recently in a report from Mexico (Young *et al*. 2010), we analysed opinions about colour, odour and taste by reviewing comments from those interviewed, and calculating those who found, or thought their infants found, the various sensory characteristics acceptable, as percentages of those interviewed. We analysed hedonic responses for overall degree of liking by determining the percentage of those interviewed who gave each particular ranking to the LNS product. We calculated the percentages of women or mothers who: (1) had perceived health benefits from consuming the supplement or feeding it to their infants; and (2) were willing to use the supplements again, if made available in future. Data for pregnant and lactating women from the exit interviews were first analysed together, and then separately, because the taste and food preferences of pregnant women may be different from those of lactating women. However, we did not attempt to assess statistical significance of differences between pregnant and lactating women because that was not an a *priori* objective.

Results

Acceptability of LNS-20gM

Infants and background characteristics

In total, 23 infants were screened, and all of them were enrolled into the study. The mother of one child did not show up with him again after enrolment, and could not be contacted. Therefore, 22 infants (Table 2) who completed the study were included in the data analysis. These infants included 13 boys (59%) and 9 girls (41%), and their mean (±SD) age was 8.0 (±1.5) months. Most children were of first (32%) or second (50%) birth order. Mean (±SD) age and years of maternal education were 29.5 (±5.4) and 8.0 (±3.0) years, respectively. Before each test feeding on days 2 and 3, a few infants were reported to have some morbidity symptoms (including nasal secretion, cough and diarrhoea), but the percentages of infants with these symptoms did not differ significantly by day of test.

Part I trial involving LNS-20gM

Infants arrived at the feeding centre at a mean time of 8:01 am on the day they tasted the LNS-20gM (day 2) and at 8:16 am on the day they tasted the Nutributter (day 3). These times of arrival did not differ signifi-

Table 2. Baseline characteristics of infants who completed the entire study

Characteristics	Infants ($n = 22$)	
Sex = males (%)	59	
Age (month, Mean ± SD)	8.1 ± 1.5	
Birth order (%)		
First	32	
Second	50	
Maternal age (year, Mean ± SD)	29.5 ± 5.4	
Maternal education (year, Mean ± SD)	8.0 ± 3.0	
Morbidity in past 24 h (% [#], day 2/day3)		
Nasal secretion	23 [5]	/ 18 [4]
Cough	22 [5]	/ 18 [4]
Difficulty breathing	0	/ 5 [1]
Diarrhoea	0	/ 9 [2]
Fever	9 [2]	/ 14 [3]
Vomiting	0	/ 14 [3]
Malaria	0	/ 0
Ear infection	5 [1]	/ 5 [1]

Table 3. Results of test feeding of *koko** mixed with LNS-20gM or Nutributter

	Koko + LNS-20gM (Day 2) ($n = 22$)	*Koko* + Nutributter (Day 3) ($n = 22$)	*P*-value†
Time arrived – mean (min, max)	08:01 (07:00, 09:02)	08:16 (07:19, 09:50)	0.15
Emotional state – % (#)			
Calm	68 (15)	68 (15)	0.15
Fussy	5 (1)	23 (5)	
Crying	27 (6)	9 (2)	
Proportion of food consumed (%)			
Mean ± SD	76.2 ± 24.3	71.1 ± 22.3	0.35
95% CI (lower–upper)	65.4–87.0	60.4–81.9	
Time (min) taken to consume food – (Mean ± SD)	6.0 ± 3.0	5.0 ± 3	0.59
Hedonic responses – median (min, max)‡			
Mother's overall liking	5 (4, 5)	5 (4, 5)	1.00
Colour	5 (4, 5)	5 (4, 5)	0.25
Odour	5 (4, 5)	5 (4, 5)	1.00
Taste	5 (4, 5)	5 (4, 5)	1.00
Infant's liking (mother's opinion)	5 (4, 5)	5 (4, 5)	1.00

**Koko* is a fermented maize porridge commonly fed to infants as a complementary food, and eaten by adults as a breakfast food. †Paired Student's *t*-test for continuous variables, chi-squared test for proportions, and the non-parametric Wilcoxon signed rank sum test for the hedonic responses. ‡Hedonic scale: 1 = Dislike a lot, 2 = Dislike a little, 3 = Neither like nor dislike, 4 = Like a little, 5 = Like a lot.

cantly ($P = 0.15$). In general, infants were calm during each test feeding. Infants consumed (mean ± SD) 76.2 ± 24.3% of the *koko* + LNS-20gM mixture, which took them 6.0 ± 3.0 min, and 71.1 ± 22.3% of the *koko* + Nutributter mixture which took them 5.0 ± 3 min. Neither the amounts of the two test meals consumed ($P = 0.35$), nor the times taken to consume them ($P = 0.59$) differed significantly. The 95% CI of the mean proportion of the *koko* + LNS-20gM mixture consumed by infants was 65.4%–87.0%. Thus, the lower end of the CI was more than the 50% cut-off point above which we had decided a *priori* to consider the LNS-20gM acceptable to infants. The 95% CI of the mean proportion of the *koko* + Nutributter mixture consumed by infants was 60.4%–81.9%. On the 5-point hedonic scale, median response for each sensory quality (overall liking by mothers, colour, odour, taste and mother's opinion about overall liking by infant) of LNS-20gM was 5 ('Like a lot'), and ranged from 4 to 5. Similar results were obtained for Nutributter (Table 3).

Part 2 trial of LNS-20gM: mothers' practices, perceptions of children's reactions and beliefs

As shown in Table 4, nearly all mothers (18/22) said they usually mixed the LNS-20gM with porridge for their infants, as was suggested by field workers. Several (10/22) said they also mixed the supplement with other foods including stews and soup. The vast majority (20/22) of mothers said that when their infants were offered food mixed with LNS-20gM, the infants consumed the entire portion offered 'every time'. Median (min, max) weight of LNS-20gM consumed by children per day during the 14-day home-use period was 19.3 g (3.5 g, 29.6 g). All mothers said their infants liked the taste of LNS-20gM, while 91% made a similar comment for the odour. Only two mothers said their infants did not like the odour, with one commenting 'he does not like the odor. . . . if I mix it with *koko*, he smells it and then rejects it'. On a 5-point hedonic scale for infants' degree of liking of the supplement, most mothers (81%) rated the supplement '5' ('Like a lot'), except one mother who gave a rating of 1 ('Dislike a lot'). Except for three mothers who said their infants had diarrhoea because of the supplement, most mothers did not think their infants had any problems after consuming the supplement. Most (55%) women believed that the supplement had a positive health effect. Only one mother was not willing to feed her child with the supplement if made available in future, saying 'I had a lot of pressure from my mother not to use the supplement after my child got diarrhea'.

Table 4. Summary of mothers' ($n = 22$) practices, perceptions of children's reactions to LNS-20gM and beliefs after feeding LNS-20gM to children in homes for 14 days

Mothers' practices, perceptions of children's reactions to LNS-20gM and beliefs	Mothers ($n = 22$)*
Practices	
Mixed supplement with porridge all or most of the time	82 (18)
Sometimes mixed supplement with other foods besides porridge	46 (10)
Infants consumed the entire portion of food + LNS-20gM mixture offered 'every time'	91 (20)
Amount (g) of LNS-20gM consumed by child per day during 14-day period – median (min, max)	19.3 (3.5, 29.6)
Perception of child's reactions	
Infant likes taste	100 (22)
Infant likes odour	91 (20)
Hedonic response for child's overall degree of liking†	
1 = 'Dislike a lot'	5 (1)
4 = 'Like a little'	14 (3)
5 = 'Like a lot'	81 (18)
Infant had diarrhoea after consuming supplement	14 (3)
Beliefs	
Positive health effect on child	55 (12)
Willing to feed LNS-20gM to their infants in future	95 (21)

*Values are % (n) except indicated. †Hedonic response: 1 = Dislike a lot, 2 = Dislike a little, 3 = Neither like nor dislike, 4 = Like a little, 5 = Like a lot.

Acceptability of LNS-P&L

Women and background characteristics

We screened 25 women (12 pregnant, 13 lactating) and enrolled all of them, of whom 24 completed the Part 1 trial (test feeding), and 23 (11 pregnant, 12 lactating) completed the entire study (test feeding + home use for 14 days); one woman could not be contacted again after consent, and another left the area after the Part 1 trial. Mean (±SD) age and years of education of those who completed at least the Part 1 trial were 26.4 (±6.4) and 8.5 (±3.1) years, respectively. Two women reported cough in the previous 24 h when they showed up at the feeding centre, prior to taking part in the trial procedures on days 2 and 3, and the same number of women, who were both pregnant, reported vomiting in the previous 24 h, prior to taking part in the day 2 tasting (Table 5).

Table 5. Background information for pregnant and lactating women who completed the test feeding trial

Characteristics	Women ($n = 24$)	
Age (year, Mean ± SD)	26.7 ± 6.3	
Education (year, Mean ± SD)	8.6 ± 3.2	
Morbidity in past 24 h (% [#], day 2/day 3)		
Nasal secretion	0	/ 0
Cough	8 [2]	/ 8 [2]
Difficulty breathing	0	/ 0
Diarrhoea	0	/ 0
Fever	0	/ 0
Vomiting	8 [2]*	/ 0
Malaria	0	/ 0
Ear infection	0	/ 0

*Both women were pregnant.

Part 1 trial involving LNS-P&L

Mean ± SD proportion of *koko* + LNS-P&L mixture consumed (day 2) was 87.1% ± 14.5%, which took women a mean ± SD time of 2.0 ± 1.0 min. On day 3, mean ± SD proportion of *koko* + Nutributter mixture consumed was 88.6% ± 5.3%, which took the women approximately the same time as on day 2 (2.0 ± 1.0 min). These mean proportions of offered food consumed on day 2 and day 3 were not significantly different ($P = 0.52$). The 95% CI of the mean proportion of the *koko* + LNS-P&L mixture consumed by women was 82.4%–91.7%. Thus, the lower end of the CI was more than the 50% cut-off point above which we had decided a *priori* to consider the

Table 6. Results of test feeding of *koko** mixed with LNS-P&L or Nutributter

	Koko + LNS-P&L ($n = 24$)	*Koko* + Nutributter ($n = 24$)	*P*-value†
Proportion of food consumed (%)			
Mean ± SD	87.1 ± 14.5	88.6 ± 5.3	0.52
95% CI (lower–upper)	82.4–91.7	84.0–93.2	
Time (min) taken to consume food – Mean ± SD	2.0 ± 1.0	2.0 ± 1.0	0.49
Hedonic responses – median (min, max)‡			
Women's overall liking	5 (3, 5)	5 (4, 5)	0.50
Colour	5 (3, 5)	5 (4, 5)	0.19
Odour	5 (2, 5)	5 (4, 5)	0.16
Taste	5 (2, 5)	5 (3, 5)	0.31

**Koko* is a fermented maize porridge commonly fed to infants as a complementary food, and eaten by adults as a breakfast food. †Paired Student's *t*-test for continuous variables, chi-squared test for proportions, and the non-parametric Wilcoxon signed rank sum test for the hedonic responses. ‡Hedonic scale: 1 = Dislike a lot, 2 = Dislike a little, 3 = Neither like nor dislike, 4 = Like a little, 5 = Like a lot.

Table 7. Summary of women's ($n = 23$) practices, reactions to LNS-P&L and beliefs after consuming LNS-P&L in homes for 14 days

Women' practices, reactions to LNS-P&L and beliefs	Pregnant ($n = 11$)*	Lactating ($n = 12$)*	All ($n = 23$)*
Practices			
Mixed supplement with porridge all or most of the time	73 (8)	75 (9)	74 (17)
Mixed supplement with other foods besides porridge (e.g. stews and soup)	91 (10)	100 (12)	96 (22)
Consumed entire portion of food + LNS-P&L mixture prepared 'every time'	91 (10)	100 (12)	96 (22)
Number of sachets of LNS-P&L consumed per day during the 14-day period – median (min, max)	1 (0.8, 1.2)	1 (0.4, 1.1)	1 (0.4, 1.2)
Reactions to sensory qualities			
Consider colour acceptable	100 (11)	100 (12)	100 (23)
Consider odour acceptable	82 (9)	92 (11)	87 (20)
Consider taste acceptable	82 (9)	67 (8)	74 (17)
Think supplement is too oily	18 (2)	0	9 (2)
Hedonic response for overall degree of liking†			
3 = 'Neither like nor dislike'	0	8 (1)	4 (1)
4 = 'Like a little'	36 (4)	25 (3)	31 (7)
5 = 'Like a lot'	64 (7)	67 (8)	65 (15)
Beliefs			
Positive health effect on child	82 (9)	67 (8)	74 (17)
Willing to feed LNS-P&L to their infants in future	91 (10)	100 (12)	96 (22)

*Values are % (*n*) except for number of sachets of LNS-P&L consumed by women per day during the 14-day period. †Hedonic responses: 1 = Dislike a lot, 2 = Dislike a little, 3 = Neither like nor dislike, 4 = Like a little, 5 = Like a lot.

LNS-P&L acceptable to pregnant or lactating women. The 95% CI of the mean proportion of the *koko* + Nutributter mixture consumed by the women was 84.0%–93.2%. On the 5-point hedonic scales, women rated the LNS-P&L slightly lower than Nutributter, considering the lower ends of the ranges of responses given for each product, but for each rating the medians were 5 for both products (Table 6).

Part 2 trial of LNS-P&L: mode of administration and reactions

Table 7 summarizes how women said they consumed the LNS-P&L in their homes, and their impressions after using the supplement for 2 weeks. Many women (17/23) said they mixed the LNS-P&L supplement with porridge as field workers suggested, but a greater number (22/23) said they mixed it with other foods

besides porridge. These foods ranged widely, and included soups, stews, bread and other traditional dishes (*banku*, *waakye* and yam). Nearly all women (22/23) said they ate the entire portion of food mixed with the supplement 'every time' they prepared the mixture. During the 14-day period, average daily consumption of the LNS-P&L supplement ranged from 0.4 sachets to 1.2 sachets, with a median of one sachet, which was the recommended dose.

While all women (100%) found the colour of the LNS-P&L acceptable, a slightly lower percentage (87%) found the odour acceptable. The taste of the LNS-P&L attracted negative comments from six women (26%). Some of the comments about the taste were: 'I did not like the taste. . . . I took it only because I was asked to do so'. Another woman said 'it had a bitter after-taste no matter the food I mixed it with'. A few women (2/23) said the supplement was too oily, with comments like 'there is too much oil in it . . .' and 'I don't like the oily nature of the supplement'. On the hedonic scale for overall degree of liking, the majority (65%) of women rated the LNS-P&L '5' ('Like a lot'), and no one rated it lower than '3' ('Neither like nor dislike'). Most women (74%) believed that the LNS-P&L had a positive health effect. All women said they would be willing to use the supplement again if it was available in the future, except one who said she was not sure because she did not like the groundnut odour.

Results of the separate analyses for pregnant and lactating women did not suggest any consistent differences in how the two groups responded. For instance, whereas a greater percentage of lactating women said they found the odour of the supplement acceptable (92% vs. 82%), the reverse was true for taste (67% vs. 82%). However, the two women who complained about the supplement being too oily were both pregnant.

Discussion

Our results suggest that both LNS products were well accepted, although there were fewer complaints about the sensory characteristics of the LNS-20gM for infants than the LNS-P&L for pregnant or lactating women.

LNS-20gM

The assessment of the acceptability of the LNS-20gM was a bit of a challenge because we had to depend almost entirely on the opinions of mothers whose tastes and food preferences, as adults, may be different from those of infants. For these reasons, we took the approach of using the mean proportion of offered food consumed by the infants themselves as a proxy indicator for acceptability in Part 1 of the study. Our rationale was that with no forced-feeding, the amount of the offered food consumed by infants would depend largely on the extent to which they liked the food, given that none of the infants had been fed for at least 1 h prior to the test meal. Infants consumed an average of 76% of the food offered, so we can say with reasonable certainty that infants accepted the LNS-20gM well when mixed with koko. The hedonic responses from the mothers suggested a high level of acceptability, but as observed in a similar study in Mexico (Young *et al*. 2010), such hedonic responses may not be conclusive because respondents could be reluctant to give negative evaluations (Albaum 1997). Thus, combining the results from both the test-feeding and the 14-day home use trial is probably the best way to judge the acceptability of LNS-20gM.

We find the complaints from the two mothers about the odour of the supplement following the 14-day home use as important information that could not be adequately captured from the hedonic responses in Part 1 of the study. While we cannot dismiss those comments, it is possible they were made because the LNS product was new to the mothers, who needed time to get used to it. Further, mothers made the comments about sensory characteristics and overall degree of liking on behalf of their infants, and it is not known exactly how the infants themselves perceived those characteristics.

Regarding the three maternal reports of infant diarrhoea during the study, it is difficult to speculate whether this was, or was not, related to the consumption of the supplement. The main food ingredients used for the production of LNS were not entirely unfamiliar in the diets of the children in the study, so it is unlikely that the ingredients would cause an adverse reaction. It would, however, be advisable for

any future studies using LNS-20gM to monitor the incidence of diarrhoea, particularly during the first few days of consuming the supplement. The fact that most women believed the supplement had a positive health effect on the child was an important feature that could have promoted acceptability. It was therefore not surprising that most mothers said they were willing to feed the supplement to their infants in the future.

As far as acceptability of the sensory characteristics was concerned, we did not find any need to modify the formulation of the LNS-20gM supplement. The only suggested modification would be to package the supplement in 10 g sachets, instead of 140 g cups. In fact, we had originally planned to have the LNS-20gM packaged in sachets (just as the LNS-P&L), but for logistical reasons we had to use cups for the acceptability study. At present, packaging in sachets is less costly than packaging in 140 g cups, so there is an economic advantage to using the sachet packaging. Other advantages of the sachet packaging include: (1) child will receive the appropriate dose daily, and mother will not have to deal with measuring the daily dose; (2) it will reduce the possibility of excess consumption, as it will be more difficult for a child to open several sachets at a time and eat their contents than to open a 140 g cup and consume all its contents; (3) it will be more hygienic to use individual sachets daily, than opening and closing a cup multiple times over several days to scoop the supplement; and (4) it could reduce wastage (e.g. an older sibling destroying a whole cup of supplement).

LNS-P&L

As we did for LNS-20gM, we used the proportion of the offered test meal consumed in Part 1 of the study as a proxy indictor for acceptability because we expected that not every woman would consume the entire amount offered, even though it was a relatively small amount of food (50 g) for an adult. We assumed that the amount consumed would depend, to a large extent, on how much they liked the food. Therefore, the high mean proportion (>87%) of the offered dose consumed in the Part 1 of the trial suggests that the pregnant or lactating women found the *koko* mixed with LNS-P&L acceptable.

The hedonic responses for the LNS-P&L in Part 1 were generally favourable, considering that the median ranking was '5' for each sensory quality. However, for the same reason mentioned above (women may have been reluctant to give negative ratings), it is important to consider the other information collected during the home-use trial. As regards the vomiting in the previous 24 h reported by two women prior to the day 2 tasting, it is difficult to speculate about its relationship to the LNS supplement, but given that both women were pregnant, it is possible that the condition could be pregnancy-related.

The concerns raised by some women after the home-use trial about odour and taste, and the supplement being too oily, warrant some discussion. Our general observation was that women considered the supplement as food, and therefore, they seem to expect it to taste much the same way as a typical food might taste. The relatively high mineral concentration (required to meet nutrient needs during pregnancy) makes any attempt to get the supplement to taste like a typical food a challenge, from a food technology perspective. It is not certain if any modification to the current version of the LNS-P&L is necessary (for example, as regards a bitter taste/aftertaste perceived by some women), but there may be a few other ways to deal with the bitter taste/aftertaste issue: (1) women can be advised to mix the supplement with a larger portion of food such as 1–2 ladles, so as to further mask the taste of the supplement; (2) it should be explained to women that the LNS-P&L supplement, although it looks like food or a snack, has a high nutrient concentration (like a vitamin/mineral pill) and therefore may not taste like a normal food to some women; and (3) it should be reiterated that the supplement is designed to be mixed with food and not eaten alone.

Most women believed that the supplement was good for their health, which could be an important motivation for them to accept and consume it. As many of the nutrients provided in the LNS-P&L could also be provided in the form of a MMN capsule, it should be possible for women (especially during

pregnancy) who dislike LNS-P&L to take such a capsule. However, women taking MMN capsules will miss out on the EFAs provided by the LNS-P&L, and this may be a concern in a setting where the intake of EFAs is low. The efficacy study (ClinicalTrials.gov Identifier: NCT00970866) mentioned above, which is taking place in the same area where this acceptability study was conducted, is comparing the effects of LNS-P&L and MMN capsules among pregnant and lactating women.

Conclusions

We conclude that LNS-20gM and LNS-P&L are acceptable to infants and women, respectively, in Agomanya. Acceptability of LNS-20gM was comparable with that of Nutributter, despite the 50% reduction in the sugar content of the former. This is the first study presenting acceptability data on LNS for pregnant and lactating women, which is a novel way to ensure nutritional adequacy for this target group and is more complete than tablets containing only micronutrients. In the efficacy trial mentioned above (ClinicalTrials.gov Identifier: NCT00970866), approximately 280 mother-infant pairs are being randomly assigned to the LNS intervention group (out of a total target sample size of ~ 860). These mothers are receiving LNS-P&L during pregnancy and the first 6 months post-partum, and their infants are receiving LNS-20gM from 6 to 18 months of age. The trial will not only assess the effects of LNS on the nutritional status of pregnant and lactating women and the growth of their infants, but will also provide extensive information on the long-term acceptability of these LNS products and add to what we have learned from this acceptability study.

Acknowledgements

We gratefully acknowledge the assistance of Dr Per Ashorn and Jan Peerson in the design of the study and calculation of sample size. We also thank the St. Martin de Porre's Catholic Hospital at Agomanya, where the study was carried out, and the women and infants who participated in the study.

Source of funding

Funding for the study was from the Bill & Melinda Gates Foundation.

Conflicts of interest

One of the authors (Mamane Zeilani) is an employee of Nutriset S.A.S that produced the LNS supplements. The remaining authors have declared no conflicts of interest.

Contributions

SAA and AL had full access to all of the data in the study and take responsibility for the integrity of the data. SAA takes responsibility for the accuracy of the data analysis. Authors' responsibilities were as follows: Study concept and design – KGD, SAA, AL and MZ; Data collection – SAA and AL; Statistical analysis – SAA; Interpretation of the data – SAA, AL and KGD; Drafting of the manuscript – SAA and AL; Revision of the manuscript for important intellectual content – SAA, AL and KGD. All authors read, commented and approved the final manuscript.

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