Complementary Feeding With Fortified Spread and Incidence of Severe Stunting in 6- to 18-Month-Old Rural Malawians

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Objective: To compare growth and incidence of malnutrition in infants receiving long-term dietary supplementation with ready-to-use fortified spread (FS) or micronutrient-fortified maize–soy flour (likuni phala [LP]).

Design: Randomized, controlled, single-blind trial.

Setting: Rural Malawi.

Participants: A total of 182 six-month-old infants.

Intervention: Participants were randomized to receive 1 year of daily supplementation with 71 g of LP (282 kcal), 50 g of FS (FS50) (256 kcal), or 25 g of FS (FS25) (127 kcal).

Outcome Measures: Weight and length gains and the incidences of severe stunting, underweight, and wasting.

Results: Mean weight and length gains in the LP, FS50, and FS25 groups were 2.37, 2.47, and 2.37 kg (*P*=.66) and 12.7, 13.5, and 13.2 cm (*P*=.23), respectively. In the same groups, the cumulative 12-month incidence of severe stunting was 13.3%, 0.0%, and 3.5% (*P*=.01), of severe underweight was 15.0%, 22.5%, and 16.9% (*P*=.71), and of severe wasting was 1.8%, 1.9%, and 1.8% (*P*>.99). Compared with LP-supplemented infants, those given FS50 gained a mean of 100 g more weight and 0.8 cm more length. There was a significant interaction between baseline length and intervention (*P*=.04); in children with below-median length at enrollment, those given FS50 gained a mean of 1.9 cm more than individuals receiving LP.

Conclusion: One-year-long complementary feeding with FS does not have a significantly larger effect than LP on mean weight gain in all infants, but it is likely to boost linear growth in the most disadvantaged individuals and, hence, decrease the incidence of severe stunting.

Trial Registration: clinicaltrials.govIdentifier: NCT00131209.

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THE HIGH INCIDENCE AND SErious consequences of childhood undernutrition in sub-Saharan Africa and some parts of southern Asia necessitate emphasis on early prevention, but there are no easy options for it.[1-4] Infection control has not proved to be widely successful, few indigenous foods are rich in all-important nutrients or available throughout the year, and poverty limits possibilities for purchasing commercially available nutritious foods.[5] In Malawi, thin porridge made of micronutrient-enriched maize and soy flour is often promoted as the main complementary food for infants and young children. However, it has low calorie density, and it resembles the staple food in the area, which may result in displacement of habitual foods from the beneficiary's diet or diversion of the complementary food to other family members.[6]

Recently, Briend and his collaborators[7,8] developed the concept of highly nutrient- and calorie-dense spreads, which are simple to produce, need no cooking before use, and can be stored for months even in warm conditions. The best-known formulation of such spreads is called *ready-to-use therapeutic food*.[9,10] Several clinical trials[6,11-15] in Malawi have shown that ready-to-use therapeutic food is safe and effective in the rehabilitation of severely malnourished children and that a modification

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of it interferes with habitual diet less than a porridge supplement and has a positive effect on 3- to 4-year-old children who are less severely underweight and experience less stunting. Recent data from a preliminary dose-finding trial[16] suggested that home provision of fortified spread (FS) to

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Table 1. Caloric and Nutrient Contents of a Daily Ration of Each Food Supplement Used in This Trial			
	Intervention Group		
Variable	LP	FS50	FS25
Weight, g	71	50	25
Caloric intake, kcal	282	256	127
Protein, g	10.3	7.0	3.5
Carbohydrates, g	NA	13.8	6.6
Fat, g	3.1	16.9	8.5
Retinol, µg RE	138	400	400
Folate, µg	43	160	160
Niacin, mg	3	6	6
Pantothenic acid, mg	NA	2	2
Riboflavin, mg	0.3	0.5	0.5
Thiamin, mg	0.1	0.5	0.5
Vitamin B_6, mg	0.3	0.5	0.5
Vitamin B_{12}, µg	0.9	0.9	0.9
Vitamin C, mg	48	30	30
Vitamin D, µg	NA	5	5
Calcium, mg	71	366	283
Copper, mg	NA	0.4	0.4
Iodine, µg	NA	135	135
Iron, mg	5	8	8
Magnesium, mg	NA	60	60
Selenium, µg	NA	17	17
Zinc, mg	3.6	8.4	8.4

Abbreviations: FS25, fortified spread, 25 g/d; FS50, fortified spread, 50 g/d; LP, likuni phala; NA, not available; RE, retinol equivalents.

moderately underweight 6- to 17-month-old infants improves their nutritional status and results in markedly increased linear growth and improved weight gain.

Because of their efficacy in promoting growth in severely or moderately malnourished infants and their ease of use, simple production, and relatively low price, FSs might logically have a potential as complementary foods in the sub-Saharan setting. To compare the efficacy of FS with that of a traditionally used complementary food in promoting health and preventing the development of undernutrition, we conducted a randomized, controlled, single-blind trial in which initially healthy infants were provided with daily rations of either micronutrient-fortified maize–soy flour (likuni phala [LP]) or FS for 1 years. The present study analyzes the hypothesis that infants receiving FS would grow better and be less likely to develop undernutrition than those receiving LP. Morbidity and developmental outcomes will be reported in separate studies.

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METHODS

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STUDY AREA AND TIMING

This study was conducted between October 11, 2004, and December 19, 2005, in Lungwena, a rural Malawian community with a high prevalence of early childhood stunting and underweight.[2,17] The staple food, maize, was grown during the single rainy season between December and March. Exclusive breastfeeding for infants was almost nonexistent, and the infant diet was typically complemented with thin maize porridge already from 2 to 6 months of age.

ELIGIBILITY CRITERIA, ENROLLMENT, AND RANDOMIZATION

The inclusion criteria included age 5.50 to 6.99 months, residence in the study area, and informed consent from at least 1 authorized guardian. The exclusion criteria were low weight for length (<−2.0), presence of edema, history of peanut allergy, severe illness warranting hospitalization on the enrollment day, concurrent participation in another clinical trial, and any symptoms of food intolerance within 30 minutes after ingesting a 6-g test dose of FS, 1 of the food supplements used in the trial.

For enrollment, trained health surveillance assistants contacted all the families known to live in the area and known to have an infant of approximately the right age. Infants were invited to an enrollment session, where they were screened for eligibility, and guardians were given detailed information on the trial contents. Before enrollment, a guardian signed a written consent form for trial participation.

For group allocation, guardians chose 1 envelope from a set of identical-appearing opaque envelopes, each containing a piece of paper indicating an identification number and randomly assigned allocation to 1 of the 3 interventions. The randomization list and envelopes were made by individuals not involved in trial implementation, and the code was not disclosed to the researchers or to those assessing the outcomes until all data had been entered into a database.

INTERVENTIONS AND FOLLOW-UP

There were 3 intervention schemes. Infants in the control group were provided with a mean of 71 g/d of LP. Participants in the other 2 groups received a mean of either 50 or 25 g/d of micronutrient-fortified spread (FS50 or FS25, respectively). The supplements were home delivered at 3-week intervals (at each food delivery, three 500-g bags of LP, four 262-g jars of FS50, or two 262-g jars of FS25 were given).

Likuni phala was purchased from a local producer (Rab Processors, Blantyre, Malawi). Fortified spread was produced at a Malawian nongovernmental organization, Project Peanut Butter (Blantyre), from peanut paste, milk powder, vegetable oil, sugar, and premade micronutrient mixture (Nutriset Inc, Malaunay, France). All the supplements were fortified with micronutrients, but the level of fortification varied between the products. The difference between the FS50 and FS25 supplementation was in the amount of food base given (50 vs 25 g/d). The micronutrient content, however, was adjusted so that children in both FS groups received similar daily micronutrient doses. **Table 1** provides the calories and nutrient contents of a daily ration of each supplementation scheme.

Both FS50 and FS25 could be eaten as such, whereas the LP required cooking into porridge before consumption. Guardians were provided with spoons and were advised to daily offer their infants porridge containing 12 spoonfuls of LP, 8 spoonfuls of FS50, or 4 spoonfuls of FS25, divided into 2 to 3 daily doses. All mothers were encouraged to continue breastfeeding on demand and to feed their infants only as much of the food supplement as the infants wanted to consume at a time.

Participants were visited weekly at their homes to collect information on supplement use and possible adverse events. Empty food containers were collected every 3 weeks. At 17, 34, and 52 weeks after enrollment, the participants underwent a physical examination, an anthropometric assessment, and laboratory tests.

MEASUREMENT OF OUTCOME VARIABLES

The primary outcome was weight gain during 12-month follow-up. Secondary outcomes included length gain; mean change in

the anthropometric indexes of weight-for-age (WAZ), length-for-age (LAZ), and weight-for-length (WLZ) z scores; the incidence of severe (WAZ, LAZ, and WLZ <−3) or moderate to severe (WAZ, LAZ, and WLZ <−2) underweight, stunting, or wasting; change in head or middle upper arm circumference; and change in blood hemoglobin and serum ferritin concentrations.

Unclothed infants were weighed using an electronic infant weighing scale (SECA 834; Chasmors Ltd, London, England), and weights were recorded to the nearest 10 g. Length was measured to the nearest 1 mm using a high-quality length board (Kiddimetre; Raven Equipment Ltd, Essex, England). Middle upper arm circumference and head circumference were measured using nonstretchable plastic tape measures (Lasso-o Tape; Harlow Printing Ltd, South Shields, Tyne & Wear, England). Anthropometric indexes (WAZ, LAZ, and WLZ) were calculated using Epi Info 3.3.2 software (Centers for Disease Control and Prevention, Atlanta, Georgia), based on the Centers for Disease Control and Prevention 2000 growth reference.[18]

A 2-mL venous blood sample was collected, and serum was separated by means of centrifugation at the beginning and end of follow-up. Hemoglobin concentration was measured from a fresh blood drop using cuvettes and a reader (HemoCue AB, Angelholm, Sweden). Serum ferritin concentration was analyzed from frozen serum samples using commercial test kits according to the manufacturer's instructions (Ramco Laboratories, Stafford, Texas).

Thick and thin blood smears were stained with Giemsa and screened microscopically for malaria parasites from symptomatic participants at enrollment. Screening for human immunodeficiency virus infection was performed from fresh blood using 2 antibody rapid tests, and positive results were confirmed using DNA amplification technology according to the manufacturers' instructions (Determine; Abbott Laboratories, Abbott Park, Illinois; Uni-Gold; Trinity Biotech Plc, Bray, Ireland; and Amplicor HIV-1 Monitor Test Version 1.5; Hoffmann–La Roche Ltd, Basel, Switzerland).

DATA MANAGEMENT AND ANALYSIS

Collected data were recorded on paper forms, transcribed to paper case report forms, and double entered into a tailor-made database (Microsoft Access 2003; Microsoft Corp, Redmond, Washington). The 2 entries were electronically compared, and extreme or otherwise suspicious values were confirmed or corrected.

Statistical analysis was performed using Stata 9.0 (Stata Corp, College Station, Texas) on an intention-to-treat basis. Infants with no anthropometric data after enrollment were excluded from outcome analyses but were included in the comparison of baseline characteristics. The main analyses on anthropometric measures used data from all 176 analyzable children using the last values carried forward (and back-transform WAZ and LAZ at 18 months to kilograms and centimeters for metric presentation) for the 8 children who dropped out early or using the survival analysis method to deal with censoring. Sensitivity analysis limited to the 168 children with complete data gave similar findings (details not shown).

For continuous and categorical outcomes, the 3 intervention groups were compared using analysis of variance and the Fisher exact test, respectively. Survival analysis was used to determine the cumulative probability of severe or moderate malnutrition in different groups, and the differences were tested by means of the log-rank test. An event was considered to have happened at the midpoint between the time the event was detected and the previous measurement. Individuals with a particular form of malnutrition already at enrollment were excluded from survival analyses concerning the incidence of that

outcome. For the studies of compliance using visits as the unit of analysis, the Huber-White robust standard error was used to allow for correlated data (multiple visits per child).

ETHICS, STUDY REGISTRATION, AND PARTICIPANT SAFETY

This trial was performed according to International Conference on Harmonisation/Good Clinical Practice guidelines, and it adhered to the principles of the Declaration of Helsinki and regulatory guidelines in Malawi. Before the onset of enrollment, the trial protocol was reviewed and approved by the University of Malawi College of Medicine research and ethics committee and the ethical committee of Pirkanmaa Hospital District (Finland). Key details of the protocol were published at the clinical trial registry of the National Library of Medicine.

A data safety and monitoring board continuously monitored the incidence of suspected *serious adverse events*, defined as any untoward medical occurrence that either resulted in death or was life threatening or required inpatient hospitalization or prolongation of existing hospitalization or resulted in persistent or significant disability or incapacity or other serious medical conditions.

RESULTS

Of the 303 initially screened infants, 65 were too old (aged >6.99 months), 2 were too young (aged <5.5 months), and 2 were too ill on the day of screening or enrollment. Of the remaining 234 infants, 49 were not brought to the enrollment session (3 died, 16 moved away, 7 parents were not interested, and 23 parents gave no explanation) and 3 parents declined participation after receiving full information about the trial. The remaining 182 infants were randomized into 3 intervention groups (**Figure 1**). None of the eligible participants who received the 6-g test dose were allergic to FS.

Table 2 provides the baseline characteristics of the participants by intervention group. At enrollment, the mean anthropometric measurements were comparable in the LP and FS50 groups, whereas infants in the FS25 group were a mean of 250 and 380 g heavier than those in the FS50 and LP groups, respectively (Table 2). Infants in the FS25 group were also 0.3 and 0.7 cm longer than infants in the other 2 groups, respectively. No participant experienced severe wasting at the beginning. The prevalence of severe underweight in the LP, FS50, and FS25 groups was 1.6% (n=1), 3.3% (n=2), and 0.0%, respectively; and that of severe stunting was 3.3% (n=2), 6.6% (n=4), and 1.7% (n=1), respectively. Nine participants had a positive human immunodeficiency virus antibody test result at enrollment, but only 1 of them was truly human immunodeficiency virus infected, as evidenced by a positive polymerase chain reaction test result.

During the 12-month follow-up, 10 infants died, 2 were not located at the end of follow-up, and 2 were unavailable for follow-up before the age of 18 months (Figure 1). The success rate of following up to age 18 months was not significantly different among intervention groups (P=.47, Fisher exact test). Only 6 participants had no anthropometric data at all after enrollment, and there was no difference in this among intervention groups (P=.70, Fisher exact test). The assumed causes of the 10 deaths were di-
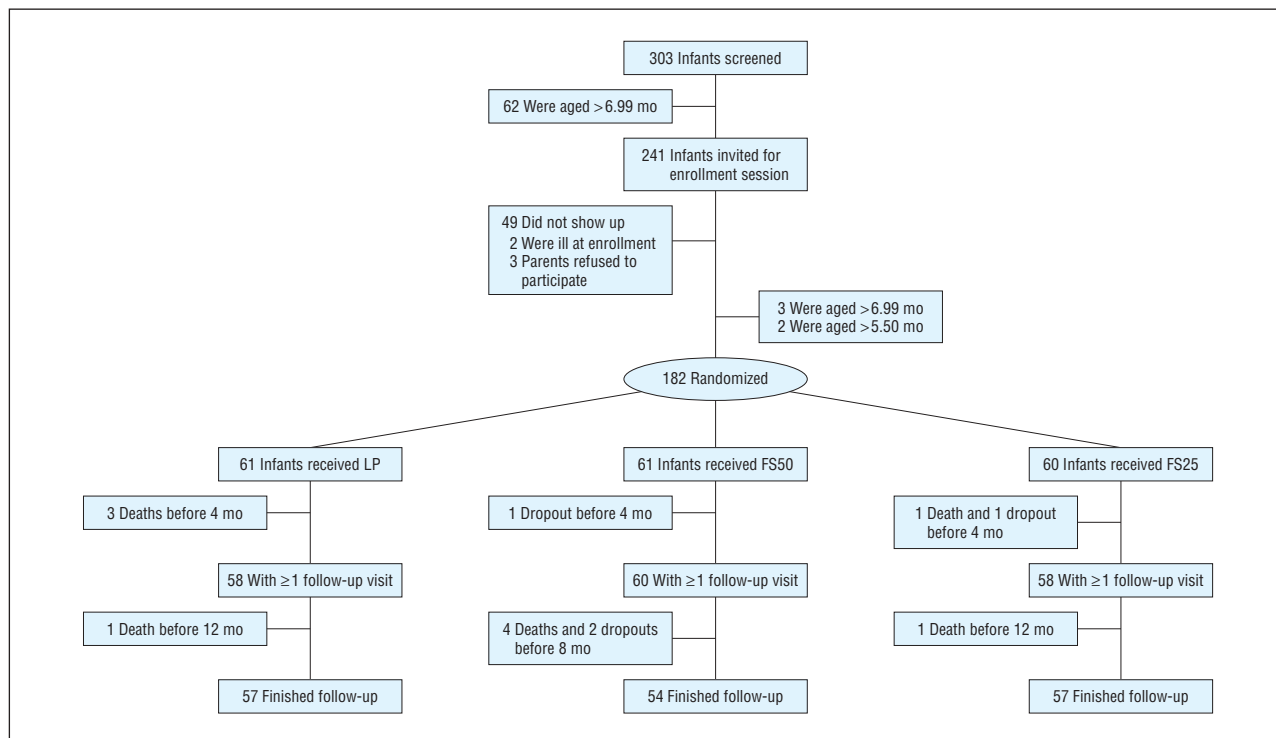
Figure 1. Flow of participants in the study. FS25 indicates fortified spread, 25 g/d; FS50, fortified spread, 50 g/d; and LP, likuni phala, 72 g/d.

Table 2. Baseline Characteristics of the 182 Participants at Enrollment

| | Intervention Group | | |
Variable	LP (n=61)	FS50 (n=61)	FS25 (n=60)
Male sex, No./total No. (%)	24/61 (39.3)	33/61 (54.1)	34/60 (56.7)
PCR-confirmed HIV infection, No./total No. (%)	0/55	0/55	1/55 (1.8)
HIV antibodies, No./total No. (%)	3/55 (5.5)	2/55 (3.6)	4/55 (7.3)
Clinical malaria, No./total No. (%)[a]	1/61 (1.6)	1/61 (1.6)	2/60 (3.3)
Children aged <5 y per participant household, mean (SD)	2 (0.9)	2 (0.8)	2 (0.9)
Age, mean (SD), mo	5.91 (0.41)	5.93 (0.44)	5.89 (0.36)
Weight, mean (SD), kg	6.92 (0.93)	7.05 (0.90)	7.30 (0.92)
Length, mean (SD), cm	62.8 (2.1)	63.2 (2.6)	63.5 (2.4)
Middle upper arm circumference, mean (SD), cm	13.4 (0.9)	13.5 (1.1)	13.9 (1.1)
Head circumference, mean (SD), cm	43.0 (1.5)	43.1 (1.7)	43.2 (1.3)
Weight-for-age z score, mean (SD)	−0.65 (1.07)	−0.62 (1.04)	−0.33 (0.94)
Length-for-age z score, mean (SD)	−1.20 (0.82)	−1.20 (1.01)	−1.00 (0.77)
Weight-for-length z score, mean (SD)	0.48 (1.08)	0.55 (0.90)	0.75 (0.86)
Blood hemoglobin concentration, mean (SD), g/dL	11.4 (1.6)	10.6 (1.7)	11.3 (1.5)
Serum ferritin concentration, mean (SD), ng/mL	56.9 (73.6)	45.7 (37.4)	67.2 (74.4)

Abbreviations: FS25, fortified spread, 25 g/d; FS50, fortified spread, 50 g/d; HIV, human immunodeficiency virus; LP, likuni phala; PCR, polymerase chain reaction.
SI conversion factors: To convert ferritin to picomoles per liter, multiply by 2.247; hemoglobin to grams per liter, multiply by 10.
[a] Reported fever and observed peripheral blood malaria parasitemia.

arrhea, malaria, and drowning in the LP group; diarrhea, meningitis, malaria, and poisoning in the FS50 group; and respiratory tract infection and malaria in the FS25 group.

All mothers reported that their infants readily ate the provided supplement, and the diversion of any portion to someone other than the intended beneficiary was reported at only 4 of 8864 food delivery interviews (0.05%), 3 in the LP group and 1 in the FS50 group. From the 3-week home visits during which leftover trial products

were checked, the percentages of visits with leftovers found were 2.8%, 9.8%, and 5.6% in the LP, FS50, and FS25 groups, respectively (P<.001).

Of the 176 participants with anthropometric data, mean gains in weight and length were 100 g (95% confidence interval [CI], −143 to 343 g) and 0.8 cm (95% CI, −0.1 to 1.7 cm), respectively, higher in the FS50 group than in the LP group. Correspondingly, mean decreases in WAZ and LAZ were smaller in FS50 infants than in FS25 or

Table 3. Outcome Changes in Infants Receiving Different Doses of FS and LP During Up to 12 Months of Follow-up

Variable	Intervention Group			P Value[a]
	LP	FS50	FS25	
Change in weight, mean (SD), kg	2.37 (0.60)	2.47 (0.77)	2.37 (0.61)	.66
Change in length, mean (SD), cm	12.7 (1.7)	13.5 (2.9)	13.2 (2.9)	.23
Change in middle upper arm circumference, mean (SD), cm	1.1 (0.9)	1.0 (1.1)	1.0 (0.8)	.64
Change in head circumference, mean (SD), cm	3.7 (0.5)	3.7 (0.8)	3.7 (0.6)	.96
Change in weight-for-age z score, mean (SD)	−1.29 (0.63)	−1.18 (0.90)	−1.32 (0.65)	.53
Change in length-for-age z score, mean (SD)	−0.74 (0.95)	−0.59 (1.22)	−0.64 (0.86)	.71
Change in weight-for-length z score, mean (SD)	−0.98 (0.83)	−1.05 (0.86)	−1.13 (0.75)	.62
Change in blood hemoglobin concentration, mean (SD), g/dL	−0.68 (2.06)	−0.04 (2.21)	−0.38 (1.82)	.28
Change in serum ferritin concentration, mean (SD), ng/mL	16.2 (116.4)	11.5 (61.2)	-0.7 (172.4)	.83

Abbreviations: FS, fortified spread; FS25, FS, 25 g/d; FS50, FS, 50 g/d; LP, likuni phala.
SI conversion factors: To convert ferritin to picomoles per liter, multiply by 2.247; hemoglobin to grams per liter, multiply by 10.
[a] Obtained by analysis of variance.

Table 4. Proportion of Participants Developing Various Forms of Undernutrition During Trial Follow-up

Variable	Intervention Group			P Value[a]
	LP	FS50	FS25	
Ever developed severe stunting (LAZ <−3), No./total No. (%)	7/56 (12.5)	0/56	2/58 (3.5)	.008
Ever developed moderate to severe stunting (LAZ <−2), No./total No. (%)	11/49 (22.5)	10/51 (19.6)	15/55 (27.3)	.64
Ever developed severe underweight (WAZ <−3), No./total No. (%)	8/57 (14.0)	11/58 (19.0)	9/58 (15.5)	.81
Ever developed moderate to severe underweight (WAZ <−2), No./total No. (%)	23/53 (43.4)	20/56 (35.7)	20/57 (35.1)	.62
Ever developed severe wasting (WHZ <−3), No./total No. (%)	1/58 (1.7)	1/60 (1.7)	1/58 (1.7)	>.99
Ever developed moderate to severe wasting (WHZ <−2), No./total No. (%)	5/58 (8.6)	7/60 (11.7)	3/58 (5.2)	.47

Abbreviations: FS25, fortified spread, 25 g/d; FS50, fortified spread, 50 g/d; LAZ, length-for-age z score; LP, likuni phala; WAZ, weight-for-age z score; WHZ, weight-for-height z score.
[a] Obtained by Fisher exact test.

LP infants, and there was also a smaller decrease in blood hemoglobin concentration in the FS50 group. None of the differences, however, reached statistical significance (**Table 3**).

There was an interaction between intervention group (FS50 vs LP) and baseline LAZ using length gain (P=.04) or weight gain (P=.002) as an outcome. In infants with baseline LAZ below the median in this trial (−1.04), the mean gain in length was 1.9 cm (95% CI, 0.3-3.5 cm) or 0.40 z score (95% CI, −0.15 to 0.95 z score) bigger in the FS50 group than in the LP group. Comparable differences in weight gain were 404 g (95% CI, 74-735 g) or 0.43 z score (95% CI, 0.07-0.80 z score). In infants with baseline LAZ above the median, the difference in length was −0.4 cm (95% CI, −1.3 to 0.5 cm) or −0.09 z score (95% CI, −0.58 to 0.39 z score); the difference in weight was −254 g (95% CI, −604 to 96 g) or −0.25 z score (95% CI, −0.64 to 0.14 z score). There was no significant interaction between intervention and baseline WAZ (P=.14).

As secondary end points, we looked at the proportion of infants who developed severe or moderate to severe underweight, stunting, and wasting during follow-up. The proportion of infants who developed other forms of malnutrition did not differ markedly among the intervention groups, but severe stunting occurred significantly less frequently in the FS50 and FS25 groups than in the LP group (**Table 4**). After enrollment, no infants

in the FS50 group, 3.5% in the FS25 group, and 12.5% in the LP group developed severe stunting (P=.008, Fisher exact test). The 95% CI for the difference between the FS50 and LP groups was 3.8% to 21.2%.

The cumulative incidence of stunting during the 12-month period was also calculated based on survival analysis methods that dealt with censoring differently from the analysis given in Table 4. This approach confirmed that severe stunting developed less often and later in the FS50 and FS25 groups than in the LP group (0.0%, 3.5%, and 13.3%, respectively; P=.01, log-rank test) (**Figure 2**A). The cumulative incidence of moderate to severe stunting was similar in the 3 groups, but infants in the FS50 group developed the condition on average somewhat later. However, the latter result was not significant (P=.66, log-rank test) (Figure 2B). Calculated from the absolute risk reduction, the number of infants needed to be supplied for 1 year with FS50 to prevent 1 case of severe stunting was 8 (95% CI, 5-26).

The proportion of those developing severe and moderate to severe underweight and severe and moderate to severe wasting did not differ significantly between the trial groups (Table 4). The cumulative incidence of severe underweight was 15.0%, 22.5%, and 16.9% for the LP, FS50, and FS25 groups, respectively (P=.71); the cumulative incidence of severe wasting was 1.8%, 1.9%, and 1.8% for the same groups, respectively (P>.99).
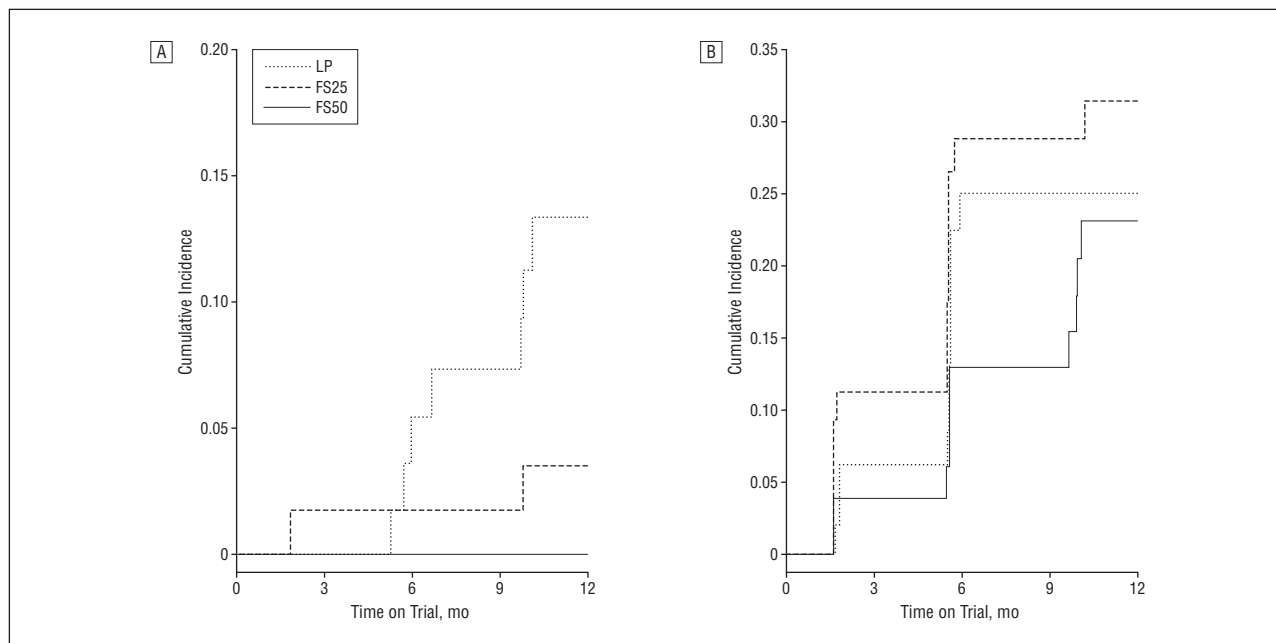
Figure 2. Cumulative incidence functions of severe stunting (A) and moderate to severe stunting (B) in children in the likuni phala (LP), fortified spread, 25 g/d (FS25), and fortified spread, 50 g/d (FS50) groups.

All the interventions were well tolerated by the participants. In addition to the 10 deaths (4, 4, and 2 in the LP, FS50, and FS25 groups, respectively) (Figure 1), 3 other participants (1 in each intervention group) were hospitalized and recorded as having experienced a serious adverse event during follow-up. The LP, FS50, and FS25 groups shared 5, 5, and 3 of these serious adverse events, respectively (*P* = .82, Fisher exact test). Three of the serious adverse events were considered to be unrelated, and 10 were probably unrelated to the trial interventions.

COMMENT

The present trial was performed to test the growth-promoting effects of 2 micronutrient-fortified, calorie-dense, ready-to-use spreads (FS50 and FS25) when used as complementary foods for 6- to 18-month-old infants in rural Malawi. The enrollment rate for the trial was high, group allocation was random, follow-up was identical for all groups, loss to follow-up and unavailability for follow-up were infrequent, and the people measuring the outcomes were masked to group allocation. Hence, the observed results are likely to be unbiased and, thus, representative of the population from which the sample was drawn.

In this sample, infants receiving FS50 or FS25 for 1 year gained on average slightly more weight and length than those receiving an approximately isoenergetic portion of LP. However, the mean differences between the FS50 and LP groups were modest (100 g and 0.8 cm), and statistical hypothesis testing could not exclude the possibility of random findings. Therefore, the data do not support the initial hypothesis that 1 year of complementary provision of FS to all infants older than 6 months in rural Malawi would be noticeably better than LP in promoting their mean weight or length gain by 18 months of age. Instead, the results seem to be mostly in line with the modest findings from other dietary intervention trials[19-24] for infants in similar settings, documenting a 0- to 0.6-SD higher mean weight (SD, 0-400 g) or length (SD, 0-1 cm) gains in the intervention groups than in unsupplemented controls.

In contrast to the mean gains, the present study demonstrated a marked and statistically significant difference in the incidence of severe stunting between the FS50 and LP groups. Also, a stratified analysis suggested an interaction between initial height and intervention group, as demonstrated by bigger between-group differences in length and weight gain in infants with at least mild stunting at enrollment. Caution must be exercised when interpreting these results because the incidence of severe stunting was only one of several secondary outcomes of the trial and the interaction finding came from a post hoc exploratory analysis. The results are, however, biologically plausible, and there was a trend toward a dose response. Therefore, we believe that the results in this sample appropriately represent the larger population. Furthermore, the results are consistent with those of an earlier trial from West Africa[25] in which supplementation of children with FS who experienced stunting induced marked catch-up growth among them. These data suggest that a dietary intervention with FS can boost linear growth and reduce the incidence of the severest forms of stunting, especially when directed to initially disadvantaged infants. If the whole unselected infant group needs to be targeted, the intervention should probably also address the other major risk factors for growth failure (infections and inappropriate child care).[26]

In the present sample, 8 infants needed supplementation for 1 year with FS50 to prevent 1 case of severe stunting. It is difficult to assess the public health impact resulting from such an intervention and the potential reduction in severe stunting. Stunting is associated with various adverse sequelae, such as developmental delay,

lower work capacity, worse economic status as an adult, and delivery problems.[27] However, it is not known whether these outcomes are particularly associated with any linear growth failure or only its most severe forms. Such associations and the possibility of preventing various health consequences with an FS intervention need to be addressed in later trials. Such studies are further justified by recent evidence from a Ghanaian trial, suggesting that infant motor development can be markedly enhanced in a low-income setting by a 6-month-long provision of Nutributter, another lipid-based nutrient supplement.[24]

Although we collected information on compliance, it came from parental recollections, which are often unreliable in dietary interventions. Hence, we cannot rule out the possibility of food sharing and its potential effect on the results, especially because the 2 supplement types differed in many ways from each other. In fact, earlier studies from the same research site suggest that LP and FS are shared within families, but this occurs more often with LP.[6,28] In this respect, this trial, thus, looked at effectiveness (ie, infant outcomes after the provision of different food supplements to the family), rather than assessing growth under ideal conditions in which participants truly ate all the supplements that were intended for them.

Another major limitation of the trial is the lack of a nonsupplemented control group; therefore, we can make solid conclusions only on the relative value of FS and LP supplementation but not on their independent effect. In a previous study[17] conducted 10 years earlier in the same area, the differences in the 50th percentile weight and length between 6 and 18 months of age were 2.3 kg and 11.9 cm, respectively, in unsupplemented infants (ie, 0.1 kg and 0.8 cm less than mean gains for the LP control group in the present trial). However, the different anthropometric methods used in the earlier trial and its historical nature limit its use for conclusive comparisons.

The ex-factory price of FS, when made in Malawi, is approximately US $4 per kilogram, corresponding to a daily cost of US $0.20 for a 50-g dose. Unsubsidized, this price is presumably unaffordable to many families in rural Malawi. The present results with FS25, and those from a recent Ghanaian trial[24] using a daily dose of 20 g, suggest, however, that a lower and markedly cheaper dose may be as efficient in growth and development promotion as the FS50 dose used in the present trial. Other potential means for increased affordability include amendments to the FS recipe (eg, a cheaper protein source) and social marketing, both of which are being tested in the sub-Saharan African setting.

Taken together, these results suggest that 1-year-long complementary feeding with FS does not have a markedly larger effect than LP supplementation on mean weight gain in all infants, but it seems to boost linear growth in the most disadvantaged individuals and, hence, decrease the incidence of severe stunting in a population in which it is otherwise common. A larger and longer trial, however, is needed to confirm the finding and to look at the effect on outcomes other than growth, to analyze whether LP supplementation has some health impact, to see whether the growth effect persists beyond the age of 18 months, and to guide policy decisions on the use of spreads or corn–soy flour in malnutrition preven-

tion in Malawi and similar settings. Further studies on the possible mechanisms of the growth-promoting effect of FS are also warranted.

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Correction

Errors in Abstract and Table. In the Article by Phuka et al, titled "Complementary Feeding With Fortified Spread and Incidence of Severe Stunting in 6- to 18-Month-Old Rural Malawians," published in the July issue of the *Archives* (2008;162[7]:619-626), minor errors with respect to the energy (caloric) and nutrient (protein, carbohydrate, fat, copper, and iodine) contents of the used supplements occurred in the Abstract and in **Table 1**. However, the differences are small and the conclusions of the study results are unaffected by them. On page 619, the Intervention segment of the Abstract should have read as follows: "Participants were randomized to receive 1 year of daily supplementation with 71 g of LP (282 kcal), 50 g of FS (FS50) (264 kcal), or 25 g of FS (FS25) (130 kcal)." A corrected copy of Table 1, published on page 620, is reprinted here in its entirety.

Table 1. Caloric and Nutrient Contents of a Daily Ration of Each Food Supplement Used in This Trial

Variable	Intervention Group		
	LP	FS50	FS25
Weight, g	71	50	25
Caloric intake, kcal	282	264	130
Protein, g	10.3	7.6	3.8
Carbohydrates, g	NA	15.4	8.3
Fat, g	3.1	16.5	8.3
Retinol, µg RE	138	400	400
Folate, µg	43	160	160
Niacin, mg	3	6	6
Pantothenic acid, mg	NA	2	2
Riboflavin, mg	0.3	0.5	0.5
Thiamin, mg	0.1	0.5	0.5
Vitamin B_6, mg	0.3	0.5	0.5
Vitamin B_{12}, µg	0.9	0.9	0.9
Vitamin C, mg	48	30	30
Vitamin D, µg	NA	5	5
Calcium, mg	71	366	283
Copper, mg	NA	0.4	0.5
Iodine, µg	NA	90	90
Iron, mg	5	8	8
Magnesium, mg	NA	60	60
Selenium, µg	NA	17	17
Zinc, mg	3.6	8.4	8.4

Abbreviations: FS25, fortified spread, 25 g/d; FS50, fortified spread, 50 g/d; LP, likuni phala; NA, not available; RE, retinol equivalents.