



Cost-Effectiveness of 4 Specialized Nutritious Foods in the Prevention of Stunting and Wasting in Children Aged 6–23 Months in Burkina Faso: A Geographically Randomized Trial

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ABSTRACT

Background: There is a variety of specialized nutritious foods available for use in programs targeting undernutrition, but evidence supporting the choice of product is limited.

Objectives: We compared the cost-effectiveness of 4 specialized nutritious foods to prevent stunting and wasting in children aged 6–23 mo in Burkina Faso.

Methods: Four geographic regions were randomly assigned to 1 of 4 intervention arms: Corn-Soy Blend Plus (CSB+) programmed with separate fortified vegetable oil (the reference food), Corn-Soy-Whey Blend (CSWB; a new formulation) with oil, SuperCereal Plus (SC+), and ready-to-use supplementary food (RUSF). We compared the effects of each intervention arm on growth (length-for-age z score (LAZ), weight-for-length z score (WLZ), end-line stunting (LAZ < -2), and total monthly measurements of wasting (WLZ < -2). Rations were ~500 kcal/d, distributed monthly. Children were enrolled in the blanket supplementary feeding program at age ~6 mo and measured monthly for ~18 mo. Average costs per child reached were linked with effectiveness to compare the cost-effectiveness of each arm with CSB+ with oil.

Results: In our sample of 6112 children (CSB+, *n* = 1519; CSWB, *n* = 1503; SC+, *n* = 1564; RUSF, *n* = 1526), none of the foods prevented declines in growth. Children in the SC+ and RUSF arms were not significantly different than those in the CSB+ with oil arm. Children in the CSWB with oil arm experienced higher end-line (measurement at age 22.9–23.9 mo) stunting (OR: 2.07; 95% CI: 1.46, 2.94) and more months of wasting (incidence rate ratio: 1.29; 95% CI: 1.09, 1.51). CSB+ with oil was the least-expensive ration in all costing scenarios (\$113–131 2018 US dollars/enrolled child) and similar in effectiveness to SC+ and RUSF, and thus the most cost-effective product for the defined purposes.

Conclusions: CSB+ with oil was the most cost-effective ration in the prevention of wasting and stunting in this trial. This trial was registered at clinicaltrials.gov as NCT02071563. *Curr Dev Nutr* 2020;4:nzaa006.

Keywords: food aid, children, supplementary feeding, complementary feeding, cost-effectiveness, corn-soy blend, lipid-based nutrient supplements, low-income countries, stunting, wasting

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Upon publication of this manuscript, the datasets generated and analyzed during the current study will be made available on the Development Data Library of USAID, found at <https://data.usaid.gov>. The study protocol is available upon request.

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Abbreviations used: CSB+, Corn-Soy Blend Plus; CSWB, Corn-Soy-Whey Blend; DHS, Demographic and Health Surveys; FBF, fortified blended flour; FVO, fortified vegetable oil; IRB, institutional review board; IRR, incidence rate ratio; LAZ, length-for-age z score; LNS, lipid-based nutrient supplement; LNS-SQ, small-quantity lipid-based nutrition supplements; LTFU, lost to follow-up; MAM, moderate acute malnutrition; MUAC, midupper arm circumference; RUSF, ready-to-use supplementary food; RUTF, ready-to-use therapeutic food; SBCC, social behavior change communication; SC+, SuperCereal Plus; SNF, specialized nutritious food; USAID, US Agency for International Development; USD, US dollars; VIM, Victoire sur la Malnutrition; WLZ, weight-for-length z score.

Introduction

Stunting (low height-for-age) and wasting (low weight-for-height) often start during the first 1000 d of life, a critical window of opportunity for growth and development (1, 2). In the period when children are

between 6 and 23 mo of age (3), they are no longer sufficiently nourished by breast milk alone and require nutrient-dense complementary foods (3–6). In settings where food insecurity is common, complementary foods are typically inadequate in quantity and quality, so children often experience growth faltering. Interventions that make appropriate

complementary foods available are central to the prevention of stunting and wasting in these populations (2, 3, 7–9). A common strategy for such interventions is the provision of supplementary foods to all children <2 y, regardless of their nutritional status (10). However, evidence for the cost-effectiveness of various designs of food aid supplementation programming remains insufficient (2).

Aid organizations around the world spend billions of dollars on food assistance every year, funding for which has more than doubled since 2009 (11). In 2013, blanket supplementary feeding programs designed to prevent moderate acute malnutrition (MAM) reached 7 million children in 44 different countries (9). With the distribution of such a high volume of food aid around the world, the value for money of such products, in relation to program goals, is an important concern.

A major scientific review published in 2011 recommended several changes to food aid products to address deficiencies in product formulation (10). Notably, these included modifications to the commonly programmed Corn-Soy Blend Plus (CSB+). The WHO and its partners recommended the use of ready-to-use therapeutic food (RUTF), a lipid-based nutrient supplement (LNS) for community-based management of severe acute malnutrition in 2007, but did not mention its use for prevention of MAM (12). Its success led to an extension of the use of LNSs in the prevention and treatment of MAM, despite limited evidence on their cost-effectiveness (13). Concerns regarding the formulation of CSB+ stemmed from its lower nutrient and calorie density compared with more expensive LNS products. In addition, CSB+ lacks essential growth factors provided by animal-source foods such as dairy (10, 14–16). Recommended changes to the product thus included the addition of an animal-source food and an updated micronutrient premix to reflect recent scientific evidence for optimum micronutrient content. It was also recommended to encourage the preparation of porridge with fortified vegetable oil (FVO) in the ratio of 30 g FVO per 100 g CSB to increase calorie density and enhance absorption of fat-soluble vitamins. Considering these recommendations, a new specialized nutritious food (SNF), called Corn-Soy-Whey Blend (CSWB), was proposed to improve the efficacy of the CSB+ while keeping costs low (10).

In addition to product and programming recommendations, the report advocated for strengthening the evidence base for innovations in products and programming by testing in the field the effectiveness and cost-effectiveness of any recommended modification (10). Not only do the products and programs need to be effective in preventing undernutrition, they need to be cost-effective to achieve the desired impact while maximizing reach.

A variety of SNFs are used in food aid programming, and each organization that intervenes in the sphere of malnutrition has its own preferences, despite little evidence to support cost-effective choices (17). This study tested differences in growth outcomes and assessed the comparative cost-effectiveness among 4 SNFs in the prevention of stunting and wasting in children aged 6–23 mo in Burkina Faso, West Africa.

Methods

Setting

This study took place in 4 areas of the Sanmatenga Province in the Center-North region of Burkina Faso: Barsalogo, Kaya, Namissiguima, and Pissila. Burkina Faso has high levels of food insecurity (18).

In 2010, the Center-North regional average for stunting in children <5 y was 29%. This is lower than the national average of 35%, but the regional average for wasting, 25%, was higher than the national average of 16% (18).

The study was embedded in a pre-existing blanket supplementary feeding program designed to prevent undernutrition in high-risk areas by providing all pregnant and lactating women and children aged 6–23 mo in the catchment area with a monthly ration of a nutritious supplemental food accompanied by educational social behavior change communication (SBCC). During the “lean season” from June to September, all participants were also provided with a household ration of 10 kg of split peas and 4 L of vegetable oil, but for the rest of the year participants were provided with rations designated for a single, targeted recipient. The program, called “Victoire sur la Malnutrition” (ViM), was implemented by ACDI/VOCA and Save the Children and reached 44,663 recipients in 199 villages with food distribution between August 2011 and September 2016 (19). The study team worked in close collaboration with the ViM program while making a concerted effort not to influence their programming in order to capture the realistic effectiveness of the 4 foods in the context of a large blanket supplementary feeding program. The ViM program, which included agricultural and water and sanitation components as well as the nutrition component, relied on community volunteers to distribute the foods at 48 distribution points (distribution committees) and disseminate SBCC messages (lead mothers).

The SBCC modules on the SNFs discussed the nutritional composition of the foods, preparation instructions (including a cooking demonstration for the flours), feeding instructions that stressed breastfeeding before giving the supplement to the child, information about hygienic storage of the supplements, targeting of the supplement to the index child, and reinforcement of the idea that the foods are meant to be supplemental to the child’s diet and not a replacement for household foods. Prior to the study, the ViM program had been distributing CSB+ with oil to all recipients in the region; thus, all recipients had received the SBCC module on the CSB+ with oil. ViM program participants (even those who continued to receive CSB+ with oil) were thus given an additional SBCC module on the new foods once the study began and the SNFs changed. While other SBCC modules (e.g., family planning, hygiene, and health services) were delivered monthly on a rotating basis, those pertaining to food use were delivered only once to each recipient once the study began.

Population and sampling

Study population.

Children whose caregivers had been participating in the ViM program from pregnancy onwards were enrolled in the study when the ration was transferred from the caregiver to the child, typically at age 6 mo when children are ready for complementary foods.

Sample size calculation.

Due to the lack of comparable published data, we were unable to conduct a full power calculation based on regression models prior to the study; rather, the number of participants per group was predetermined at ~1500, given the program’s budget and our desire to maximize coverage. We based our effect size calculation for the target sample size of 1500 children per arm on the ability to determine if each of the 4 arms is

associated with a significant reduction in stunting and wasting. According to the 2010 Demographic and Health Surveys (DHS) report (18), stunting and wasting rates at study inception were 22.8% and 18.8%, respectively. We present detectable difference calculations. Given the pre-determined sample size of ~1500 per study arm, with a statistical power of 80% and type 1 error rate of 5%, we can detect a 4-percentage-point difference in stunting or wasting in each group compared with the reference arm, assuming the stunting and wasting rates in the reference arm are as reported by DHS.

Enrollment criteria and recruitment.

Enrollment occurred on a rolling basis from August 2014 until July 2015, when the target sample size for each study arm was reached. Eligible children were identified using lists of 6-mo-old children published by the ViM program each month. Children on this list who were effectively receiving the child ration for the first time were enrolled, as were those whose names did not appear on the list but who had been transferred the ration per the decision of the Health and Nutrition Promoter. Names of children who were not present at the food distribution point were kept on the list of eligible children until they were enrolled or reached 12 mo, at which point they were excluded, based on the ViM program criteria for enrolling children in the distribution program. Children exhibiting signs of severe acute malnutrition, defined by a midupper arm circumference (MUAC) <11.5 cm and/or bilateral edema, were also excluded and referred to health centers for treatment. No explicit follow-up was conducted on children or caregivers once they had been referred to the proper treatment facilities.

Study foods and intervention

The US Agency for International Development's (USAID's) most commonly used product, CSB+ programmed along with oil (CSB+ w/oil), was compared with the new product, CSWB also provided with oil (CSWB w/oil), the standard-of-care for the World Food Program [SuperCereal Plus (SC+)], and a ready-to-use lipid-based nutrient supplement (RUSF). Prior to the effectiveness trial, taste tests were conducted to test the acceptability of each of the 4 foods among members of the intended population. ViM program participants from all 4 study arms were invited to taste each of the 4 foods; thus, acceptability of each food is applicable to the populations of all 4 study arms. All foods were determined to be acceptable, and recipients reported no complaints regarding the introduction of new foods. Details on the protocol and results for these taste tests can be found in the Food Aid Quality Review report, "ViM Beneficiary Taste Tests of Title II Food Aid Products, Sanmatenga Province, Burkina Faso" (20).

The 4 foods were delivered in monthly isocaloric rations of ~500 kcal/d, in keeping with the previously established schedule of the ViM program for monthly distributions. The 3 fortified blended flours (FBFs)—CSB+, CSWB, and SC+—are all mixes of cornmeal, soy flour (CSWB), or soybeans (CSB+, SC+) and a vitamin/mineral premix. Both the CSB+ and CSWB were delivered with a separate ration of vegetable oil fortified with vitamins A and D; the fundamental difference between the CSB+ and the CSWB is the added whey component and enhanced micronutrient premix in the CSWB. The SC+ contains dried skimmed milk powder and is supposed to have a larger quantity of oil in the premix than CSB+ and CSWB and is thus not distributed with oil on the side. However, when prepared as intended, both CSB+

and CSWB have a higher energy density than SC+, closer to that of RUSF. The FBFs are intended to be prepared into a porridge for target children. The RUSF, which contains oilseeds, peanuts, pulses, cereals, sugar, dairy protein, vegetable oil, and a vitamin/mineral premix, is meant to be consumed "as is" directly from the package (21). The nutrient compositions of the 4 foods are compared in Table 1. In addition to the SBCC disseminated through the health and nutrition promoters and lead mothers, the ViM program employed "food monitors" whose job it was to visit households to ensure that the supplements provided were being consumed as intended. While data were collected from households about the use of the foods and trainings received, the study team stayed separated from the ViM programming so as not to influence the intervention.

Study design

This was a longitudinal, 4-pronged cost-effectiveness trial with random assignment to study arm by geographic region. The intent of the study was to evaluate the 4 foods in a true programmatic setting, consistent with how the program had been implemented before the introduction of the study foods. This was not an efficacy trial. There were 48 food distribution points, which were divided into 4 geographically contiguous study arms, and the arms were randomly assigned 1 of the 4 foods (Figure 1). Geographic grouping was done due to the logistical constraints of the existing distribution program and to avoid potential cross-contamination of the products across study arms. The 4 regions were assigned numbers and input into a randomization website, randomization.com, to generate a random sequence to allocate each of the 4 interventions to 1 of the 4 geographic regions (22). This was done once prior to study implementation. All eligible individuals within a given geographic region were approached for participation. Enrollment occurred simultaneously in all geographic regions until the desired sample size was reached. The team statistician who was not involved with the field work generated the sequence independently. No blinding was used in this study; both the participants and those distributing the food knew what type of food ration was being provided.

Data collection

Data were collected by a team of enumerators independent from the ViM implementation team, who were provided extensive training and standardization in anthropometric and survey techniques. All data collection tools were pretested on a population of children in the ViM program who had aged out of eligibility for study participation. Data were double-entered into CSPro Version 6.0 (U.S. Census Bureau) and corrected for consistency, as well as implausible and missing values, before being converted to SAS 9.3 (SAS Institute) and Stata 13.1 (StataCorp) formats for analysis (23–25). The use of multiple statistical software packages for data management and analyses was due to the diverse nature of our team members from both Burkina Faso and the United States, who have differing proficiencies in and access to these software packages. Implausible values for anthropometry were set based on biological plausibility. All data collection materials can be made available upon request.

Monthly data collection.

Children's weight, MUAC, and recumbent length were measured monthly for the 18-mo period in which they were receiving food

TABLE 1 Nutrient composition of the 4 foods compared in the cost-effectiveness trial for prevention of stunting and wasting in children aged 6–23 mo in Burkina Faso, per ~500 kcal/d ration¹

	CSB+ with oil	SC+	CSWB with oil	RUSF
Ration size, g	75 CSB+, 22.5 FVO	126	75 CSWB, 22.5 FVO	100
Energy, kcal	483.15	500	487.92	500
Protein, g	9.66	18.02	12.91	13
Total lipid (fat), g	26.52	10.19	27.72	26
Carbohydrate, g	51.28	82.9	46.96	51
Fiber, total dietary, g	3.75	5.3	4.8	<5
Sugars, total, g	2.05	19.66	3.82	22
Minerals				
Calcium, mg	381.75	766.42	320.77	600
Iodine, µg	30.01	50.51	30.01	150
Copper, mg	0.29	0.48	1.04	1.2
Iron, mg ferrous fumarate	3.01	5.05	5.04	5.5
Iron, mg EDTA	1.88	3.16	1.88	2.5
Iron, total	7.89	13.01	9.94	10
Magnesium, mg	60.75	106.06	63.38	150
Manganese, mg	0.48	0.77	0.57	0.68
Phosphorous, mg	381.75	717.17	367.5	457
Potassium, mg	457.5	906.57	567.38	770
Sodium, mg	3.75	60.61	97.97	<250
Selenium, µg	0	15.15	5.7	35
Zinc, mg	4.88	8.48	4.48	15
Vitamins				
Vitamin C, total ascorbic acid, mg	68.4	115.66	67.5	100
Pantothenic acid, mg	1.46	2.72	1.64	3
Thiamin, mg	0.36	0.62	0.33	1
Riboflavin, mg	1.21	2.2	1.02	2.5
Niacin, mg	6.75	11.34	6.93	15
Vitamin B-6, mg	5.79	1.53	0.94	1.5
Folate, µg DFE	156.75	261.36	146.25	230
Vitamin B-12, µg	1.5	2.93	1.5	3
Vitamin A, µg RAE	1047	1318.9	779.07	1200
Vitamin A, IU	4074	4532.84	4061.25	4001.16
Vitamin E (α-tocopherol), mg	8.26	11.1	8.46	16.5
Vitamin D (D ₃), µg	11	13.89	8.28	12
Vitamin D, IU	720.75	569.45	713.7	480
Biotin, µg	6.15	10.35	0	12
Vitamin K (phylloquinone), µg	70.93	56.69	72.13	30

¹CSB+, Corn-Soy Blend Plus; CSWB, Corn-Soy-Whey Blend; DFE, dietary folate equivalents; FVO, fortified vegetable oil; RAE, retinol activity equivalents; RUSF, ready-to-use supplementary food; SC+, SuperCereal Plus.

rations and for 3 consecutive months postintervention. Each of the 3 measurements was taken twice at each visit and averages of the double measurements used during data analyses. Other monthly data collection included morbidities at the time of measurement and in the previous 2 wk, receipt of any medications or supplements including vitamin A in the previous month, and receipt of a ration that month. If children were absent from the food distribution point, enumerators were sent to measure them in their households to minimize missing data points; however, to capture the real-world effectiveness of the foods in a normal programmatic setting, they did not bring the rations to recipients since, without the presence of the study team, those recipients would not have received the rations for that month. In addition, in-depth surveys, in-home observations, and focus groups were conducted to explore factors that potentially influenced the effectiveness of the 4 foods. For details on this methodology and results, see the related paper on factors influencing effectiveness (26).

Inclusion and exit data collection.

In addition to monthly anthropometric measurements, caregivers were administered a socioeconomic survey at study enrollment and exit. This included a household possessions questionnaire based on that used by the Demographic and Health Survey Program in Burkina Faso (18) and the Household Food Insecurity Access Scale (27). Village-level data on access to health care, markets, and education were collected as well through community questionnaires with key informants from each village.

Costing data.

Costing data were collected on each of the 8 costing components (Figure 2) identified throughout the food distribution supply chain, including any losses sustained at each point. Cost data were collected through historical data, realistic price quotes, billing and accounting records, warehouse observations and records, distribution observations,

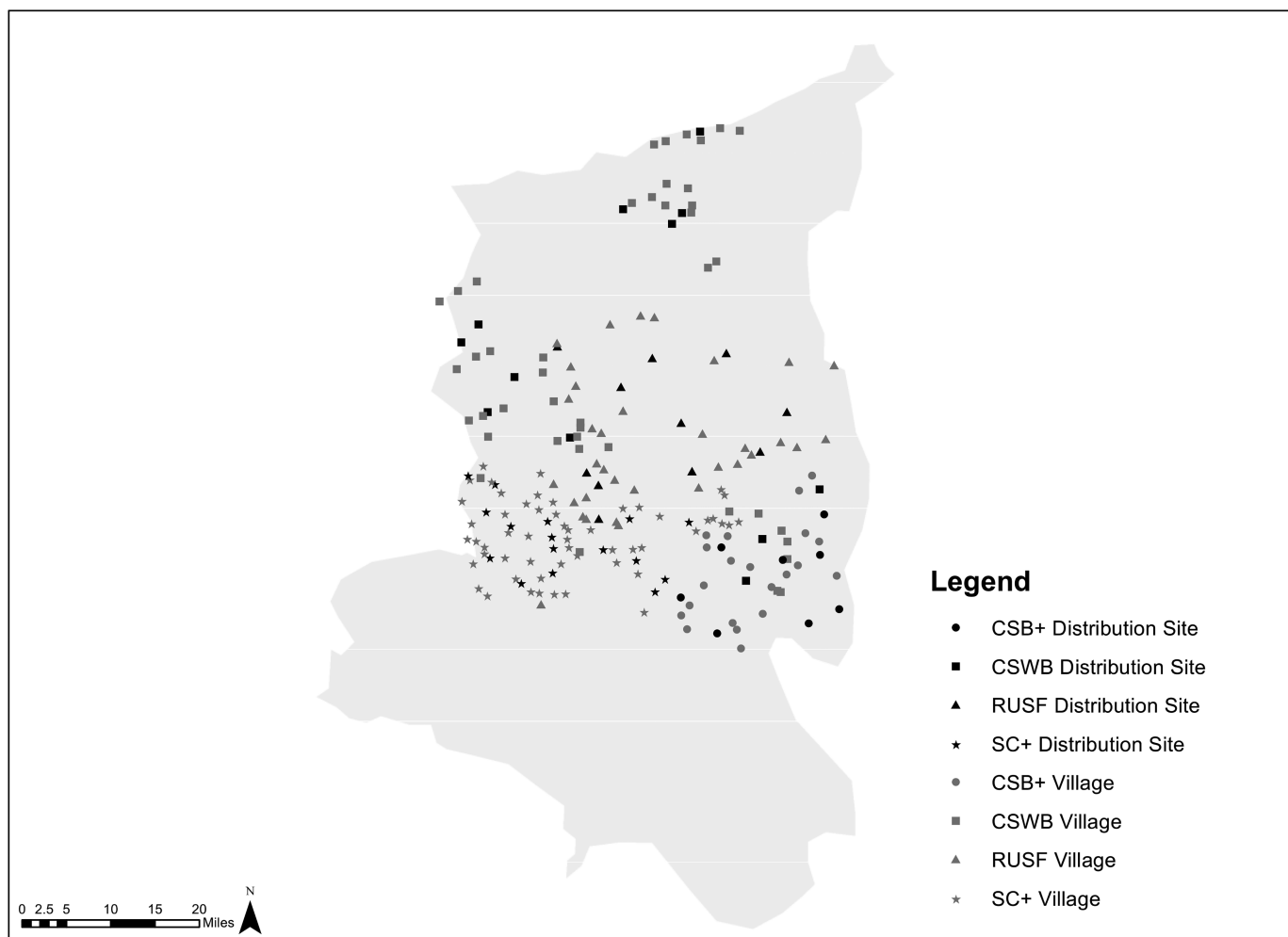


FIGURE 1 Map of food distribution sites and surrounding villages for the Food Aid Quality Review study in Sanmatenga Province, Burkina Faso, 2014–2016. CSB+, Corn-Soy Blend Plus; CSWB, Corn-Soy-Whey Blend; RUSF, ready-to-use supplementary food; SC+, SuperCereal Plus.

and in-home observations and interviews with the recipients. Costs incurred specifically for the research, especially those for procurement and international freight, may be different from realistic average program costs, since the quantities procured were smaller than for a typical program. For this analysis, realistic costs from suppliers' and freight forwarders' historical records were used rather than study-incurred costs. Details on this methodology are presented elsewhere (Y Shen, I Cliffer, D Suri, B Langlois, S Vosti, P Webb, B Rogers, manuscript in revision at *Nutrition Journal*, 2019).

Statistical analyses

Primary independent variable.

The primary independent variable was the study arm, modeled as a 4-level categorical variable, with the CSB+ w/oil arm as the reference group.

Primary outcomes.

The primary outcomes were stunting at endline and total number of monthly measurements of wasting. Stunting was modeled at

endline, whereas wasting was modeled throughout the study because once a child is stunted it is less likely that the status will be reversed, whereas children can fluctuate between wasted and not wasted (28). Anthropometric indices were calculated using the SAS macro developed based on the 2006 WHO Child Growth Standards (29, 30). Stunting was defined as length-for-age z score (LAZ) < -2 . The endline was defined as the visit when the child was between 22.9 and 23.9 mo, since this was typically the last time they received a ration. Children who did not have a measurement between 22.9 and 23.9 mo were considered lost-to-follow-up (LTFU) for the purpose of the stunting models. The total number of monthly measurements of wasting was calculated by counting the number of times the child had a weight-for-length z score (WLZ) < -2 at a monthly measurement throughout the study period. The definition of LTFU was not relevant for the wasting outcome, as the outcome was considered throughout the study period. Instead, for wasting, models controlled for children's total contributing monthly measurements in the study.

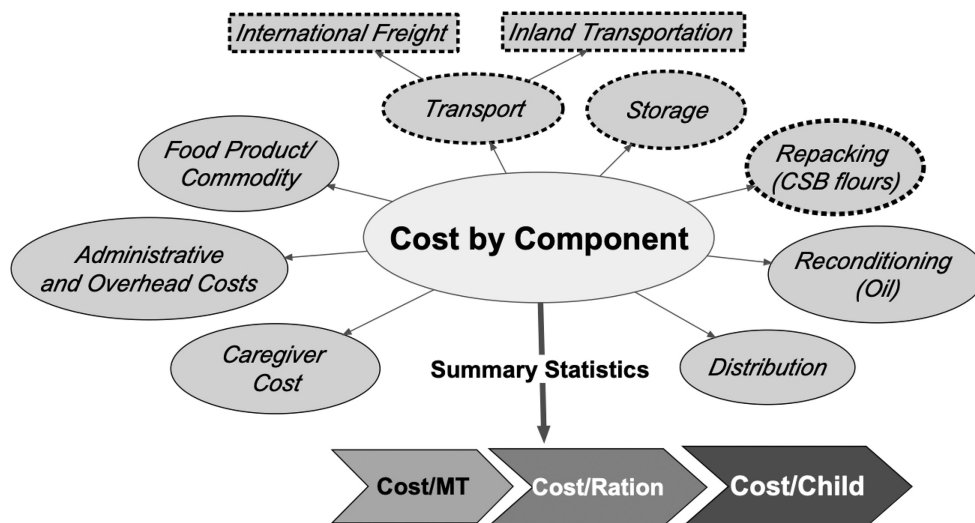


FIGURE 2 Cost calculations in study comparing the cost-effectiveness of 4 supplementary foods in the prevention of stunting and wasting. Dotted borders are where adjustments for losses incurred were made. CSB, Corn-Soy Blend; MT, Metric Ton.

Modeling strategy.

Since the study was geographically clustered, prior to modeling, the intracluster correlation coefficient was calculated for each outcome to evaluate whether the variation among the clusters (food distribution points) within each study arm was homogeneous. Intracluster correlation coefficients were sufficiently low (<0.01) to justify the omission of food distribution points from the models; however, to better isolate the effect of the intervention, we controlled for community-level covariates. Tests for balance of baseline individual- and community-level characteristics among study arms were conducted using ANOVA for continuous variables and chi-square tests for categorical variables. Potential individual- and community-level confounders were selected as covariates a priori based on a directed acyclic graph (Figure 3). A wealth quintile was calculated using principal components analysis with data on household assets and characteristics. Morbidity variables were combined into a dichotomous indicator of child illness in the previous 2 wk.

For stunting at endline, logistic regression models were used to assess the ORs for each arm compared with CSB+ w/oil, the reference arm. Negative binomial models were built to examine incidence rate ratios (IRRs) for the total number of monthly measurements showing wasting. Gaps in measurement visits, and thus varying total number of months in which children were measured, were controlled for using an offset for the natural log of the total number of months in which the child was measured. Longitudinal mixed-effects models were also constructed to model the effects of the study foods over time, using monthly LAZ and WLZ as continuous outcomes. ORs, IRRs, and β -coefficients with P values <0.05 , and whose 95% CIs did not include the null value, were considered statistically significant.

Sensitivity analyses were done to see if children who were LTFU or those with missing data influenced the results. To assess whether there were any inherent differences among those who were LTFU, models were fit both with and without these cases. For logistic regression (stunting at endline outcome), models including children who were LTFU were simulated 30 times with children selected randomly as stunted with a probability of 20% assuming a normal distribution, as the

unadjusted overall prevalence of stunting was 23%. For negative binomial regression (total monthly measurements of wasting outcome), models including children who were LTFU included an indicator variable of LTFU in the model while the offset variable accounted for their time in the study. Missing data for individual-level explanatory variables were imputed using multiple imputation methods (31). Coefficients were then examined and compared for consistency across all models.

All models were assessed for interactions using Wald tests in which P values <0.05 were considered significant. Models were checked for multicollinearity using variance inflation factor cutoffs of ≥ 10 and assessed for influential outliers using leverage plots. All analyses were conducted using SAS version 9.3 and Stata version 13.1 (25) and are reported in adherence with CONSORT guidelines for cluster-randomized trials (32).

Summary costs.

The summary cost measure is cost per child reached, which was calculated for each arm using a multistep, activity-based ingredients approach. Costing components were adjusted for losses using percentage of losses at each step for which sufficient data were available. Ultimately, a loss-adjusted cost per child reached was calculated for each study arm. Costs are presented in 2018 US dollars (USD). Figure 2 diagrams the costing components and related calculations.

This article presents cost-effectiveness results from the program-only perspective, which includes all cost components incurred by the donors, implementers, and volunteers of the program. Sensitivity analyses and additional perspectives that consider opportunity costs to the caregivers of the recipients are reported elsewhere (Y Shen, I Cliffer, D Suri, B Langlois, S Vosti, P Webb, B Rogers, manuscript in revision at *Nutrition Journal*, 2019).

Cost-effectiveness.

Using the effectiveness models described above, we obtained adjusted marginal predicted probabilities of stunting at endline and total number

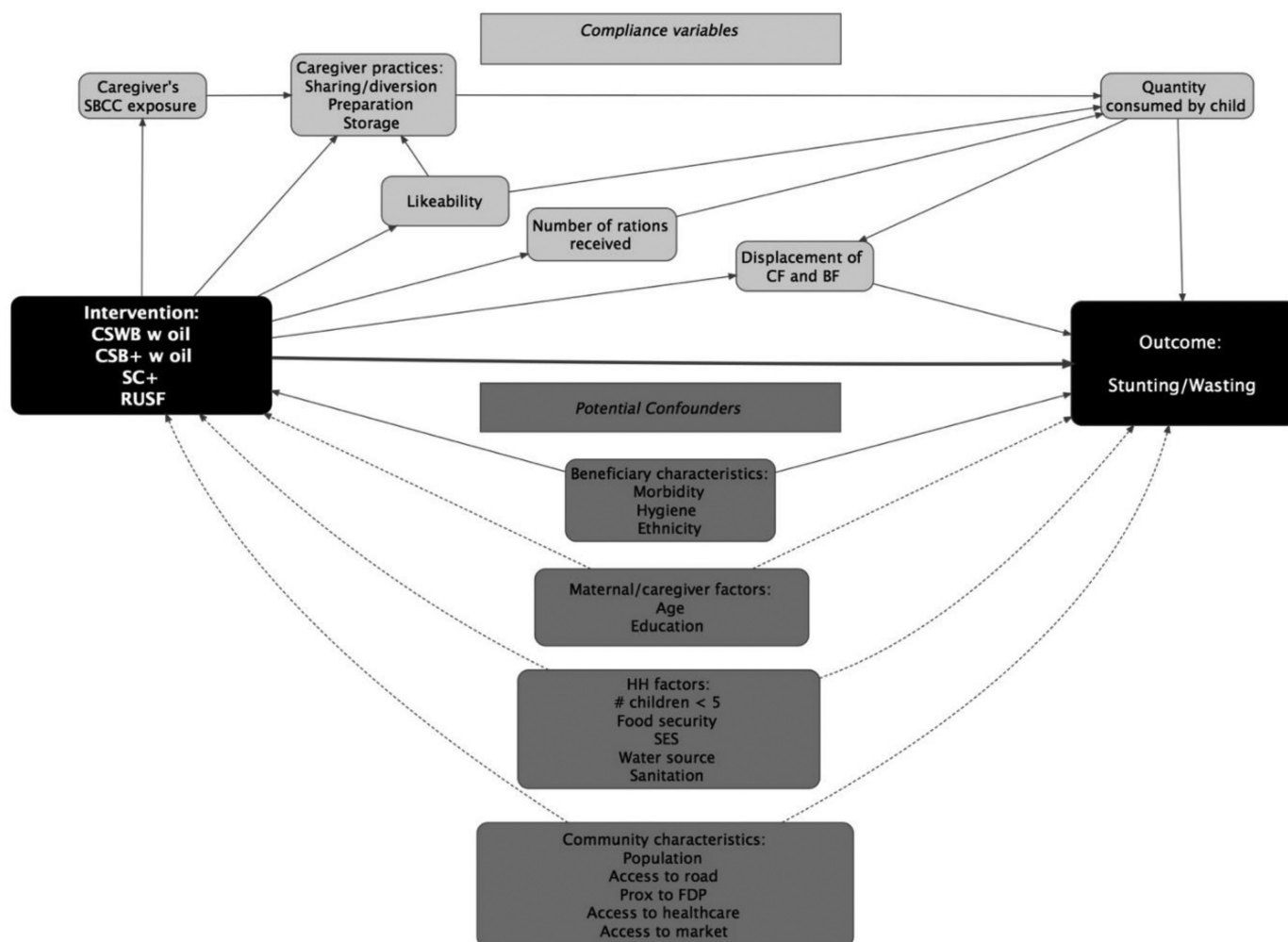


FIGURE 3 Directed acyclic graph showing relations among intervention arms, outcomes, mediating factors, and potential confounders. BF, breastfeeding; CF, complementary feeding; CSB+, Corn-Soy Blend Plus; CSWB, Corn-Soy-Whey Blend; FDP, food distribution point; HH, household; RUSF, ready-to-use supplementary food; SBCC, social behavior change communication; SC+, SuperCereal Plus; SES, socioeconomic status.

of monthly measurements showing wasting for each arm. To evaluate relative cost-effectiveness of each study arm, differences in the average cost per child reached were plotted against the differences in the point estimates for these predicted probabilities. Uncertainty ranges for the effectiveness measurements were their 95% CIs, and uncertainty ranges for total cost per child were constructed based on the minimum and maximum of the realistic product cost for each of the commodities. This provided a visual comparison of relative cost-effectiveness across the 4 arms. Cost-effectiveness analyses were completed in Excel (Microsoft Corporation) and R (33, 34).

Ethics

This study was reviewed and approved by the Tufts University Health Sciences Institutional Review Board [institutional review board (IRB) no. 10899] and the ethics board of the Ministry of Health in Burkina Faso (no. 2013-10-090). Informed consent to participate in the study was obtained from all participants and was provided for underage participants by their parents and/or legal guardians. Due to the high

prevalence of illiteracy in the participating population, the consent process was explained verbally, and participants signified their consent by placing their thumbprint on the consent forms. This process was approved by the Tufts IRB as well as the ethics board in Burkina Faso. In addition to receiving the food supplements as compensation for participation, participants were each provided with 2 bars of local soap upon completion of the study, as a small, culturally relevant token of appreciation. The trial was registered at ClinicalTrials.gov on 26 February 2014 under identifier NCT02071563.

Results

Enrollment and baseline characteristics

A total of 6112 children were enrolled across the study arms. There were no major differences in programmatic exposure (number of rations received) or loss to follow-up by study arm (Figure 4). Baseline demographic, socioeconomic, and anthropometric data were similar

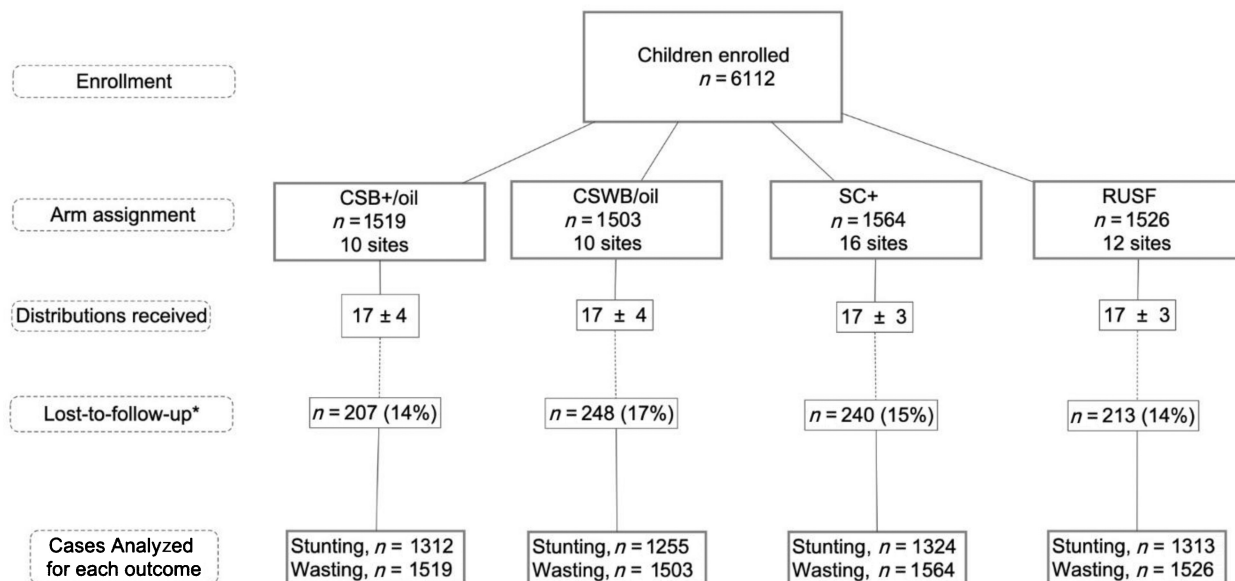


FIGURE 4 Enrollment flow chart, children aged 6–23 mo, Sanmatenga Province, Burkina Faso. Values for distributions received are means ± SDs. Outcomes are stunting at endline (measurement between 22.9 and 23.9 mo) and monthly measurements of wasting throughout the study period. *Lost-to-follow-up only applicable for stunting models and defined as no endline measurement between 22.9 and 23.9 mo. CSB+, Corn-Soy Blend Plus; CSWB, Corn-Soy-Whey Blend; RUSF, ready-to-use supplementary food; SC+, SuperCereal Plus.

among the study arms, except there were more people in the lowest wealth quintile in the CSB+ w/oil arm than in the other 3e arms (Table 2). Due to the large sample size, there are several statistically significant differences in the individual baseline covariates among the study arms, even when the magnitude of these differences are quite small and not economically significant (35). At the community level, some minor differences were observed in market, phone service, and public transport availability across the study arms (Table 3). Some differences were observed in consumption patterns of the foods. Although exact quantities of the foods consumed were not measured, the CSWB w/oil was reportedly consumed significantly less often by the target recipients than any of the other foods. Details about the use and consumption of the foods in the households are presented in a companion to this article (26).

Effectiveness

Overall, 23% of children were stunted at endline; children spent a mean of 2.2 (SD = 4.3) mo being characterized as wasted (Table 4). In adjusted models, children in the CSWB w/oil arm were twice as likely to be stunted at endline than those in the CSB+ w/oil arm (OR: 2.07; 95% CI: 1.46, 2.94), whereas the probabilities for those in the SC+ and RUSF arms were not significantly different from that of children in the CSB+ w/oil arm (Table 5). Results from LTFU simulations were consistent with the main model excluding LTFU; *P* values for the SC+ arm (average OR: 0.92) ranged from 0.14 to 0.94, and those for the RUSF arm (average OR: 1.11) ranged from 0.04 to 0.97 and were not significantly different from the CSB+ w/oil arm, with the exception of 1 simulation for RUSF (OR: 1.3; *P* = 0.04). *P* values for the CSWB w/oil arm (average OR: 1.52) ranged from 0.0005 to 0.042 and were all statistically significantly different from the CSB+ w/oil arm. We can therefore

remain confident in the main stunting models excluding children who were LTFU.

Results from the negative binomial model for wasting showed that children in the CSWB w/oil arm were expected to have 29% more monthly wasted measurements than those in the CSB+ w/oil arm (IRR: 1.29; 95% CI: 1.09, 1.51), whereas those in the SC+ and RUSF arms did not differ significantly from those in the CSB+ w/oil arm (Table 6).

Mixed-effects longitudinal models revealed that LAZ declined over time in all arms, with the steepest and only significantly different decline in the CSWB arm (Figure 5). WLZ trajectories looked similar, with children in all 4 study arms declining between ages 6 and 14 mo before stabilizing and increasing again at ~18 mo (Figure 6). Children in the RUSF arm showed a significantly slower rate of decline in WLZ than those in the other 3 study arms, and therefore had faster recovery. When longitudinal models were extended to include postintervention follow-up measurements (up to 3 mo postintervention, until age 27 mo), relations between the foods for LAZ persisted, whereas the 4 study arms converged for WLZ by age 27 mo.

Cost-effectiveness

From a program perspective, the most expensive intervention arm was RUSF, at \$245 per child enrolled, followed by SC+ (\$226), CSWB w/oil (\$140), and finally CSB+ w/oil (\$122) (Table 7). Costs per enrolled child increased slightly when children who were LTFU were excluded, as the costs are spread over fewer recipients. Since the CSB+ w/oil arm was not less effective than any of the other foods for either stunting or wasting prevention, and was the least expensive, it was the most cost-effective product in this study (Figures 7 and 8). The least cost-effective arm in this study, for both wasting and stunting prevention, was CSWB w/oil, as it was more expensive than CSB+ w/oil and significantly less effective in preventing stunting and wasting.

TABLE 2 Demographic characteristics of children in the blanket supplementary feeding program ViM at enrollment by study arm, Sanmatenga Province, Burkina Faso, 2014–2016¹

	Study arm				
	Overall (n = 6112)	CSB+ w/oil (n = 1519)	CSWB w/oil (n = 1503)	SC+ (n = 1564)	RUSF (n = 1526)
Child age,*** mo	6.25 ± 0.94	5.93 ± 0.78	6.56 ± 0.92	6.31 ± 0.72	6.20 ± 1.16
Maternal age,*** y	25.98 ± 6.40	25.87 ± 6.31	25.90 ± 6.48	26.50 ± 6.49	25.63 ± 6.30
Weight,*** kg	7.04 ± 0.94	6.87 ± 0.91	7.15 ± 0.95	7.16 ± 0.93	6.98 ± 0.93
Length,*** cm	65.71 ± 2.77	64.94 ± 2.58	66.31 ± 2.85	65.97 ± 2.59	65.62 ± 2.88
MUAC,*** cm	13.62 ± 1.07	13.52 ± 1.08	13.64 ± 1.06	13.74 ± 1.07	13.55 ± 1.06
Length-for-age z score***	-0.60 ± 1.10	-0.72 ± 1.07	-0.56 ± 1.16	-0.53 ± 1.04	-0.58 ± 1.11
Weight-for-length z score***	-0.54 ± 1.05	-0.54 ± 1.05	-0.58 ± 1.04	-0.44 ± 1.04	-0.59 ± 1.04
Wasted (WLZ < -2), n (%)	478 (8)	121 (8)	125 (8)	111 (7)	121 (8)
Stunted (LAZ < -2),* n (%)	531 (9)	148 (10)	135 (9)	110 (7)	138 (9)
Male sex, n (%)	3110 (51)	774 (51)	779 (52)	802 (51)	755 (49)
Current breastfeeding, n (%)	6095 (100)	1515 (100)	1498 (100)	1556 (100)	1526 (100)
Child is a twin,* n (%)	229 (4)	49 (3)	59 (4)	50 (3)	71 (5)
Ethnic majority,*** n (%)	5535 (91)	1398 (92)	1342 (89)	1418 (91)	1377 (90)
Caregiver educational level,*** n (%)					
None	4987 (83)	1327 (88)	1217 (82)	1229 (79)	1214 (81)
Literate	422 (7)	86 (6)	121 (8)	103 (7)	112 (7)
Primary	356 (6)	61 (4)	78 (5)	112 (7)	105 (7)
Secondary	199 (3)	23 (2)	44 (3)	81 (5)	51 (3)
Higher	1 (0)	0 (0)	0 (0)	1 (0)	0 (0)
Number of children <5 y in HH,*** n (%)					
0–1	1178 (19)	248 (16)	276 (18)	375 (24)	279 (18)
2	2033 (34)	499 (33)	505 (34)	581 (37)	448 (30)
3	1178 (19)	304 (20)	287 (19)	281 (18)	306 (20)
4	753 (12)	201 (13)	178 (12)	151 (10)	223 (15)
≥5	941 (15)	264 (17)	253 (17)	166 (11)	258 (17)
Food security, n (%)					
Food secure	2630 (44)	607 (41)	654 (44)	699 (46)	670 (45)
Mildly food insecure	1043 (17)	280 (19)	257 (17)	243 (16)	263 (18)
Moderately food insecure	1487 (25)	381 (25)	362 (25)	385 (25)	359 (24)
Severely food insecure	844 (14)	230 (15)	201 (14)	204 (13)	209 (14)
Wealth quintiles,*** n (%)					
Lowest	1196 (20)	375 (25)	267 (18)	294 (19)	260 (17)
Mid-low	1209 (20)	297 (20)	309 (21)	302 (20)	301 (20)
Medium	1206 (20)	331 (22)	297 (20)	288 (19)	290 (19)
Mid-high	1206 (20)	263 (18)	293 (20)	317 (21)	333 (22)
Highest	1205 (20)	232 (15)	323 (22)	341 (22)	309 (21)
Current illness, n (%)					
Fever**	487 (8)	121 (8)	113 (8)	105 (7)	148 (10)
Diarrhea***	352 (6)	86 (6)	69 (5)	116 (7)	81 (5)
Edema	9 (0)	4 (0)	3 (0)	1 (0)	1 (0)

¹Values are means ± SDs unless otherwise indicated. Testing for differences in means among the study arms were conducted using ANOVA for continuous variables and chi-square tests for categorical variables. **P* < 0.10; ***P* < 0.05; ****P* < 0.01. CSB+, Corn-Soy Blend Plus; CSWB, Corn-Soy-Whey Blend; HH, household; MUAC, midupper arm circumference; RUSF, ready-to-use supplementary food; SC+, SuperCereal Plus; ViM, Victoire sur la Malnutrition.

Discussion

Results from this trial suggest that the existing USAID standard, CSB+ delivered with oil, remains the most cost-effective approach to preventing both stunting and wasting in children aged 6–23 mo in Burkina Faso based on the tested products. Rigorous studies of the effectiveness of preventive supplementary feeding programs are rare, and our results add evidence to the existing literature comparing LNSs with FBFs, investigating associations between animal-sourced foods and growth in children, and evaluating blanket supplementary feeding programs for the prevention of malnutrition. Furthermore, this study had the advantage of being conducted based on a large-scale existing supplementary

feeding program rather than in a highly controlled environment that may not be generalizable to actual programming.

This study provides important insight into the question of whether LNS products, such as relatively costly RUSFs, are not just effective (36) but also cost-effective in preventing stunting and wasting. In the longitudinal models we did see that the RUSF arm showed slower declines in WLZ during the intervention; however, this difference did not persist during the postintervention follow-up period and did not translate to significant differences in wasting rates. Furthermore, the RUSF arm did not differ from the other arms in its linear growth pattern. This phenomenon requires further investigation into the links between linear and ponderal growth trajectories. Overall, the results of

TABLE 3 Community characteristics of study villages by study arm, Sanmatenga Province, Burkina Faso, 2014–2016¹

	Study arm				
	Overall (n = 199)	CSB+ w/oil (n = 29)	CSWB w/oil (n = 55)	SC+ (n = 70)	RUSF (n = 45)
Population in 2014,** n	1614 ± 1399	2220 ± 1219	1652 ± 1882	1339 ± 860	1596 ± 1400
Distance to closest market if no market in village, km	4.3 ± 4.6	2.7 ± 3.3	4.9 ± 4.6	4.3 ± 3.7	4.6 ± 6.1
Months per year road is passable by motorbike	9.35 ± 2.21	10.07 ± 2.14	9.38 ± 2.29	9.37 ± 2.25	8.8 ± 2.01
Months per year road is passable by vehicle	8.00 ± 2.87	8.69 ± 2.73	7.95 ± 2.53	7.67 ± 3.51	8.13 ± 2.14
Services present, n (%)					
Market**	61 (31)	13 (45)	15 (27)	14 (20)	19 (42)
Telephone service or mobile coverage***	144 (72)	25 (86)	49 (89)	46 (66)	24 (53)
Public transport access	38 (19)	2 (7)	11 (20)	14 (20)	11 (24)
Primary school	151 (76)	22 (76)	44 (80)	52 (74)	33 (73)
Secondary school	11 (6)	2 (7)	3 (5)	3 (4)	3 (7)
Health center	26 (13)	5 (17)	8 (15)	9 (13)	4 (9)
Pharmacy	28 (14)	5 (17)	8 (15)	10 (14)	5 (11)
ViM distribution site	48 (24)	8 (28)	13 (24)	16 (23)	11 (24)
Community health agents	191 (96)	27 (93)	53 (96)	66 (94)	45 (100)
Traditional birth attendant	136 (68)	21 (72)	36 (65)	45 (64)	34 (76)
Number of water pumps, n (%)					
None	10 (5)	1 (3)	3 (5)	3 (4)	3 (7)
1	36 (18)	2 (7)	11 (20)	16 (23)	7 (16)
2–3	53 (27)	9 (31)	11 (20)	20 (29)	13 (29)
4–5	47 (24)	5 (17)	15 (27)	16 (23)	11 (24)
≥6	53 (27)	12 (41)	15 (27)	15 (21)	11 (24)
Number of protected wells,* n (%)					
None	115 (58)	23 (79)	30 (55)	39 (56)	23 (51)
≥1	84 (42)	6 (21)	25 (45)	31 (44)	22 (49)
Number of unprotected wells, n (%)					
None	144 (72)	21 (72)	34 (62)	55 (79)	34 (76)
≥1	55 (28)	8 (28)	21 (38)	15 (21)	11 (24)
Number of surface water areas, n (%)					
None	145 (73)	19 (66)	40 (73)	57 (81)	29 (64)
≥1	54 (27)	10 (34)	15 (27)	13 (19)	16 (36)

¹Values are means ± SDs unless otherwise indicated. Testing for differences in means among the study arms were conducted using ANOVA for continuous variables and chi-square tests for categorical variables. **P* < 0.10; ***P* < 0.05; ****P* < 0.01. CSB+, Corn-Soy Blend Plus; CSWB, Corn-Soy-Whey Blend; RUSF, ready-to-use supplementary food; SC+, SuperCereal Plus; ViM, Victoire sur la Malnutrition.

this study indicate that RUSFs used in this setting are not significantly more effective in the prevention of stunting and wasting than commonly programmed FBFs, and they are considerably more costly than CSB+ w/oil.

Similar studies comparing FBFs with LNS products have found comparable results. In a study comparing the effectiveness of LNSs with

SC+ in preventing acute malnutrition and stunting in children aged 6–23 mo in Niger, no differences were found between the 2 products (37). Another study in Malawi comparing CSB with LNS products in the incidence of stunting and linear growth faltering in infants aged 6–18 mo also found no statistically significant differences between the 2 groups (38). A systematic review on the management

TABLE 4 Unadjusted stunting and wasting outcomes by study arm, Sanmatenga Province, Burkina Faso, 2014–2016¹

	Study arm				
	Overall (n = 6112)	CSB+ w/oil (n = 1519)	CSWB w/oil (n = 1503)	SC+ (n = 1564)	RUSF (n = 1526)
Stunting					
Stunted at endline, ² n (%)	1200 (23)	335 (26)	329 (26)	239 (18)	297 (23)
Total number of months with stunting	3.5 ± 6.3	3.9 ± 6.6	3.8 ± 6.5	3.0 ± 5.9	3.3 ± 6.1
Ever stunted throughout study period, n (%)	2047 (33)	554 (36)	537 (36)	451 (29)	505 (33)
Wasting					
Wasted at endline, n (%)	479 (9)	111 (8)	146 (12)	111 (8)	111 (8)
Total number of months with wasting ²	2.2 ± 4.3	2.2 ± 4.1	2.6 ± 4.6	2.1 ± 4.4	2.0 ± 3.8
Ever wasted throughout the study period, n (%)	2532 (41)	637 (42)	687 (46)	564 (36)	644 (42)

¹Values are means ± SDs unless otherwise indicated. Stunting was defined as length-for-age z score < -2. Wasting was defined as weight-for-length z score < -2. Endline measurements exclude lost-to-follow-up (overall, n = 5204; CSB+, n = 1312; CSWB, n = 1255; SC+, n = 1324; RUSF, n = 1313; no endline measurement between 22.9 and 23.9 mo). CSB+, Corn-Soy Blend Plus; CSWB, Corn-Soy-Whey Blend; RUSF, ready-to-use supplementary food; SC+, SuperCereal Plus.

²Primary outcomes.

TABLE 5 ORs (95% CIs) from logistic regression models for stunting at endline among children aged 6–23 mo, Sanmatenga Province, Burkina Faso, 2014–2016¹

Stunting at endline ²	Crude OR	95% CI	Adjusted ³ OR	95% CI
Model 1, excludes lost-to-follow-up	n = 5204		n = 4268	
Study arm (ref = CSB+ w/oil)				
CSWB w/oil	1.04	0.87, 1.24	2.07*	1.46, 2.94
SC+	0.64*	0.53, 0.77	1.02	0.73, 1.44
RUSF	0.85	0.71, 1.02	1.21	0.89, 1.66
Model 2, multiple imputations, excludes lost-to-follow-up ⁴	n = 5204		n = 5204	
Study arm (ref = CSB+ w/oil)				
CSWB w/oil	NA	NA	1.65*	1.28, 2.12
SC+	NA	NA	0.88	0.68, 1.14
RUSF	NA	NA	1.02	0.80, 1.29

¹*P < 0.05. CSB+, Corn-Soy Blend Plus; CSWB, Corn-Soy-Whey Blend; NA, Not Applicable; ref, reference; RUSF, ready-to-use supplementary food; SC+, SuperCereal Plus.

²Stunting defined as length-for-age z score < -2.

³Adjusted models control for age; sex; maternal age; wealth; baseline anthropometric status; twin status; caregiver education; ethnicity; children <5 y in the household; household food insecurity; illness in the last 2 wk; season total distributions received; village-level access to water, sanitation, market, phone service, road, public transport, transport methods from the village, pharmacy, health center, and health agents.

⁴Multiple imputations procedures used for missing covariate data.

of severe acute malnutrition and MAM in humanitarian emergencies found no significant differences in mortality rates among children who received an RUSF compared with those who received CSB products (39). The finding that CSB+ w/oil is much less costly than RUSF yet similar in effectiveness should be considered in decision making surrounding the programming of SNFs in a preventive setting.

Animal-sourced foods, including dairy and specifically whey, have contributed to increases in the effectiveness of SNFs in the treatment of children with MAM (10, 14–16), although a recent systematic review found that, in some studies, anthropometric measurements did not improve with animal-sourced food consumption (40). The results of this effectiveness trial are one more case in which the provision of animal-sourced foods were not more effective in preventing stunting and wasting than the provision of non-animal-sourced foods. Nev-

ertheless, the finding in this study that CSWB w/oil was less effective and cost-effective than CSB+ w/oil, despite the addition of whey protein to the CSWB, is surprising and requires further investigation. Two potential pathways may explain the poor performance of CSWB w/oil relative to the other products: 1) the products could be metabolized differently in the body or 2) differences in the intake or use of the products in the home may have influenced their relative effectiveness. Given the lack of evidence of any adverse effects of CSWB w/oil on the population, the addition of whey protein is unlikely to have led to higher stunting levels. We thus hesitate to ascribe the poor performance of CSWB to product composition (micro- and macronutrient profile). Rather, we posit that it is related to the use and consumption of the food in the home. Although all 4 foods were deemed acceptable for consumption during taste tests prior to the study, and were laboratory tested both before shipping and prior to distribution in country,

TABLE 6 IRRs (95% CIs) from negative binomial regression models for total number of monthly wasting measurements among children aged 6–23 mo, Sanmatenga Province, Burkina Faso, 2014–2016¹

Total monthly measurements wasted ²	Crude IRR	95% CI	Adjusted ³ IRR	95% CI
Model 1, includes lost-to-follow-up	n = 6112		n = 4995	
Study arm (ref = CSB+ w/oil)				
CSWB w/oil	1.19*	1.01, 1.39	1.29*	1.09, 1.51
SC+	0.93	0.80, 1.09	1.01	0.86, 1.18
RUSF	0.93	0.80, 1.09	0.95	0.82, 1.09
Model 2, multiple imputations ⁴	NA		n = 5204	
Study arm (ref = CSB+ w/oil)				
CSWB w/oil	NA	NA	1.29*	1.13, 1.46
SC+	NA	NA	0.98	0.86, 1.12
RUSF	NA	NA	0.91	0.80, 1.03

¹*P < 0.05. CSB+, Corn-Soy Blend Plus; CSWB, Corn-Soy-Whey Blend; IRR, incidence rate ratio; NA, Not Applicable; ref, reference; RUSF, ready-to-use supplementary food; SC+, SuperCereal Plus.

²Wasting defined as weight-for-length z-score < -2.

³Adjusted models control for age; sex; maternal age; wealth; baseline anthropometric status; twin status; caregiver education; ethnicity; children <5 y in the household; household food insecurity; illness in the last 2 wk; season total distributions received; village-level access to water, sanitation, market, phone service, road, public transport, transport methods from the village, pharmacy, health center, and health agents.

⁴Multiple imputations procedures used for missing covariate data.

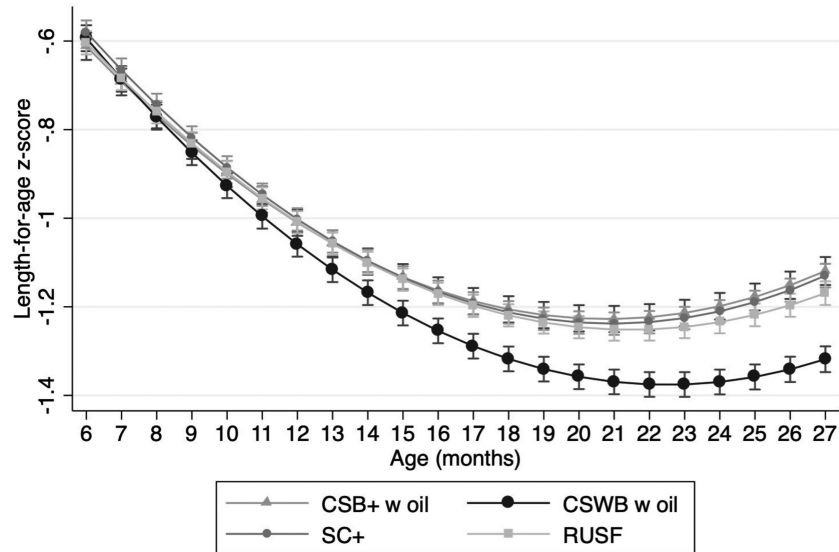


FIGURE 5 Adjusted marginal predictions from linear mixed-effects regression model for length-for-age z scores over time in children aged 6–27 mo in Sanmatenga Province, Burkina Faso, 2014–2016. Error bars are 95% CIs. CSB+, Corn-Soy Blend Plus; CSWB, Corn-Soy-Whey Blend; RUSF, ready-to-use supplementary food; SC+, SuperCereal Plus.

there were some indications based on recipient feedback during focus group discussions that the CSWB flour developed a bitter taste. This deterioration in taste probably occurred after months-long storage in the unavoidable extreme heat conditions in Burkina Faso to which all 4 foods and the vegetable oil were exposed. The CSWB flour was the only 1 of the 4 foods that the research team received flavor complaints about after storage in these conditions, and it is known that whey pro-

tein concentrates can have issues with flavor stability after exposure to storage at high temperatures (41, 42). As is common with large-scale food distribution programs, the foods were stored in 1 shared warehouse in the capital city (Ouagadougou) for several months prior to their distribution in the field. The warehouse was kept clean, fumigated as needed for pests, and followed the “first-in, first-out” procedure to ensure that foods had the shortest possible duration of warehouse stay

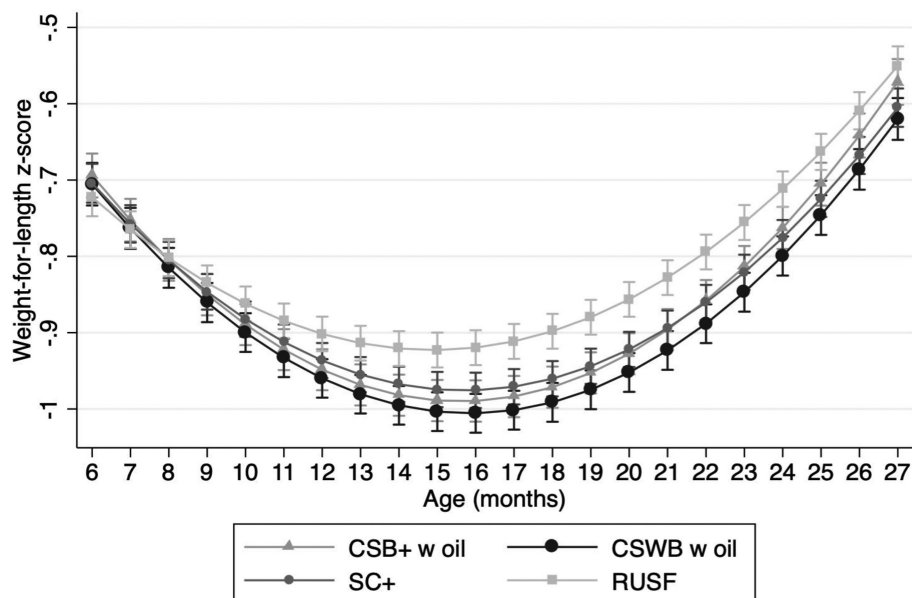


FIGURE 6 Adjusted marginal predictions from linear mixed effects regression model for weight-for-length z scores over time in children aged 6–27 mo in Sanmatenga Province, Burkina Faso, 2014–2016. Error bars are 95% CIs. CSB+, Corn-Soy Blend Plus; CSWB, Corn-Soy-Whey Blend; RUSF, ready-to-use supplementary food; SC+, SuperCereal Plus.

TABLE 7 Linking average cost per child reached (\$USD) by the supplementary feeding program ViM to effectiveness outcomes among children aged 6–23 mo, Sanmatenga Province, Burkina Faso, 2014–2016¹

	CSB+ w/oil	CSWB w/oil	SC+	RUSF
Program cost per child reached, excluding LTFU (uncertainty range ²)	\$127 (\$117, \$136)	\$146 (\$143, \$148)	\$237 (\$216, \$258)	\$254 (\$237, \$271)
Predicted ³ percentage stunted ⁴ at endline (95% CI)	20.1 (18.0, 22.2)	27.5 (25, 30)	21.9 (20, 23.9)	20.3 (18.3, 22.4)
Program cost per child reached, including LTFU (uncertainty range)	\$122 (\$113, \$131)	\$140 (\$137, \$142)	\$226 (\$207, \$246)	\$245 (\$229, \$261)
Predicted no. of monthly measurements showing wasting ⁵ per child (95% CI)	2.4 (2.1, 2.7)	3.1 (2.7, 3.5)	2.4 (2.1, 2.7)	2.3 (2.0, 2.5)

¹Costs calculated using realistic values for procurement and freight. Costs per child reach including LTFU are lower due to costs being spread over more recipients. CSB+, Corn-Soy Blend Plus; CSWB, Corn-Soy-Whey Blend; LTFU, lost to follow-up; RUSF, ready-to-use supplementary food; SC+, SuperCereal Plus; USD, US dollars; ViM, Victoire sur la Malnutrition.

²Uncertainty ranges for total cost per child were constructed based on minimum and maximum of the realistic product/commodity cost for CSB+, RUSF, SC+, and fortified vegetable oil. Uncertainty ranges for adjusted number of months with wasting were constructed based on 95% CIs around the adjusted marginal means estimated from the respective model.

³Predicted values are margins from logistic regression (stunting) and negative binomial regression (wasting) models. Models control for age; sex; maternal age; wealth; baseline anthropometric status; twin status; caregiver education; ethnicity; children <5 y in the household; household food insecurity; illness in the last 2 wk; season total distributions received; village-level access to water, sanitation, market, phone service, road, public transport, transport methods from the village, pharmacy, health center, and health agents.

⁴Stunting defined as length-for-age z score < -2. Model excludes LTFU.

⁵Wasting defined as weight-for-length z score < -2. Model includes LTFU.

prior to distribution. However, it was not air conditioned, and temperatures in Burkina Faso almost always exceed the recommended temperature limit of 26°C for storage of these products. The ViM program halted distribution of the reportedly bitter-tasting CSWB flour that had been stored for >9 mo and replaced it with a newer batch, but there were no problems with rancidity of any of the products. Laboratory testing confirmed that even the bitter CSWB was still safe for consumption. This differential reaction to storage conditions may have contributed to the finding based on self-report and direct observation of recipients, discussed in detail elsewhere, that the CSWB was diverted more than other products from the target recipient and not consumed as readily as the other study foods (26). Clearly, if the CSWB was consumed less by the target recipient than the other foods, potentially due to issues with acceptability after storage, it could not have been as effective in preventing undernutrition.

The study results confirm other recent research findings showing that foods used in blanket supplementary feeding programs have limited effectiveness in preventing declines in both wasting and stunting z scores. None of the 4 foods in this study was able to prevent the typical declines in z scores that occur during the last 18 mo of the critical 1000 d (4), although we do not know what would have occurred in a nonfood control group due to ethical considerations and the comparative purpose of this study. We found no recent studies of blanket supplementation that show significant effectiveness in preventing wasting. In both the studies above that compared LNSs with FBFs, the mean LAZ declined in all arms during the study follow-up periods, just as it did in our study (37, 38).

Many additional studies report similar results: despite supplementation with various SNFs, LAZ and WHZ declined in all intervention groups (13, 43–45). This limited effectiveness may be influenced by households that receive food supplements over long periods of time, adjusting intrahousehold allocation in a way that conforms with their assessment of the needs of the entire household instead of 1 target child. Although many studies have found high levels of diver-

sion from the target child (46–49), including the present study [results on this aspect are presented elsewhere; (26)], the theory that this may be related to long-term food supplementation has yet to be tested. Future studies should investigate how households adjust food allocation during long-term preventive supplementary feeding. We also know there are many factors besides food that affect growth and development (50–53), and supplementary feeding as an approach to improving growth may not be effective enough on its own. Taken together, these results call into question the effectiveness of the blanket supplementary feeding approach.

We estimated that the total program cost per enrolled child ranged from USD \$122 to USD \$245. Overall, it appears that the costs per enrolled child in this study are fairly comparable to those found in other similar studies. The Rang-Din Nutrition Study in Bangladesh reported USD \$156 per mother–child pair reached for maternal and child supplementation with 20 g/d small-quantity lipid-based nutrition supplements (LNS-SQ) for an intervention period of 12 mo, and USD \$102 per mother–child pair for maternal supplementation during pregnancy and lactation with iron/folic acid plus child supplementation with LNS-SQ (54). A study in urban Chad reported 374 euros (USD \$426) per child for the additional cost of adding 5-mo-long RUSF supplementation for children aged 6–26 mo in a general food-assistance program (13). Including cost in the evaluation of effectiveness in this study had implications for the overall conclusion. Three of the study arms performed similarly in effectiveness; this result alone implies that the choice of supplementary feeding product among these 3 arms would be inconsequential. However, integrating cost into the analysis reveals that only 1 product was the most cost-effective among the 4 choices. We argue that conclusions about food choices based on effectiveness results without consideration of cost-effectiveness are insufficient to inform policy decisions. Studies of supplementary feeding product effectiveness need to include such economic analysis in order to inform policy and programming recommendations more clearly.

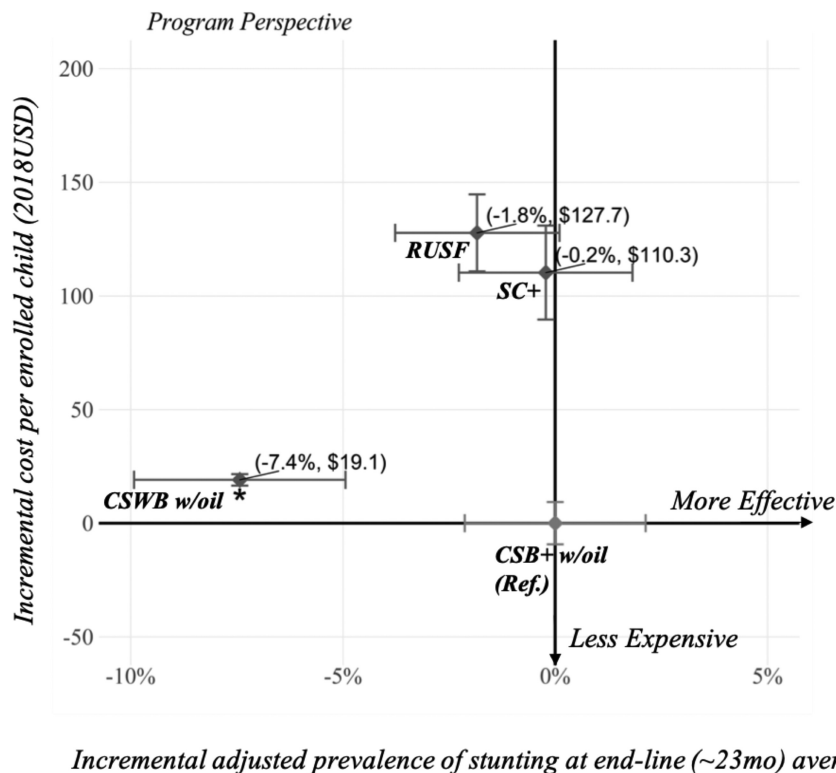


FIGURE 7 Incremental cost-effectiveness plane for stunting prevention among children participating in the supplementary feeding program “Victoire sur la Malnutrition” (ViM) in Sanmatenga Province, Burkina Faso, showing the program perspective and realistic procurement costs, 2014–2016. Both axes were constructed comparing each of the SC+, RUSF, and CSWB w/oil arms with the reference arm, CSB+ w/oil. Vertical uncertainty ranges for incremental costs from the program perspective were constructed based on 1 SD above and below the mean realistic product costs. Horizontal uncertainty ranges for adjusted incremental effectiveness were constructed based on 95% CIs around the adjusted marginal means estimated from the stunting statistical model that excluded lost to follow-up. * $P < 0.001$. Data label: (point estimate on incremental adjusted stunting prevalence, point estimate on incremental cost per enrolled child). CSB+, Corn-Soy Blend Plus; CSWB, Corn-Soy-Whey Blend; Ref., reference; RUSF, ready-to-use supplementary food; SC+, SuperCereal Plus; USD, US dollars.

Limitations

The most important limitation of this study is that it was not designed as a cluster-randomized trial, but rather, a geographically clustered one, due to logistical feasibility and concern for cross-contamination. It is possible that this study design could have affected our results if the clustered arms had homogeneous characteristics that could bias the results; however, the intracluster correlation coefficients for both the stunting and wasting outcomes were sufficiently low to allow the assumption that the outcomes in each geographic cluster were not correlated with each other more than they would be with those outside the cluster. In addition, we took measures to control for confounding of the geographic nature by including community-level characteristics in the models. We believe we accounted for all potential confounding factors and that arms were not inherently different from each other in ways that would affect our conclusions.

A second limitation is the definition of “lost to follow-up.” This definition was set based on the programmatic definition of endline to be the last visit when children would receive food rations. This means that there may be children who were missing only that single measurement but who were considered LTFU, and vice versa children who were missing many measurements but did have a value for the set endline

measurement. However, models excluding LTFU and those assuming best- and worst-case scenarios produced comparable results, so this definition of LTFU does not seem to have affected the study results.

Third, as we were not able to blind participants or researchers in this study, we cannot be sure that factors that may have influenced the comparative effectiveness of the foods, such as consumption of the foods by the target recipients, were not themselves influenced by participant or researcher preconception about the foods. However, standard SBCC messages regarding each of the foods ensured that none of the 4 foods was presented as more desirable, or of higher quality, than the others. No mention was made of one food being an improved version of another; all 4 foods were presented as having equal potential for stimulating growth and health. Further, in each geographic cluster, all beneficiaries received the same food. Therefore, it is unlikely that knowledge of which food was received, and thus any preconceptions about each food, influenced the way that recipients consumed the foods. There was little chance for communication among recipients of the different foods, thus little chance for consumption and preparation decisions to have been influenced by comparison of the received food with one of the other foods. It is more likely that the different qualities of the products lent themselves to differences in how caregivers prepared the foods and fed

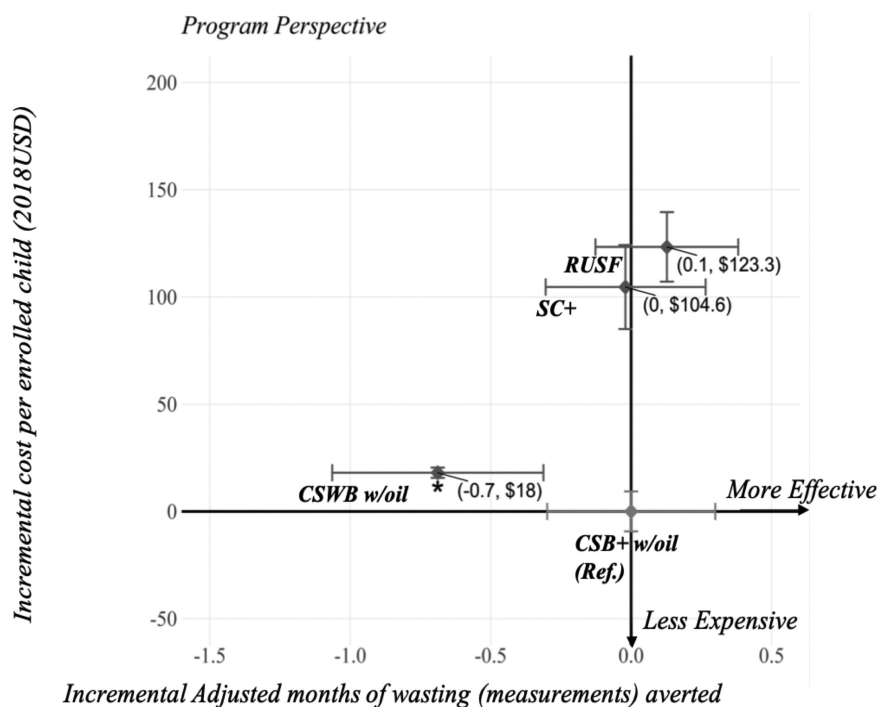


FIGURE 8 Incremental cost-effectiveness plane for wasting prevention among children participating in the supplementary feeding program “Victoire sur la Malnutrition” (ViM) in Sanmatenga Province, Burkina Faso, showing the program perspective and realistic procurement costs, 2014–2016. Both axes were both constructed comparing each of the SC+, RUSF, and CSWB w/oil arms with the reference arm, CSB+ w/oil. Vertical uncertainty ranges for incremental costs from the program perspective were constructed based on 1 SD above and below the mean realistic product costs. Horizontal uncertainty ranges for adjusted incremental effectiveness were constructed based on 95% CIs around the adjusted marginal means estimated from the wasting statistical model that included lost to follow-up. * $P = 0.02$. Data label: (point estimate on incremental adjusted months of wasting, point estimate on incremental cost per enrolled child). CSB+, Corn-Soy Blend Plus; CSWB, Corn-Soy-Whey Blend; Ref., reference; RUSF, ready-to-use supplementary food; SC+, SuperCereal Plus; USD, US dollars.

them to their children, which would not have been influenced by blinding. These differences in use of the foods are discussed in detail in a companion to the current paper (26).

Last, this study was designed to measure cost-effectiveness in terms of anthropometric outcomes. We therefore did not consider outcomes beyond anthropometry that may provide better indications of whether a child is thriving in the long term, such as neurocognition or body composition. Future studies should consider outcomes additional to anthropometry.

Conclusions

We found CSB+ w/oil to be the most cost-effective of 4 SNF products for the prevention of stunting and wasting among young children in Burkina Faso. However, the relative differences among the products' effectiveness were small, and overall, none of the products prevented declines in growth trajectories, calling into question the blanket supplementary feeding approach as a cost-effective strategy to prevent malnutrition on its own. Programmers and policy makers should note the importance of conducting detailed cost-effectiveness studies to evaluate how products work in true-to-life programs. Future studies should investigate programming options that can improve the performance of blanket food supplementation, regardless of product choice. With the

significant amount of money invested in food assistance, more cost-effectiveness research is needed to provide value-for-money and prevent malnutrition in as many children as possible.

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data management and analysis plans, assisted with statistical analyses and interpretation, and critically reviewed the manuscript; FG: supervised data collection and critically reviewed the manuscript; KC: assisted in research design and sample size calculation, advised on statistical analysis, and critically reviewed and edited the manuscript; SV: advised on cost-effectiveness analyses and critically reviewed the manuscript; SW and IR: assisted in research design and critically reviewed and edited the manuscript; PW: conceptualized and designed the study, advised on data collection and analysis decisions, and critically reviewed and edited the manuscript; BLR: conceptualized and designed the study, advised on data collection and analysis decisions, critically reviewed and edited the manuscript, and had primary responsibility for final content; and all authors: read and approved the final manuscript.

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