

## Original Article

# Impact of lipid-based nutrient supplements and corn–soy blend on energy and nutrient intake among moderately underweight 8–18-month-old children participating in a clinical trial

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## Abstract

Nutrition interventions have an effect on growth, energy and nutrient intake, and development, but there are mixed reports on the effect of supplementation of energy-dense foods on dietary intake. This substudy aimed at assessing the effect of supplementation with corn–soy blend (CSB) or lipid-based nutrient supplement (LNS) on energy and nutrient intake in moderately underweight children participating in a clinical trial. A total of 188 children aged 8–18 months participated and received daily either 284 kcal from CSB or 220 kcal from LNS and no supplements (control). An interactive 24-h recall method was used to estimate energy and nutrient intakes in the groups. Total mean energy intake was 548 kcal, 551 kcal and 692 kcal in the control, CSB and LNS groups, respectively ( $P = 0.011$ ). The mean (95% confidence interval) intake of energy and protein were 144 (37–250;  $P < 0.001$ ) and 46 (1.5–7.6;  $P < 0.001$ ) larger, respectively, in the LNS group than among the controls. No significant differences were observed between the control and CSB groups. Energy intake from non-supplement foods was significantly lower in the CSB group compared with the control group, but not in the LNS group, suggesting a lower displacement of non-supplement foods with LNS. Both CSB and LNS supplementation resulted in higher intakes of calcium, iron, zinc and vitamin C compared with controls (all  $P \leq 0.001$ ). This study indicates that LNS might be superior to CSB to supplement underweight children as it results in higher energy intake, but this requires confirmation in other settings.

**Keywords:** CSB, infant, interactive 24-h recall, LNS, Sub-Saharan Africa, undernutrition.

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## Introduction

Nutrition interventions during the complementary feeding period have shown to be effective in promoting child growth and development and in improving macronutrient and micronutrient intake (Dewey & Adu-Afarwuah 2008). Provision of all the necessary nutrients to rapidly growing or underweight infants during the complementary feeding period has proven difficult, especially where animal source foods are limited. To fill the nutrient gaps during this period,

World Health Organization (WHO) recommended use of fortified products or nutritional supplements (PAHO/WHO 2003).

Supplementary foods are widely used in the treatment of severe or moderate malnutrition in children. While the supplementation is usually associated with improved weight gains when used in a hospital setting, the impact has often appeared smaller when used at home. One possible explanation has been that at home, in uncontrolled conditions, the supplement replaces other foods.

A previous trial by our study team showed increased weight gain among children supplemented with Lipid-based nutrient supplement (LNS), but not those supplemented with corn-soy blend (CSB) compared with a control group receiving no supplement (Thakwalakwa *et al.* 2010a). In this study, we wanted to test three hypotheses: (1) that both LNS and CSB are associated with increased micronutrient intakes (because both are fortified); (2) that LNS, but not CSB, is associated with increased total energy and macronutrient intakes; and (3) that CSB, but not LNS, supplementation is associated with reduced energy, macronutrients and micronutrients intakes from non-supplement foods.

## Methods and materials

### Study design

This study was part of a clinical intervention trial in moderately underweight 6–15-month-old children receiving either: (1) CSB; (2) LNS; or (3) no supplementation (control; Thakwalakwa *et al.* 2010a). Children received 71 g of CSB or 43 g of LNS corresponding to 284 kcal and 220 kcal, respectively. The composition of supplements is shown in Table 1. Underweight was defined as low weight-for-age [weight-for-age z-score (WAZ) <−2] relative to the National Center for Health Statistics reference median.

### Trial setting

The study was conducted in the Lungwena area, Mangochi District, Malawi, South-Eastern Africa. In Lungwena, underweight (defined as WAZ <−2) and stunting [defined as length-for-age z-score (LAZ) <−2] are very common with a prevalence of 40% and

**Table 1.** Nutrient composition of daily dose of corn-soy blend (CSB) or lipid-based nutrient supplement (LNS)

	CSB	LNS
Weight, g	71	43
Energy, kJ*	1188	920
Protein, g	10.4	6.0
Carbohydrates, g	NA <sup>†</sup>	11.9
Fat, g	3.1	13.5
Retinol, µg RE	139	400
Folate, µg	43.2	160
Niacin, mg	3.5	6
Pantothenic acid, mg	NA <sup>†</sup>	2
Riboflavin, mg	0.3	0.5
Thiamin, mg	0.13	0.5
Vitamin B6, mg	0.3	0.5
Vitamin B12, µg	0.9	0.9
Vitamin C, mg	48	30
Cholecalciferol, µg	NA <sup>†</sup>	5
Calcium, mg	72	366
Copper, mg	NA <sup>†</sup>	0.4
Iodine, µg	NA <sup>†</sup>	135
Iron, mg	5.46	8
Magnesium, mg	NA <sup>†</sup>	60
Zinc, mg	3.6	8.4

\*1 kcal = 4.184 kJ. <sup>†</sup>No information provided by the manufacturer. NA, not applicable; RE, retinol equivalent.

almost 80% by 18 months of age, respectively (Maleta *et al.* 2003a). Farming and fishing form the main occupations. A significant proportion of households have poor food security, as cultivated land areas are usually small. The area has one rainy season between December and March during which maize, the staple food, and other crops are grown. During this season, food security in the area is typically at its lowest and weight and length gain of children are poorer than during the rest of the year (Maleta *et al.* 2003b). Maize is normally harvested from April to May. The energy and nutrient intake assessment was conducted between March and May 2007.

### Key messages

- Lipid-based nutrient supplement (LNS) and corn-soy blend (CSB) supplementation results in increased micronutrient intakes.
- LNS and not CSB supplementation is associated with increased total energy and macronutrient intakes.
- CSB and not LNS supplementation is associated with reduced energy and macronutrient intakes.
- LNS appears to be superior to CSB to supplement underweight children, but this requires confirmation in other settings.

### Eligibility

All 192 children who were enrolled in the clinical intervention trial were eligible for this substudy.

### Data collection method

Data collection for the substudy occurred when the participants had been enrolled into the clinical trial for 9 weeks. A structured interactive 24-h dietary recall method (Ferguson *et al.* 1989, 1995) was used to assess food intake. This is a modified version of the 24-h recall and was used to quantify dietary intakes among pregnant women and 3–4-year-old children in Lungwena (Ndekha *et al.* 2000; Maleta *et al.* 2004). The validity of the method has been documented (Ferguson *et al.* 1995; Thakwalakwa *et al.* 2010b).

To help reduce memory lapses, the participant's mother was given a local food picture calendar. The mother was advised to tick on the calendar all foods the child would eat the following day starting from the very first food in the morning until the very last food on that day. The actual structured interactive 24-h recall was conducted 3 days after the calendars were delivered.

On the data collection day, the parent was asked to handover the marked food picture calendar to the enumerator. Then the parent was asked to recite all foods taken by the participant the preceding day. The enumerator compared oral information with what was marked on the calendar. The parent was then asked to describe in detail each of the foods or beverage consumed by the child. This included ingredients and methods used to prepare the food or beverage.

To help estimate the portions consumed, standard spoons, cups and plates were provided to measure servings of all different foods including nsima, the stiff maize-based porridge, dry fish, boiled cassava and sweet potatoes. All the collected information was recorded in specially developed structured interactive 24-h recall questionnaire.

Data were collected by research assistants (RA) in the local Chiyao language. These RAs went through a 5-day training in conducting dietary intake surveys

using the structured interactive 24-h recall method (Ferguson *et al.* 1989, 1995)

### Data management and analysis

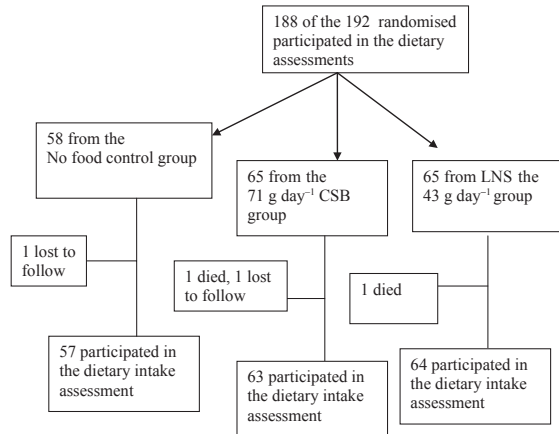
All statistical analyses were conducted using Stata 9.0 (Stata Corp, College Station, TX, USA). The analysis compared mean intakes of energy, protein, calcium, iron, zinc, vitamin A and vitamin C between each of the intervention groups versus the control group. All children were analysed in the group where they were initially randomised, i.e. on an intention to treat basis. The Huber White robust standard error (Binder 1983) was used for statistical inference without making distributional assumption. To guard against inflated type 1 error because of multiple group comparisons, hypotheses for pairwise comparison would not be rejected unless the global null hypothesis of no difference among all groups is rejected. Hypothesis testing was not done for comparisons between the two intervention groups. Mean energy and nutrient intakes were compared between the intervention groups and the control group. Mean energy and nutrient intakes from non supplement foods in each of the two intervention groups were also compared with those from the control group.

### Ethical approval and consent

The study was approved by the College of Medicine Research and Ethics Committee (COMREC), Malawi, 29.09.2004 (COMREC decision P.03/04/268R) and Pirkanmaa Health Care Area Ethics Committee, Finland, 14.09.2004 (PSHP EC decision 17, approval number R04111). Clinical Trials.gov Identifier: NCT00131209. An informed consent was sought from at least one parent before conducting this assessment.

### Results

Out of the 192 children randomised into the clinical trial, 188 gave consent and were included in the dietary intake assessment study. The participant flow is shown in Fig. 1. Nutrient composition of daily dose of CSB or LNS is shown in Table 1. The control and



**Fig. 1.** Participant flow for the participants supplemented with lipid-based nutrient supplement (LNS), corn-soy blend (CSB) or nothing.

**Table 2.** Baseline information of study participants\*

Variable	Control	CSB	LNS
Participants, <i>n</i>	58	65	65
Age, months	13.3 ± 2.58	13.3 ± 2.80	13.5 ± 2.54
Weight, kg	7.35 ± 0.79	7.23 ± 1.10	8.29 ± 5.75
Length, cm	67.4 ± 8.7	68.1 ± 4.3	69.0 ± 3.6
Mid-upper arm circumference, cm	13.6 ± 0.8	14.0 ± 4.3	13.9 ± 0.9
Head circumference, cm	44.8 ± 1.5	44.4 ± 1.6	44.6 ± 1.3
Weight-for-age <i>z</i> -score	-3.20 ± 0.84	-3.36 ± 1.16	-2.91 ± 0.85
Weight-for-length <i>z</i> -score	-1.14 ± 0.84	-1.17 ± 0.97	-0.90 ± 0.94
Length-for-age <i>z</i> -score	-2.63 ± 0.82	-2.75 ± 1.05	-2.47 ± 0.74

\*Values are mean ± standard deviation. CSB, corn-soy blend; LNS, lipid-based nutrient supplement.

CSB groups had slightly lower baseline age, weight, length, LAZ, WAZ and weight-for-length *z*-score than the LNS group (Table 2).

Mean energy intake was 548 kcal, 551 kcal and 692 kcal in the control, CSB and LNS groups, respectively ( $P = 0.01$ ). Mean protein intakes were 13.7 g, 15 g and 18.3 g ( $P \leq 0.001$ ). Compared with the control group, children in the LNS group had on average [95% confidence interval (CI)] 144 kcal (37–250,  $P \leq 0.001$ ) higher energy intake and 4.6 g (1.5–7.6,  $P \leq 0.001$ ) higher protein intake. CSB group had slightly higher energy and protein intakes as compared with the control group (both  $P \geq 0.05$ ). Both CSB and LNS groups had higher intake of calcium,

iron, zinc and vitamin C compared with control (all  $P \leq 0.001$ ). Comparable vitamin A intakes were observed between the control group and either of the intervention groups (Table 3).

When the food supplements were excluded from the analysis, the mean energy intake was 548 kcal in control group, 366 kcal in CSB group and 596 kcal in LNS group ( $P \leq 0.001$ ). Mean protein intakes were 13.7 g, 11.1 g and 15.7 g in control, CSB and LNS groups, respectively ( $P = 0.045$ ). Compared with the control group, infants in the LNS group had a higher energy intake from the non-supplement foods ( $P \geq 0.05$ ). Infants in the CSB group had on average (95% CI) 182 kcal (-286 to 79,  $P \leq 0.001$ ) lower energy intake from the non-supplement foods than the control group. Both CSB and LNS groups had comparable intakes from non-supplement foods of protein, calcium, iron, zinc, vitamin A and vitamin C with the control group (Table 4).

## Discussion

In this trial, supplementation with CSB or LNS led to higher intakes of energy and proteins in moderately underweight 8–18-month-old children compared with control children. This increase, however, was significant only in children who received LNS. Children who received CSB reduced their intake of non-supplement foods in contrast to children receiving LNS. This is likely to have reduced the effect of CSB supplement on overall energy intake.

This result seems likely to reflect a true difference between the supplements, as the groups were randomised. The study was not blinded, however, and it cannot be excluded that some preference of the caretaker led to a biased estimation of intake in the one of the groups. It would be important to confirm these findings in other settings.

One weakness in this study is that during randomisation into the clinical trial (Thakwalakwa *et al.* 2010a), a participant was asked to pick an envelope from all the remaining reshuffled sealed envelopes. Some envelopes may not have been shuffled properly leading to unequal numbers in the groups. However, the groups were comparable at enrolment.

**Table 3.** Comparison of mean energy and nutrient intake in the three trial arms (Food supplements included)

Outcome	Results by study group				Comparisons between CSB and control		Comparisons between LNS and control	
	Control	CSB	LNS	<i>P</i> *	Difference <sup>†</sup> (95% CI)	<i>P</i> *	Difference <sup>†</sup> (95% CI)	<i>P</i> *
Mean energy, kcal	548 (38)	551 (56)	692 (54)	0.011	3 (-107 to 113)	0.961	144 (37–250)	0.009
Mean protein, g	13.7 (1.1)	15.0 (1.8)	18.3 (1.6)	0.004	1.3 (-2.2 to 4.8)	0.469	4.6 (1.5–7.6)	0.004
Mean calcium, m	136 (21)	392 (53)	331 (38)	<0.001	256 (151–360)	<0.001	195 (119–270)	<0.001
Mean iron, mg	4.9 (0.3)	9.0 (0.8)	9.2 (0.7)	<0.001	4.1 (2.5–5.6)	<0.001	4.3 (3.0–5.6)	<0.001
Mean zinc, mg	4.7 (1.0)	9.6 (1.4)	10.2 (1.5)	<0.001	4.9 (2.2–7.6)	0.001	5.5 (2.5–8.5)	<0.001
Vitamin A, µg	357 (61)	350 (77)	408 (78)	0.660	-7 (-160 to 146)	0.930	51 (-103 to 205)	0.513
Vitamin C, mg	15.9 (1.9)	33.3 (3.7)	30.2 (4.0)	<0.001	17 (10–25)	<0.001	14 (6–22)	<0.001

\*Huber–White Robust standard error. <sup>†</sup>Differences are mean values in intervention group – mean value in control group. CI, confidence interval; CSB, corn–soy blend; LNS, lipid-based nutrient supplement.

**Table 4.** Comparison of energy and nutrient intake in the three trial arms (food supplements not included)

Outcome	Results by study group				Comparisons between CSB and control		Comparisons between LNS and control	
	Control	CSB	LNS	<i>P</i> *	Difference <sup>†</sup> (95% CI)	<i>P</i> *	Difference <sup>†</sup> (95% CI)	<i>P</i> *
Mean energy, kcal	548 (38)	366 (52)	596 (53)	<0.001	-182 (-286 to -79)	<0.001	48 (-58 to 158)	0.373
Mean protein, g	13.7 (1.0)	11.1 (1.7)	15.7 (1.5)	0.045	-2.6 (-6.0 to 0.8)	0.134	2.0 (-1.1 to 5.0)	0.206
Mean calcium, mg	136 (21)	155 (49)	172 (34)	0.580	18 (-78 to 115)	0.707	35 (-32 to 103)	0.301
Mean iron, mg	4.9 (0.3)	3.8 (0.6)	5.7 (0.6)	0.017	-1.1 (-2.3 to 0.1)	0.075	0.8 (-0.3 to 2.0)	0.138
Mean zinc, mg	4.7 (1.0)	4.2 (1.3)	6.5 (1.5)	0.228	-0.5 (-3.1 to 2.1)	0.689	1.8 (-1.1 to 4.7)	0.213
Vitamin A, µg	357 (61)	261 (75)	234 (74)	0.251	-96 (-245 to 52)	0.203	-123 (-270 to 0.24)	0.101
Vitamin C, mg	16 (2)	14 (3)	17 (4)	0.621	-2 (-7 to 3)	0.487	1.2 (-6 to 8)	0.733

\*Huber–White Robust standard error. <sup>†</sup>Differences are mean values in intervention group – mean value in control group. CI, confidence interval; CSB, corn–soy blend; LNS, lipid-based nutrient supplement.

Our results are consistent with the findings of another study, also from Malawi, in underweight stunted children receiving either CSB or ready-to-use therapeutic food, another form of LNS (Maleta *et al.* 2004). This previous study reported a decrease of intake in non-supplement foods in children receiving CSB, but not in those receiving LNS resulting in a higher overall energy intake in the LNS group. This previous study, however, did not have a control group receiving no supplement, and our study shows that the groups supplemented with CSB reduces its energy intake from non-supplement foods compared with children receiving no supplement.

The selective effect of LNS on energy intake may be related to its energy density. All LNS have an energy density >500 kcal/100 g, which is considerably

higher than for CSB, which is cooked with water and usually have an energy density of 100 kcal/100 g or less when given to the child. There is an abundant literature suggesting that high-energy density foods, and in particular fat foods, have a smaller suppressing effect on appetite than other foods (Rolls 2009; Rolls & Bell 1999).

Often, children in poor communities have low-energy intakes as a result of poor appetite, which has been attributed to insufficient intake of key nutrients such as zinc or potassium or magnesium (Golden 1991). The presence of such a mechanism cannot be ruled out in our sample, but it seems unlikely to explain the difference of energy intake between LNS and CSB, both supplements providing approximately the same amount of zinc, calcium, iron and vitamin

C. A difference of zinc absorption or a difference of intake in another nutrient cannot be ruled out, however.

While a recent study has shown that LNS has poor acceptability of LNS among malnourished children in South Asia (Ali *et al.* 2013), some studies in Africa have shown that LNS has an excellent acceptability by the children (Flax *et al.* 2009; Hess *et al.* 2011; Phuka *et al.* 2011;) and appears to have an appetising effect that could significantly induce higher energy intakes of the complementary (non-supplemented) food. With this, LNS would be able to deliver a high energy-dense diet to those in need of increased dietary energy intakes. However, as there are different cultural and behavioural factors that can affect the acceptability of an intervention in different settings, there is need to conduct some more studies in South Asia to determine acceptability of LNS in South Asia since it was the first acceptability trial to be conducted in that setting.

The higher energy intake in the LNS group suggests it should be preferred to CSB to supplement underweight children. The effect of LNS on recovery of underweight children compared with food supplements made from fortified flours is not clear, however (Patel *et al.* 2005; Phuka *et al.* 2009; Nackers *et al.* 2010). It is plausible that the increased energy intake observed in the LNS group is preferentially used for physical activity, and not for growth, which would minimise the impact on anthropometry of LNS compared with CSB.

In conclusion, our study suggests that both LNS and CSB are effective to increase intake of zinc, calcium, iron and vitamin C, but that LNS seems superior to provide extra energy. While it is important to confirm these findings, LNS cannot be recommended compared with CSB in underweight children without clear evidence that it is superior to CSB in terms of anthropometric recovery or increased physical activity or other functional outcome.

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## Conflicts of interest

The authors declare that they have no conflicts of interest.

## Contributions

All authors designed the trial, PA wrote the protocol and raised trial funding; CT was responsible for data collection; YBC designed the details of statistical analysis; and CT and JP did the analysis. CT wrote the first draft of the paper under the supervision of KM, PA and AB. All authors commented on the analysis and participated in writing of the paper. KM had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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