Complementary Feeding of Sorghum-Based and Corn-Based Fortified Blended Foods Results in Similar Iron, Vitamin A, and Anthropometric Outcomes in the MFFAPP Tanzania Efficacy Study

Nicole M Delimont (ID),[1] Christopher I Vahl,[2] Rosemary Kayanda,[4] Wences Msuya,[4]

Michael Mulford,[4] Paul Alberghine,[5] George Praygod,[6] Julius Mngara,[6] Sajid Alavi (ID),[3]

and Brian L Lindshield (ID)[1]

Departments of [1]Food, Nutrition, Dietetics and Health, [2]Statistics and [3]Grain Science and Industry, Kansas State University, Manhattan, KS; [4]Project Concern International—Tanzania, Mwanza, Tanzania; [5]USDA Foreign Agriculture Service; and [6]National Institute for Medical Research—Tanzania, Mwanza, Tanzania

ABSTRACT

Background: Fortified blended foods (FBFs) are micronutrient-fortified food aid products containing cereals and pulses. It has been suggested to reformulate FBFs to include whey protein concentrate, use alternative commodities (e.g., sorghum and cowpea), and utilize processing methods such as extrusion to produce them. The Micronutrient Fortified Food Aid Pilot Project (MFFAPP) efficacy study was designed to test the efficacy of complementary feeding of newly formulated FBFs.

Objectives: The aim of this study was to test the effectiveness of 5 newly formulated FBFs in combating iron deficiency anemia and vitamin A deficiency compared with traditionally prepared corn-soy blend plus (CSB+) and no intervention. A secondary aim was to determine the impact on underweight, stunting, wasting, and middle-upper arm circumference.

Methods: A 20-wk, partially randomized cluster study was completed. Two age groups (aged 6–23 and 24–53 mo) with hemoglobin status <10.3 g/dL, and weight-for-height z scores >−3 were enrolled and assigned to diet groups. Biochemical and anthropometric measurements were collected at 0, 10, and 20 wk.

Results: Both hemoglobin concentrations and anemia ORs were significantly improved in all intervention groups except for CSB+ and the no-intervention groups at week 20. Only extruded corn-soy blend 14 and the no-intervention age groups failed to significantly decrease vitamin A deficiency risk ($P < 0.04$). There were no consistent significant differences among groups in anthropometric outcomes.

Conclusions: FBFs reformulated with sorghum, cowpea, corn, and soy significantly improved anemia and vitamin A deficiency ORs compared with week 0 and with no intervention. Although newly formulated FBFs did not significantly improve vitamin A deficiency or anemia compared with CSB+, CSB+ was the only FBF not to significantly improve these outcomes over the study duration. Our findings suggest that newly formulated sorghum- and cowpea-based FBFs are equally efficacious in improving these micronutrient outcomes. However, further FBF refinement is warranted. This trial was registered at clinicaltrials.gov as NCT02847962.   *Curr Dev Nutr* 2019;3:nzz027.

Background

Approximately 29% of the world's 7 billion people suffer from micronutrient malnutrition (1). The most common micronutrient deficiencies are iron and vitamin A; nearly 2 billion people are iron deficient (2), and vitamin A deficiency remains the most common cause of preventable childhood blindness worldwide (3). Protein energy malnutrition is also common among children; Africa is the only region in the world that has experienced increased stunting numbers from 1990-2018, and in 2018, Southern Asia had the greatest number of stunted and wasted children (4).

Fortified blended foods (FBFs) are micronutrient-fortified cereal- and legume-based products that have been the primary source of food aid supplied globally for nearly 50 y (5). The primary form of food aid distributed by the USDA and the United States Agency for International Development (USAID) is corn-soy blend plus (CSB+) (6), a micronutrient-fortified, roasted FBF that is partially cooked, and hundreds of thousands of metric tons of specialized nutritious foods like it are distributed annually by the World Food Programme (7). The cost-nutrition benefits of FBFs have prompted their continued use as food aid (8); however, they have been criticized for their limited efficacy in treating young, malnourished children (9).

A 2011 food aid quality review report commissioned by the USAID encouraged development of new FBFs, specifically suggesting that sorghum could be a suitable commodity because it is not genetically modified, is locally and regionally available in many food aid–receiving areas, and is commonly consumed in sub-Saharan Africa (10). Cowpea is a potentially complementary commodity to sorghum because of its amino acid composition (11), its potential for intercropping, and its common availability in food aid–receiving regions (12). Despite potential benefits, sorghum has been found to have poor iron bioavailability and protein digestibility (13), potentially limiting its use in FBFs. One potential solution to this barrier is through the use of extrusion processing, which may improve the protein digestibility (14) and iron bioavailability (15) of sorghum through reductions in antinutritional factors (16) such as tannins or phytates.

To improve FBF formulation and related outcomes, the Micronutrient Fortified Food Aid Pilot Project (MFFAPP) team at Kansas State University created new FBFs, based on sorghum and cowpea, for infant and toddler complementary feeding through the collaboration of nutrition, agricultural economics, sensory analysis, and grain science investigators (17). Newly formulated FBF consumption resulted in similar protein quality, vitamin A, and iron bioavailability regardless of sorghum, cowpea, corn, and soy formulation in rats. CSB+ consumption resulted in significantly inhibited growth compared with newly formulated FBFs, suggesting that CSB+ might have poor protein quality compared with its newly formulated counterparts (18). The MFFAPP Tanzania efficacy study was designed to determine the effectiveness of newly formulated FBFs based on sorghum, cowpea, corn and soy in the field to improve iron, vitamin A, and anthropometric status, in complementary-fed children aged 6–53 mo.

Our primary hypotheses were that consumption of newly formulated FBFs would result in the following: *1*) similar or better vitamin A and iron outcomes compared with CSB+; and *2*) improved outcomes compared with no intervention. To that end, RBP and hemoglobin were our primary outcome measures. Secondary hypotheses were that newly formulated FBFs would result in the following: *1*) similar or improved anthropometric outcomes compared with CSB+; and *2*) improved outcomes compared with no intervention. Anthropometric outcomes are secondary due to the relatively short study duration (20 wk), and the expected limited change in anthropometric outcomes in this time frame.

Methods

Study design and setting

The details of this trial have been published in a protocol paper previously (17), and the trial was registered at clinicaltrials.gov as NCT02847962. In brief, a 20-wk cluster randomized trial was conducted in the Mara region of Tanzania in partnership with Project Concern International, who had an established McGovern Dole school-based feeding program in the region, and the National Institute for Medical Research, Tanzania. After written and verbal guardian consent was obtained, 21 village-based health facilities were divided into 7 diet groups with 2 age-group arms (6–23 and 24–53 mo). Randomization procedures are described elsewhere (17). In brief, age groups were chosen to determine the effect of FBFs *1*) during the transition from exclusive breastfeeding to solid foods; and *2*) in preschool children (17).

Interventions

Five intervention groups received newly formulated extruded sorghum-cowpea FBFs [white sorghum-cowpea (WSC1), WSC2, red sorghum-cowpea (RSC)], a white sorghum-soy FBF (WSS), an extruded corn-soy FBF (CSB14), or a traditional nonextruded corn-soy FBF (CSB+); the no-intervention group did not receive any FBF during the study period. Participants in the intervention group did not receive any incentive for their participation beyond the food products. The no-intervention group received a ball or soap as incentive to have the 0- and 10-wk measurements collected, and received FBF for 20 wk after the intervention period. After their 20-wk measurements were collected, they received their first FBF distribution. Newly formulated, extruded FBFs were developed based on USAID/Food Aid Quality Review recommendations (17), and were distributed with the expectation that infants and children aged 6–12, 12–24, and 24–60 mo would consume 65, 120, and 230 g, respectively, of FBF daily (∼50% of daily caloric and micronutrient requirements), consistent with USAID/Food Aid Quality Review recommendations (10). Households with children receiving FBF were provided with enough food for 3 other children or family members (500 g/d) to increase the likelihood that the participating child would consume the FBF. Caregivers received instructions on how to prepare and feed the FBF in a manner consistent with the child's normal feeding practices (19), but were encouraged to feed the child 3 times/d, and continue breastfeeding, if they were doing so. To monitor compliance to study protocols, several methods were employed. At each 2-wk pickup, caregivers were asked about porridge preparation and acceptability. At week 10, caregivers were asked about portion sizes, and how often the child was receiving porridge (unpublished results). During home visits, researchers observed preparation, measured temperatures, looked at storage conditions, and measured consistency (thickness of the porridge) of the porridge (unpublished results).

Subjects, randomization, and recruitment

Subjects were recruited by Project Concern International–Tanzania in conjunction with village and health facility leaders, and except for the no-intervention group, were randomly assigned to FBFs. Guta village was assigned as the no-intervention group nonrandomly because of its geographic proximity away from the other health facilities, to minimize FBF sharing or selling to this group. For practical reasons, neither study participants nor the study staff were blinded to the FBF provided. The protocol was approved by ethics boards of the National Medical Research Institute, Tanzania, and Kansas State University (IRB #7184).

Children were aged 6–53 mo, nonexclusively breastfeeding, were not enrolled in school, met 2 health criteria [hemoglobin <10.3 mg/dL, or weight-for-height z score (WHZ) >−3] based on screening data obtained prior to study initiation, and caregivers were willing to travel to health facility sites for assessment and FBF pickups (17).

Outcome measurements

Study assessments were conducted by the National Medical Research Institute, Tanzania, at weeks 0, 10, and 20 of intervention (17). Assessments included a health-screening questionnaire, anthropometric measurements [height/length, weight, and middle-upper arm circumference (MUAC)], and hemoglobin concentration (Hemocue); dried blood spots were obtained for later C-reactive protein (CRP) and retinol-binding protein (RBP) analysis (17).

Anemia classification was categorized by 2011 WHO definitions (20). Before analysis and classification, raw RBP and CRP were log transformed (21, 22), and RBP was adjusted for the lowest decile of CRP from aggregate subject data with the use of the equation:

$$\text{adjusted RBP} = [\text{unadjusted RBP} - (\text{regression coefficient for CRP})$$
$$\times (\text{CRP} - (\text{maximum CRP in lowest 10\% of CRP}))] \ (21).$$

From these data, vitamin A deficiency was categorized by RBP <17.325 ng/dL (23).

Weight-for-age z scores (WAZs), height for age z scores (HAZs), and WHZs (24) were calculated according to the 2006 WHO definitions for each intervention group at each measurement point with the use of data management software (ENA Smart, 2011). Stunting and underweight prevalence were classified based on WAZ and HAZ; stunting was defined as HAZ $\leq$ −2, and underweight as WAZ $\leq$ −2 (24).

Sample size and statistical analysis

Statistical analysis procedures are outlined elsewhere (17). In brief, sample size was calculated with a paired t test calculator with a power of 0.8 and α of 0.05 where differences were calculated from efficacy studies assessing hemoglobin and serum retinol. Hemoglobin sample size was used because it was larger, and a 25% attrition estimate was added.

Overview of analysis.

Data were analyzed with SAS Studio version 3.6 statistical software; statistical significance was set in a 2-factor test where $P < 0.05$. All data are presented as mean $\pm$ SD, and were measured and analyzed at the individual participant level. Before analysis, all data were assessed for normality via quantile-quantile plots and homogeneity of variance through the use of Levene's tests. Variables that were nonnormal were

transformed before analysis. Log-transformed variables were included in stepwise variable selection in adjusted model building. All log-transformed data were back-transformed for presentation of the results. For all outcomes, pairwise comparisons were made only after rejecting the null hypothesis ($P < 0.05$, 2-sided testing) for the outcome.

Analysis of baseline and dropout data.

Before outcomes analysis, participants excluded from analysis were removed from the data set, and all week 0 data, including outcome and potential covariate variables, were analyzed for significant differences between FBF groups in each age category in order to define adjustments needed in outcomes analysis. Numeric data [including age, weight, height, WAZ defined elsewhere (17)] were analyzed with multivariate ANOVA by FBF and age groups. Categoric data [gender, illness state, and others defined elsewhere (17)] were analyzed by chi-square testing. Drop-out reasons and attrition rates were compared by FBF and age group through ANOVA testing, and through Bonferroni pairwise comparison.

Confounding and covariate analysis of baseline data.

In addition to individual factor analysis, composite scores for improved and unimproved toilet and water sources, technology, animal ownership, animal and plant protein consumption, green leafy vegetable consumption, and carotenoid-rich food consumption were generated by creating sum-scores from binary data categories to potentially increase the power of individual variables assessed during data collection (17). Composite scores for improved and unimproved water sources were qualified by WHO definitions (25), previously correlated with WAZs and HAZs in children. We defined composite score factors, including technology sum score, meat livestock ownership, household members, illness score, dietary diversity, meat consumption, animal protein consumption, plant protein consumption, green leafy vegetable consumption, and carotenoid-rich food consumption, from week 0 data collection time points due to their potential impact on outcomes measures with the use of data from similar studies (25–31).

In order to build models for analysis, all individual and composite nonoutcomes data were analyzed through manual backwards regression to identify significant covariates for each outcome measure in each age group. Both composite and individual covariates were then incorporated into model building after defining significant models for each outcome variable.

Outcomes analysis

Variables found to be nonnormal and log adjusted for analysis through the use of the methods above included RBP and CRP. Differences in continuous data, including height, length, hemoglobin, RBP, MUAC, WAZ, HAZ, and WHZ, were analyzed by ANOVA with Bonferroni adjustment (for unadjusted models) and ANCOVA (for adjusted models) at weeks 0, 10, and 20. Categoric data, including anemia, vitamin A deficiency, underweight (WAZ $<$ −2), stunting (HAZ $<$ −2), and wasting (WHZ $<$ −2), were analyzed by multiple logistic regression analysis with Bonferroni adjustment. Multiple regression was used to adjust outcomes for repeated (health facility) and random covariates found to be significant at week 20 for each outcome measure for numeric (hemoglobin, RBP, WAZ, HAZ, MUAC, and WHZ) and categoric (anemia and vitamin A deficiency) variables (17). The

unadjusted effect of treatment was first assessed, and the analysis was repeated with covariates that were associated with the outcome ($P < 0.05$, established in manual backwards regression outlined above). For categoric outcomes, statistical comparison was based on the log OR of the outcome occurring. Absolute risk reduction and number needed to treat for anemia was calculated for all FBFs compared with CSB+.

In addition to comparisons at week 0, 10, or 20 for each outcome, timewise comparisons were made to compare movement between illness states. Data were defined by category: anemia was classified as severe, moderate, or mild; WAZ, HAZ, and WHZ were defined within z score movements (0, -1, -2, or -3); and RBP was classified as vitamin A deficiency or no deficiency (RBP cutoff <17.325 ng/dL). From these data, movement between categories for each outcome measure were defined as improvement, maintenance, or deterioration of each outcome measure from week 0 to week 20. Week 20 outcomes were then analyzed by multiple logistic regression and adjusted for covariates through manual backwards regression. Final outcomes (anemia, vitamin A deficiency, underweight, stunting, and acute malnutrition) were presented by the probability of improvement, maintenance, or deterioration from week 0 to week 20.

Effect size and post-hoc sample analysis.
To quantify the effect of FBFs, we calculated effect sizes of anthropometric outcomes through the use of Hedges' g at a 95% CI (32).

We calculated post-hoc sample size to look at anthropometric power with the use of the Power and Sample Size calculation version 3.12 (2014; http://biostat.mc.vanderbilt.edu/wiki/Main/PowerSampleSize) with $\alpha = 0.05$ and power $= 0.90$.

Results

For the sake of brevity, only week 0 and week 20 results are described, although week 10 results are also presented in the tables and figures.

Participant enrollment and retention
Screening for the trial is outlined elsewhere (17). In brief, total eligibility for the study was 23.6% of potential participants screened from August to December 2015. Intervention group sizes ranged from 234 to 289 participants; the primary reason for ineligibility in the study were hemoglobin values >10.3 mg/dL (71.7% of participants screened). Subject inclusion rates for the study within diet groups ranged from 19% to 47%. The final number of participants was 2186 (1160 and 1026 in the 6–23- and 24–53-mo age groups, respectively); 84.4% and 86.7% of the 6–23- and 24–53-mo age groups, respectively, completed the study, which was conducted between January and July 2016 (**Figure 1**). There were no significant differences in dropout rates between all intervention groups and the no-intervention group ($P = 0.07$).

The major reasons subjects had for terminating their participation in the study included travel restrictions that prevented the caregiver from receiving the FBF (34.1%), voluntary discontinuation (25.6%), hospitalization (22.0%), marriage separation (13.3%), or death (3.8%). Reasons for dropout from the study were similar across diet groups. Children were excluded from analysis post hoc for late measurement that lead to multiple days of missed FBF consumption ($n = 30$ and 40 in the 6–23- and 24–53-mo groups, respectively), and hospitalization for

illness during the study [15 total, from malaria ($n = 9$), life-threatening anemia ($n = 2$), or fever ($n = 4$)]. The CSB+ group notably had the highest rate of attrition and late measurement days (34.3% and 23.7% in the 6–23- and 24–53-mo age groups, respectively), 75% of voluntary discontinuation attrition was in the CSB+ group (36 of 48). Final analysis included 951 and 858 children in the 6–23- and 24–53-mo age groups, respectively.

Week 0 demographics and outcomes measurements
Among both age groups, there were no significant differences in age, gender, maternal education, housing, livestock ownership, number of main meals consumed daily, breastfeeding, porridge preparation, handwashing, and symptoms of acute illness in the 2 wk before the survey was conducted (**Table 1**). In the 6–23-mo age groups, consumption of plant ($P < 0.001$) and animal proteins ($P = 0.02$), improved water and toilet sources ($Ps = 0.001$), and access to electricity ($P = 0.01$) among the groups were significantly different, whereas there were significant differences in consumption of animal ($P = 0.02$) and plant proteins ($P = 0.001$) among the 24–53-mo age groups.

There were limited significant anthropometric differences between diet groups. The 6–23-mo RSC group had significantly greater MUACs and WAZs than the no-intervention group (14.2 $\pm$ 1.0 cm compared with 13.7 $\pm$ 1.4 cm, $P = 0.047$; and -1.5 ± 1.3 compared with -1.0 ± 1.2, $P = 0.017$; Table 1). In the 24–53-mo groups, there were significantly greater body lengths and HAZs in the RSC compared with the CSB14 groups (89.3 $\pm$ 7.2 cm compared with 86.4 $\pm$ 6.8 cm, respectively, $P = 0.042$; and -2.3 ± 1.3 compared with -1.7 ± 1.3, $P = 0.005$). There was a significantly lower MUAC in the CSB+ (14.5 $\pm$ 1.2 cm) compared with the WSC2 (14.9 $\pm$ 1.4 cm) and the RSC groups (15.1 $\pm$ 1.2 cm, $P < 0.001$). The RSC group 24–53-mo MUACs (15.1 $\pm$ 1.2 cm) were significantly greater than those of the WSC1 (14.5 $\pm$ 1.2 cm) and WSS (14.3 $\pm$ 1.1 cm) groups ($P < 0.001$).

Anemia (70.2–88.4%, $Ps > 0.155$) and vitamin A deficiency (45.9%–68.3%, $Ps > 0.125$) prevalences were high, but not significantly different between groups. Underweight prevalence in the 6–23-mo group was 15.8–35.5%, and significantly greater in the no-intervention group (35.5%) compared with the CSB14 (19.8%; $P = 0.004$), RSC (15.8%, $P = 0.0003$), and WSC1 (19.9%, $P = 0.006$) groups. The WSC2 (18.0%) and RSC (15.5%) 24–53-mo age groups had significantly lower underweight prevalence than the no-intervention (30.4%, all $P < 0.02$), WSC1 (29.5%, $P < 0.03$), and WSS (34.4%, $P < 0.01$) groups. Stunting prevalence was significantly greater in the 6–23-mo no-intervention (53.2%), WSC2 (53.4%), and CSB14 (51.6%) groups compared with the CSB+ (37.5%, $Ps < 0.008$), and RSC (36.3%, $Ps < 0.004$) groups. There were no stunting (47.9–55.4%, $P = 0.135$), or wasting (1.6–5.3%, $P = 0.383$) differences observed among 24–53-mo age groups.

Week 20 outcomes
Identified covariates for model adjustment.
Variables identified as significant during backwards logistic regression for age and outcomes were identified for multivariate outcomes analysis. Hemoglobin covariates identified for participants 6–23 mo old included week 0 hemoglobin, week 0 WAZ, week 20 WAZ, week 20 MUAC, ownership of meat livestock, dietary diversity, consumption of animal protein, consumption of carotenoid-rich foods, and health and illness
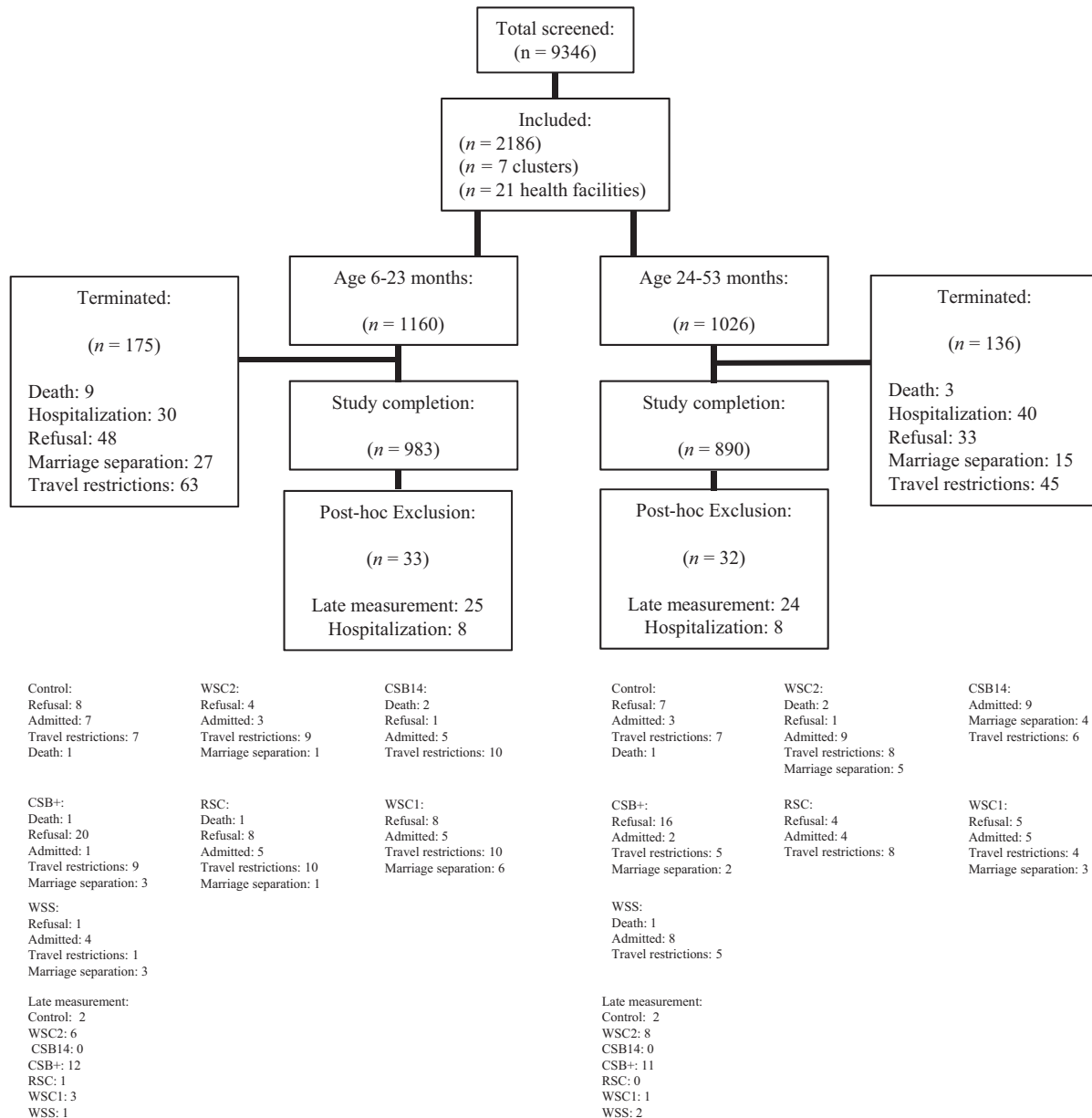
Total screened:
(n = 9346)

Included:
(*n* = 2186)
(*n* = 7 clusters)
(*n* = 21 health facilities)

Age 6-23 months:

(*n* = 1160)

Age 24-53 months:

(*n* = 1026)

Terminated:

(*n* = 175)

Death: 9
Hospitalization: 30
Refusal: 48
Marriage separation: 27
Travel restrictions: 63

Terminated:

(*n* = 136)

Death: 3
Hospitalization: 40
Refusal: 33
Marriage separation: 15
Travel restrictions: 45

Study completion:

(*n* = 983)

Study completion:

(*n* = 890)

Post-hoc Exclusion:

(*n* = 33)

Late measurement: 25
Hospitalization: 8

Post-hoc Exclusion:

(*n* = 32)

Late measurement: 24
Hospitalization: 8

Control:
Refusal: 8
Admitted: 7
Travel restrictions: 7
Death: 1

WSC2:
Refusal: 4
Admitted: 3
Travel restrictions: 9
Marriage separation: 1

CSB14:
Death: 2
Refusal: 1
Admitted: 5
Travel restrictions: 10

Control:
Refusal: 7
Admitted: 3
Travel restrictions: 7
Death: 1

WSC2:
Death: 2
Refusal: 1
Admitted: 9
Travel restrictions: 8
Marriage separation: 5

CSB14:
Admitted: 9
Marriage separation: 4
Travel restrictions: 6

CSB+:
Death: 1
Refusal: 20
Admitted: 1
Travel restrictions: 9
Marriage separation: 3

RSC:
Death: 1
Refusal: 8
Admitted: 5
Travel restrictions: 10
Marriage separation: 1

WSC1:
Refusal: 8
Admitted: 5
Travel restrictions: 10
Marriage separation: 6

CSB+:
Refusal: 16
Admitted: 2
Travel restrictions: 5
Marriage separation: 2

RSC:
Refusal: 4
Admitted: 4
Travel restrictions: 8

WSC1:
Refusal: 5
Admitted: 5
Travel restrictions: 4
Marriage separation: 3

WSS:
Refusal: 1
Admitted: 4
Travel restrictions: 1
Marriage separation: 3

WSS:
Death: 1
Admitted: 8
Travel restrictions: 5

Late measurement:
Control: 2
WSC2: 6
 CSB14: 0
CSB+: 12
RSC: 1
WSC1: 3
WSS: 1

Late measurement:
Control: 2
WSC2: 8
CSB14: 0
CSB+: 11
RSC: 0
WSC1: 1
WSS: 2

FIGURE 1 Participant inclusion, exclusion, dropout, and completion information. Nearly 9500 children were screened for study participation; the majority were excluded for hemoglobin >10.3 g/dL. Of the 2186 children included in the study, 983 aged 6–23 mo and 890 aged 24–53 mo completed the study. Post hoc, 65 participants were excluded from data analysis, either for late outcomes measurement or for hospitalization during the study.

at week 20. Hemoglobin for participants aged 24–53 mo included adjustment for baseline hemoglobin, week 0 MUAC and weight, week 20 MUAC, WAZ, HAZ, and WHZ, consumption of carotenoid-rich foods, family ownership of chickens, mother-to-child prevention of HIV therapy, week 20 illness, and health scores.

RBP was adjusted for week 0 RBP, children on antiretroviral therapy, gender, breastfeeding status, and health and illness at weeks 0 and 20 for the 6–23-mo-old groups, whereas RBP was adjusted for week 0 RBP, ownership of meat livestock, and health and illness at weeks 0 and 20 in the 24–53-month-old groups.

There were no significant adjusted models for anthropometric data, which have not been included.

Hemoglobin and Anemia.
The anemia OR was adjusted for covariates including ownership of chickens, week 0 height, MUAC, hemoglobin, and week 20 MUAC and WHZ after being identified as significant covariates in backwards regression (**Figures 2** and **3**). Unadjusted and adjusted hemoglobin concentrations in the 6–23-mo groups were significantly higher in the WSC2, CSB14, and RSC groups compared with the no-intervention

TABLE 1 Week 0 study retention, demographic, micronutrient, and anthropometric status measures[1]

| | No intervention | FBF | | | | | | P |
		WSC2	CSB14	CSB+	RSC	WSC1	WSS	
6–23 mo old, n	124	133	157	112	146	136	122	
Retention, %	85.1	84.7	87.2	77.2	86.5	81.1	87.3	0.07
Age, mo	15.2 ± 4.7	15.5 ± 5.0	15.1 ± 4.8	15.6 ± 4.7	15.1 ± 4.7	16.2 ± 4.7	15.9 ± 4.9	0.37
Gender (F), %	54.2	59.4	50.3	56.3	46.6	53.3	52.4	0.462
Breastfeeding, %	62.6	66.9	66.7	59.1	67.6	56.2	62.1	0.356
Hemoglobin, g/dL	9.7 ± 1.3	10.1 ± 1.3	10.0 ± 1.3	9.8 ± 1.4	10.0 ± 1.4	10.1 ± 1.2	9.8 ± 1.4	0.084
RBP, ng/dL	21.9 ± 66.7	19.8 ± 68.2	24.9 ± 57.4	29.9 ± 58.1	13.8 ± 51.3	18.0 ± 57.3	20.3 ± 51.9	0.176
Length, cm	73.8 ± 6.1	73.0 ± 5.8	73.8 ± 6.0	74.7 ± 6.2	74.6 ± 6.2	74.6 ± 5.0	74.3 ± 5.4	0.306
Weight, kg	8.7 ± 1.6	8.6 ± 1.7	9.0 ± 1.7	9.0 ± 2.1	9.3 ± 3.1	9.0 ± 1.4	8.9 ± 1.5	0.084
MUAC, cm	13.7 ± 1.4[a]	13.8 ± 1.1[a,b]	14.0 ± 1.2[a,b]	14.1 ± 1.1[a,b]	14.2 ± 1.0[b]	13.9 ± 1.1[a,b]	13.9 ± 1.1[a,b]	0.040
WAZ	−1.5 ± 1.3[a]	−1.4 ± 1.4[a,b]	−1.1 ± 1.2[a,b]	−1.1 ± 1.2[a,b]	−1.0 ± 1.2[b]	−1.2 ± 1.1[a,b]	−1.2 ± 1.3[a,b]	0.017
HAZ	−2.1 ± 1.4	−2.1 ± 1.8	−1.9 ± 1.5	−1.7 ± 1.4	−1.6 ± 1.3	−1.9 ± 1.2	−1.9 ± 1.6	0.108
WHZ	−0.6 ± 1.1	−0.5 ± 1.1	−0.2 ± 1.0	−0.4 ± 1.2	−0.3 ± 1.0	−0.3 ± 1.0	−0.4 ± 1.1	0.12
24–53 mo old, n	112	122	125	117	123	112	131	
Retention, %	85.5	82.8	86	82.7	89.7	86.2	89.1	0.23
Age, mo	36.4 ± 8.6	36.8 ± 8.7	35.0 ± 7.9	35.6 ± 9.2	36.1 ± 8.3	36.1 ± 8.3	35.6 ± 8.2	0.71
Gender (F), %	52.7	46.7	56.8	57.3	49.6	39.3	56.3	0.056
Breastfeeding, %	0.8	1.6	3.2	4.2	1.6	2.7	0.8	0.441
Hemoglobin, g/dL	10.1 ± 1.5	10.0 ± 1.7	10.3 ± 1.5	10.3 ± 1.4	10.5 ± 1.4	10.2 ± 1.5	10.4 ± 1.3	0.161
RBP, ng/dL	23.5 ± 38.6	23.3 ± 38.1	24.0 ± 34.2	22.3 ± 34.2	16.1 ± 34.7	23.4 ± 35.7	17.2 ± 31.3	0.07
Length, cm	87.6 ± 7.4[a,b]	88.1 ± 6.9[a,b]	86.4 ± 6.8[a]	87.4 ± 8.3[a,b]	89.3 ± 7.2[b]	87.5 ± 6.6[a,b]	86.9 ± 7.1[a,b]	0.0424
Weight, kg	12.0 ± 2.0	12.4 ± 2.1	12.2 ± 4.2	11.9 ± 2.3	12.6 ± 2.0	11.9 ± 1.8	12.0 ± 3.6	
MUAC, cm	14.7 ± 1.2[a,b,c]	14.9 ± 1.4[a,c]	14.7 ± 1.4[a,b,c]	14.5 ± 1.2[b]	15.1 ± 1.2[c]	14.5 ± 1.2[a,b]	14.3 ± 1.1[a,b]	<0.001
WAZ	−1.4 ± 1.2	−1.2 ± 1.0	−1.3 ± 1.7	−1.4 ± 1.2	−1.0 ± 1.0	−1.5 ± 1.0	−1.4 ± 2.2	0.06
HAZ	−2.0 ± 1.6[a,b]	−2.1 ± 1.2[a,b]	−2.3 ± 1.3[a]	−2.1 ± 1.6[a,b]	−1.7 ± 1.3[b]	−2.2 ± 1.2[a]	−2.2 ± 1.3[a]	0.005
WHZ	−0.3 ± 1.0	−0.0 ± 1.1	−0.2 ± 1.1	−0.3 ± 1.0	−0.3 ± 0.9	−0.4 ± 0.9	−0.4 ± 1.0	0.061

[1]Data are presented as means ± SDs, unless otherwise indicated. Different letters indicate statistical significance ($P < 0.05$). CSB14, corn-soy blend 14; CSB+, corn-soy blend plus; HAZ, height-for age z score; MUAC, middle upper arm circumference; RBP, retinol-binding protein; RSC, red sorghum-cowpea; WAZ, weight-for-age z score; WHZ, weight-for-height z score; WSC1, white sorghum-cowpea 1; WSC2, white sorghum-cowpea 2; WSS, sorghum-soy blend.

group, and hemoglobin concentrations were significantly improved from week 0 in all intervention groups but not in the no-intervention group in unadjusted models (**Tables 2** and **3**). There were no significant differences between intervention groups in the adjusted or unadjusted 24–53-mo group hemoglobin concentrations (Tables 2 and 3).

All intervention groups had significantly reduced adjusted anemia OR compared with week 0. The adjusted anemia OR was significantly decreased in both CSB14 age groups and in the 6–23-mo WSC2 and RSC groups (Figure 2). The no-intervention and CSB+ groups were the only ones that failed to significantly reduce adjusted anemia OR in either age group (Figure 2) compared with week 0. All 6–23-mo intervention groups, except CSB+, had significantly decreased adjusted anemia OR compared with the no-intervention group. Compared with CSB+, the 6–23-mo adjusted anemia OR was significantly reduced in the WSC2 and CSB14 groups. There were no significant differences in adjusted anemia OR between all 24–53-mo age groups (Figure 3). There were no significant differences in anemia classification improvement, staying the same, or worsening (Ps > 0.05) from week 0 to week 20. The probability of anemia worsening from week 0 to week 20 was 3–7.1% in the FBF groups, and 9.6 and 3.8% in the 6–23- and 24–53-mo no-intervention groups, respectively.

RBP.

Vitamin A deficiency risk was adjusted for covariates including week 0 vitamin A deficiency prevalence, health, and illness at weeks 0 and 20 in both age groups (**Figures 4** and **5**). All 6–23-mo age groups

had significantly greater unadjusted RBP concentrations than the CSB14 group (Ps < 0.0456; Table 2). The RSC group unadjusted RBP concentrations were significantly greater than all 6–23-mo age groups (Table 2). The CSB14 6–23-mo age group adjusted RBP concentrations were significantly decreased compared with the RSC group ($P = 0.025$; Table 3), which was the only intervention group whose RBP values increased during the intervention period. The 24–53-mo CSB14 group RBP concentrations were significantly lower than all other groups. All 24–53-mo age groups, except CSB14, had significantly improved RBP concentrations from week 0 to week 20 (Tables 2 and 3).

The risk of vitamin A deficiency in the 6–23-mo groups was also adjusted by gender and breastfeeding status (Figures 4 and 5). In both age groups, only CSB+, WSC1, and WSS significantly decreased vitamin deficiency risk compared with week 0. In both age groups, vitamin A deficiency risk was significantly lower in the RSC compared with the no-intervention and CSB14 groups.

There were significant decreases in vitamin A deficiency OR in both RSC age groups relative to the no-intervention ($P = 0.61$ and 0.61 compared with 0.28 and 0.25 in the 6–23- and 24–53-mo groups, respectively), and CSB 14 ($P = 0.28$ and 0.29 in the 6–23- and 24–53-mo groups, respectively) groups. In addition, vitamin A deficiency OR was significantly decreased in the 24–53-mo WSC1 ($P = 0.45$) and WSS ($P = 0.47$) groups compared with the no-intervention group. The probability of becoming vitamin A deficient during the study was 2–5% in all age groups except in the CSB14 groups; there was a probability of deterioration of 7–9% in the CSB14 and no-intervention groups.
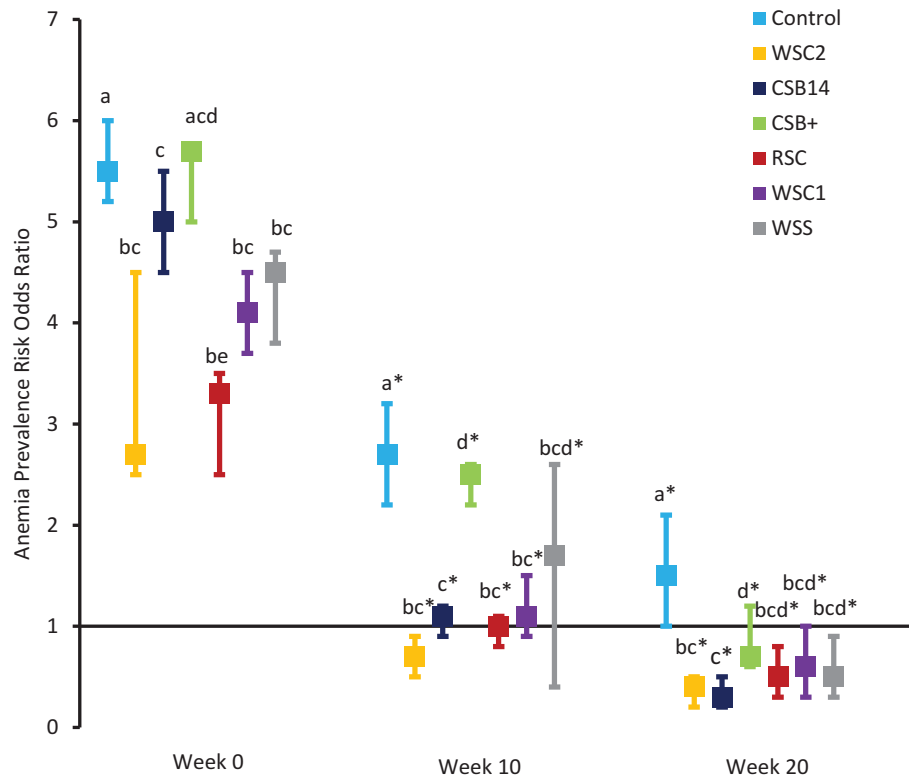
FIGURE 2 Adjusted anemia week 0, week 10, and week 20 ORs for the groups aged 6–23 mo. Week 20 anemia OR adjusted by: week 0 height, MUAC, and hemoglobin, week 20 MUAC and WHZ, and for ownership of chickens. *Significantly different compared with week 0 (*P* < 0.05). Different letters indicate significant differences between groups (*P* < 0.05). CSB14, corn-soy blend 14; CSB+, corn-soy blend plus; MUAC, middle-upper arm circumference; RSC, red sorghum-cowpea; SSB, sorghum-soy blend; WHZ, weight-for-height *z* score; WSC1, white sorghum-cowpea 1; WSC2, white sorghum-cowpea 2.

Weight, WAZ, and Underweight.

In the 6–23-mo groups, the RSC group unadjusted weight was significantly greater than the no-intervention group (Table 3), and the unadjusted WAZs were significantly greater in the CSB14 and RSC groups compared with the no-intervention and WSS groups. There were significant improvements in unadjusted 6–23-mo WSC2 group unadjusted WAZ from week 0 to week 20, and the 6–23-mo CSB14 and RSC groups had significantly greater unadjusted WAZs than the no-intervention and WSS groups. The 24–53-mo WSC and RSC group unadjusted WAZs were significantly greater than those in the WSC1 and WSS groups. There were no significant group differences in adjusted weight or WAZ.

The 6–23-mo underweight prevalence was significantly decreased in the WSC1 (4.6%) group compared with the no-intervention group (11.3%, *P* = 0.02). Compared with the 6–23-mo WSS group (15.6%), underweight prevalence was significantly decreased in the WSC1 (8.9% *P* = 0.002), WSC2 (7.6%, *P* = 0.03), and CSB+ (7.4%, *P* = 0.049) groups. The 24–53-mo underweight prevalence was significantly decreased in the WSC2 (5.2%) compared with the no-intervention (13.6%, *P* = 0.02), CSB+ (14.5%, *P* = 0.01), WSC1 (12.7, *P* = 0.03), and WSS (13.9, *P* = 0.015) groups. The underweight prevalence rate effect sizes of both CSB+ age groups were not different compared with the newly formulated FBF groups (6–23-mo groups: *d* = −0.03; 95% CI: −0.30, 0.24; *P* = 0.33; and 24–53-mo groups: *d* = 0.21; 95% CI: −0.09,

0.45; *P* = 0.19). CSB14 effect sizes were negligible and not significant compared with CSB+.

There were no significant differences in WAZ improvement, staying the same, or deterioration among the 24–53-mo groups (*P* = 0.09–0.18; *P*s > 0.05); however, there was a significantly greater probability of improvement of all 6–23-mo groups compared with WSS (*P* = 0.14–0.20 in FBFs compared with 0.07 in WSS, *P*s < 0.05). The probability of a deteriorating WAZ during the study was 5–14% for all age groups.

Length, HAZ, and stunting.

There were no significant body length or HAZ (unadjusted and adjusted) differences between the 6–23- and 24–53-mo groups (Tables 2 and 3). There were significant length improvements in all 6–23-mo FBF groups, and all 24–53-month FBFs groups except the RSC and no-intervention groups from week 0 to week 20. The 6–23-mo RSC group unadjusted HAZs were significantly decreased compared with the no-intervention (*P* = 0.047) and WSS (*P* = 0.0016) groups. There were no significant differences in 24–53-mo length or unadjusted HAZ (*P*s > 0.135), or adjusted 6–23-mo (*P*s > 0.1025) and 24–53-mo (*P*s > 0.11) HAZ.

After covariate adjustment for week 0 stunting prevalence, maternal weight, and week 0 breastfeeding, stunting rates were significantly improved in all 6–23-mo groups compared with the WSS group (prevalence rates: 31.1–39.9% compared with 59.3%, *P*s < 0.006). There
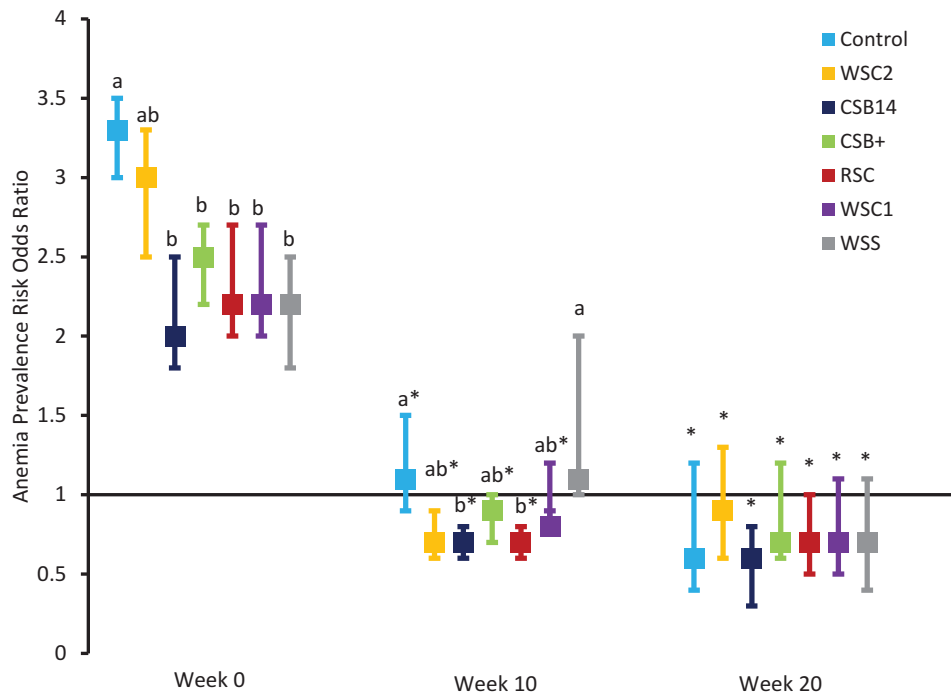
FIGURE 3 Adjusted anemia week 0, week 10, and week 20 ORs for the groups aged 24–53 mo. Week 20 Anemia odds ratio adjusted by: week 0 height, MUAC, and hemoglobin, week 20 MUAC and WHZ, and for ownership of chickens. ∗Significantly different compared with week 0 ($P < 0.05$). CSB14, corn-soy blend 14; CSB+, corn-soy blend plus; MUAC, middle-upper arm circumference; RSC, red sorghum-cowpea; SSB, sorghum-soy blend; WHZ, weight-for-height z score; WSC1, white sorghum-cowpea 1; WSC2, white sorghum-cowpea 2.

was no significant difference in 6–23-mo stunting prevalence between groups (46.8%, $Ps > 0.06$); the 24–53-mo WSC2 group had significantly reduced stunting prevalence compared with all groups (15.1% compared with 34.9–39.7%, $Ps < 0.005$). There were no significant differences in stunting effect size in the newly formulated FBF groups compared with CSB+; CSB14 effect sizes were nonsignificant and minimal compared to CSB+ in the 6–23-mo ($d = −0.02$; 95% CI: −0.30, 0.25; $P = 0.46$) and 24–53-month ($d = 0.02$; 95% CI: −0.25, 0.28; $P = 0.90$) age groups.

In time-adjusted modeling for stunting classification, there were no significant differences in subjects who improved, stayed the same, or deteriorated among groups ($P = 0.02–0.09$; $Ps > 0.06$). The probability of improvement in HAZ categorization was highest in the 24–53-mo WSC1 and WSC2 groups ($P > 0.08$), and lowest in the 6–23-mo WSS groups ($P = 0.02$). The probability of WAZ deteriorating over the course of the trial was 7–17% across age groups.

MUAC and WHZ.
There were no significant changes in unadjusted and adjusted WHZs for any age group from week 0 to week 20, but the 6–23-mo RSC group unadjusted WHZs were significantly greater than those of the no-intervention and CSB+ groups ($P = 0.02$ and 0.04, respectively; Table 2). The adjusted WHZs for both WSC2 and RSC age groups were significantly greater than the corresponding no-intervention groups ($Ps < 0.016$; Table 3). There were no significant differences in 6–23-mo unadjusted MUACs between groups. The 24–53-mo WSC2 and RSS groups unadjusted MUACs were significantly greater than those of the

WSC1 and WSS groups (Table 2). The 6–23-mo no-intervention group adjusted MUACs were significantly greater than for all groups except the WSC1 and WSS ($P < 0.017$), and the adjusted MUACs were significantly lower in the CSB+ and RSC groups compared to in the WSC1 and WSS groups ($Ps < 0.016$). There were no significant differences in WHZ effect size in the newly formulated FBF groups compared to CSB+; CSB14 effect sizes were nonsignificant and minimal compared to CSB+ in the 6–23-moh ($d = 0.02$; 95% CI: −0.25, 0.28; $P = 0.87$) and 24–53-mo ($d = 0.17$; 95% CI: −0.12, 0.41; $P = 0.60$) age groups.

In time-adjusted modeling, there were no significant differences in subjects who improved, stayed the same, or deteriorated among groups ($P = 0.08–0.16$; $Ps > 0.21$) for wasting. The probability of improvement in WHZ categorization was highest in the 6–23-mo no-intervention and CSB+ groups ($P > 0.16$), and lowest in the 24–53-mo CSB+ and WSS groups ($P = 0.08$ and 0.07, respectively). The probability of WHZ deterioration during the study was 2–3%.

Discussion

Several studies have examined food-aid formulation effectiveness in the past decade (27, 28, 33–44), but to the best of our knowledge this is the first to investigate different FBF commodities (sorghum, cowpea, corn, and soy) within new formulations that included additional oil, whey protein, and sugar (10). Beyond commodity comparison within the new FBF formulation, this study allowed for efficacy assessment of newly formulated FBFs compared with traditionally

TABLE 2 Unadjusted week 20 hemoglobin, RBP, and anthropometric outcomes[1]

	No intervention	WSC2	CSB14	CSB+	RSC	WSC1	WSS
				FBF			
6–23 mo old							
Hemoglobin, g/dL	10.2 ± 1.4^a	$11.1 \pm 1.5^{b,+}$	$11.3 \pm 1.5^{b,+}$	$10.6 \pm 1.5^{a,b,+}$	$11.1 \pm 1.4^{b,+}$	$11.1 \pm 1.7^{a,b,+}$	$10.9 \pm 1.6^{a,b,+}$
RBP, ng/dL	31.5 ± 17.2^a	33.3 ± 17.5^a	26.0 ± 14.5^b	33.1 ± 17.2^a	38.5 ± 15.4^c	$28.3 \pm 16.4^{a,b}$	30.1 ± 16.5^a
Weight, kg	$9.7 \pm 2.0^{a,+}$	$9.9 \pm 1.6^{a,b,+}$	$10.1 \pm 2.2^{a,b,+}$	$10.0 \pm 1.7^{a,b,+}$	$10.4 \pm 1.7^{b,+}$	$10.3 \pm 1.4^{a,b,+}$	$10.0 \pm 1.5^{a,b,+}$
Length, cm	$77.4 \pm 5.7^+$	$77.3 \pm 5.3^+$	$78.0 \pm 5.7^{+,*}$	$78.6 \pm 5.9^+$	$79.0 \pm 6.0^+$	$78.7 \pm 5.0^+$	$78.2 \pm 5.3^+$
MUAC, cm	14.2 ± 1.4	1.41 ± 1.1	14.3 ± 1.2	14.0 ± 1.1	14.3 ± 1.0	14.4 ± 1.1	14.2 ± 1.1
WAZ	-1.2 ± 1.2^a	$-0.9 \pm 1.2^{a,b,+}$	-0.8 ± 1.1^b	$-1.0 \pm 1.1^{a,b}$	-0.6 ± 1.1^b	$-0.8 \pm 1.0^{a,b}$	-1.2 ± 1.2^a
HAZ	-2.0 ± 1.2^a	$-1.8 \pm 1.2^{a,b}$	$-1.7 \pm 1.1^{a,b}$	$-1.6 \pm 1.1^{a,b}$	-1.4 ± 1.1^b	$-1.8 \pm 1.0^{a,b}$	-2.2 ± 1.3^a
WHZ	-0.2 ± 1.1^a	$0.1 \pm 0.9^{a,b}$	$0.2 \pm 0.9^{a,b}$	-0.2 ± 1.1^a	0.2 ± 1.0^b	$0.1 \pm 1.0^{a,b}$	$0.0 \pm 1.1^{a,b}$
24–53 mo old							
Hemoglobin, g/dL	$11.3 \pm 1.7^+$	$11.1 \pm 1.8^+$	$11.5 \pm 1.7^+$	11.0 ± 1.7	$11.4 \pm 1.5^+$	$11.1 \pm 2.0^+$	$11.5 \pm 1.7^+$
RBP, ng/dL	31.2 ± 16.4^a	35.8 ± 15.4^b	26.3 ± 15.7^c	$32.8 \pm 16.4^{a,b}$	$37.2 \pm 15.7^{a,b}$	30.5 ± 16.5^a	30.9 ± 15.4^a
Weight, kg	13.0 ± 2.1	13.5 ± 2.1	12.9 ± 1.8	13.0 ± 2.2	13.4 ± 2.2	12.8 ± 1.9	12.7 ± 1.9
Length, cm	90.5 ± 7.2	$91.9 \pm 6.7^+$	$89.8 \pm 7.1^+$	$90.8 \pm 8.2^+$	91.8 ± 7.6	$91.0 \pm 6.3^+$	$90.3 \pm 7.1^+$
MUAC, cm	$14.8 \pm 1.1^{a,b}$	15.0 ± 1.1^a	$14.8 \pm 1.2^{a,b}$	$14.6 \pm 1.1^{a,b}$	14.9 ± 1.2^a	14.5 ± 1.1^b	14.3 ± 1.0^a
WAZ	$-1.0 \pm 1.5^{a,b}$	-0.9 ± 1.1^a	$-1.1 \pm 1.0^{a,b}$	$-1.1 \pm 1.1^{a,b}$	-0.9 ± 1.2^a	-1.3 ± 1.1^b	-1.5 ± 1.2^b
HAZ	-1.7 ± 2.2	-1.7 ± 1.1	-2.0 ± 1.4	-1.8 ± 1.5	-1.7 ± 1.6	-1.9 ± 1.3	-2.2 ± 1.5
WHZ	-0.0 ± 0.9	0.1 ± 1.4	0.0 ± 0.9	-0.1 ± 1.0	0.1 ± 0.9	-0.3 ± 1.1	$-0.1 \pm 0.1^{a,b}$

[1]Data are presented as means ± SDs, unless otherwise indicated. Different letters indicate statistical significance ($P < 0.05$); +significant improvement from week 0 to week 20. CSB14, corn-soy blend 14; CSB+, corn-soy blend plus; HAZ, height-for age z score; MUAC, middle-upper arm circumference; RBP, retinol-binding protein; RSC, red sorghum-cowpea; WAZ, weight-for-age z score; WHZ, weight-for-height z score; WSC1, white sorghum-cowpea 1; WSC2, white sorghum-cowpea 2; WSS, sorghum-soy blend.

prepared CSB+, which does not contain animal-source protein, and no intervention.

Although there were some differences in individual outcomes measurements, there was an overall improvement in both iron and vitamin A deficiency OR in both age groups consuming FBFs regardless of formulation compared with the no-intervention group, and in adjusted models that there were no differences in any outcomes except in the CSB14 RBP concentrations. Consumption of all FBFs also resulted in similar anthropometric outcomes regardless of formulation. However, it should be noted that the higher attrition of the CSB+ group

TABLE 3 Adjusted week 20 hemoglobin, RBP, and anthropometric outcomes[1]

	No intervention	WSC2	CSB14	CSB+	RSC	WSC1	WSS
				FBF			
6–23 mo old[2]							
Hemoglobin, g/dL	9.4 ± 0.4^a	$10.5 \pm 0.4^{a,b}$	10.5 ± 0.3^b	$10.2 \pm 0.3^{a,b}$	10.4 ± 0.3^b	10.4 ± 0.3^b	$10.3 \pm 0.3^{a,b}$
RBP, ng/dL	$25.2 \pm 6.8^{a,b}$	$26.0 \pm 6.5^{a,b}$	18.2 ± 53.9^a	$27.6 \pm 5.6^{a,b}$	$33.0 \pm 5.9^{b,+}$	$22.8 \pm 5.7^{a,b}$	$24.5 \pm 5.4^{a,b}$
MUAC, cm	144.0 ± 0.7^a	$142.1 \pm 0.6^{b,c,d}$	$142.9 \pm 0.6^{b,d}$	$140.7 \pm 0.7^{c,d}$	$141.2 \pm 0.6^{b,c,d}$	$143.4 \pm 0.6^{a,b}$	$143.5 \pm 0.7^{a,b}$
WAZ	-0.9 ± 0.4	-0.9 ± 0.3	-0.9 ± 0.7	-0.9 ± 0.5	-0.9 ± 0.4	-0.9 ± 0.6	-1.0 ± 0.4
HAZ	-1.8 ± 0.8	-1.8 ± 0.9	-1.8 ± 0.8	-1.8 ± 0.8	-1.8 ± 0.6	-1.8 ± 0.8	-1.9 ± 0.6
WHZ	-0.2 ± 0.1^a	0.1 ± 0.1^b	$0.1 \pm 0.1^{a,b}$	$-0.1 \pm 0.2^{a,b}$	0.1 ± 0.1^b	$0.0 \pm 0.1^{a,b}$	$-0.1 \pm 0.1^{a,b}$
24–53 mo old[3]							
Hemoglobin, g/dL	10.8 ± 0.4	10.5 ± 0.5	10.8 ± 0.4	10.7 ± 0.4	10.9 ± 0.4	10.7 ± 0.4	10.9 ± 0.4
RBP, ng/dL	$31.9 \pm 42.8^{a,b,+}$	$33.3 \pm 55.0^{a,b,+}$	25.0 ± 43.2^a	$34.8 \pm 41.2^{a,b,+}$	$39.8 \pm 38.7^{b,+}$	$30.2 \pm 44.1^{a,b,+}$	$31.1 \pm 37.7^{a,b,+}$
MUAC, cm	143.5 ± 1.3^a	$141.5 \pm 1.2^{a,b}$	$141.8 \pm 1.2^{a,b}$	140.0 ± 1.2^b	140.5 ± 1.2^b	142.8 ± 1.2^a	145.3 ± 10.1^a
WAZ	-1.2 ± 0.7	-1.1 ± 0.6	-1.1 ± 0.9	-1.1 ± 1.0	-1.1 ± 1.1	-1.1 ± 1.1	-1.1 ± 1.0
HAZ	-1.8 ± 0.6	-1.9 ± 0.6	-1.8 ± 0.5	-1.8 ± 0.5	-1.8 ± 0.4	-1.8 ± 0.5	-1.9 ± 0.4
WHZ	-0.2 ± 0.1^a	$0.1 \pm 0.1^{a,b}$	$0.1 \pm 0.1^{a,b}$	$-0.1 \pm 0.1^{a,b}$	0.2 ± 0.1^b	$0.0 \pm 0.1^{a,b}$	$-0.1 \pm 0.1^{a,b}$

[1]Data are presented as means ± SDs, unless otherwise indicated. Different letters indicate statistical significance ($P < 0.05$). CSB14, corn-soy blend 14; CSB+, corn-soy blend plus; HAZ, height-for age z score; MUAC, middle-upper arm circumference; RBP, retinol-binding protein; RSC, red sorghum-cowpea; WAZ, weight-for-age z score; WHZ, weight-for-height z score; WSC1, white sorghum-cowpea 1; WSC2, white sorghum-cowpea 2; WSS, sorghum-soy blend.
[2]Hemoglobin concentrations in the 6–23-mo group were adjusted for week 0 hemoglobin, week 0 WAZ, week 20 WAZ, week 20 MUAC, ownership of meat livestock, dietary diversity, consumption of animal protein, consumption of carotenoid-rich foods, health and illness at week 20. RBP was adjusted for week 0 RBP, children on antiretroviral therapy, gender, breastfeeding status, and health and illness at week 0 and week 20.
[3]Hemoglobin concentrations in the 24–53-mo group were adjusted for baseline hemoglobin, week 0 MUAC and weight, week 20 MUAC, WAZ, HAZ, and WHZ, consumption of carotenoid-rich foods, family ownership of chickens, mother-to-child prevention of HIV therapy, week 20 illness and health scores. RBP was adjusted for week 0 RBP, ownership of meat livestock, and health and illness at week 0 and week 20. Length and weight are not included because no significant models that used the covariates were identified.
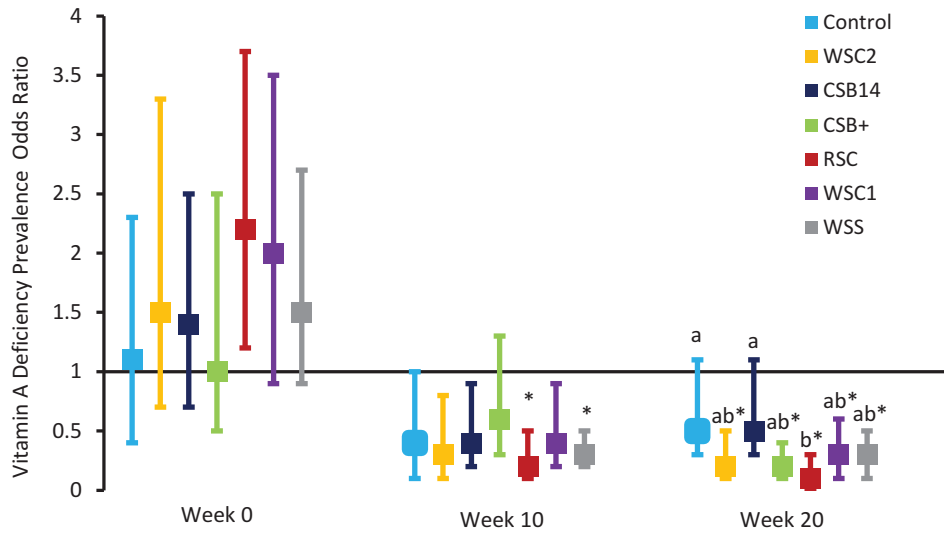
FIGURE 4 Adjusted vitamin A deficiency week 0, week 10, and week 20 ORs for the groups aged 6–23 mo. Week 20 vitamin A deficiency adjusted for week 0 vitamin A deficiency prevalence, gender, breastfeeding status, and health and illness at week 0 and week 20. *Significantly different compare with week 0 (*P* < 0.05). Different letters indicate significant differences between groups (*P* < 0.05). CSB14, corn-soy blend 14; CSB+, corn-soy blend plus; RSC, red sorghum-cowpea; SSB, sorghum-soy blend; WSC1, white sorghum-cowpea 1; WSC2, white sorghum-cowpea 2.

because of voluntary discontinuance may have affected this outcome and could affect the efficacy of CSB+ in combating undernutrition in the field. The fact that participants preferred the taste of the new FBFs over CSB+ and the faster preparation of the new formulations may have contributed to this difference. However, direct comparison of these findings does not suggest improved iron, vitamin A, or anthropometric outcomes in CSB14 compared with CSB+ (effect size range: −0.02,

0.17, *P*s > 0.19), suggesting that blend reformulation with nonionic EDTA iron, less vitamin A, 9% whey protein concentrate, increased oil, extrusion processing, and other micronutrient reformulations were not critical factors in improving these outcomes. Overall, these findings suggest 1) that multiple FBF formulations were efficacious, including ones including sorghum, cowpea, corn, and soy; and 2) that reformulation costs should be weighed against anticipated outcomes,
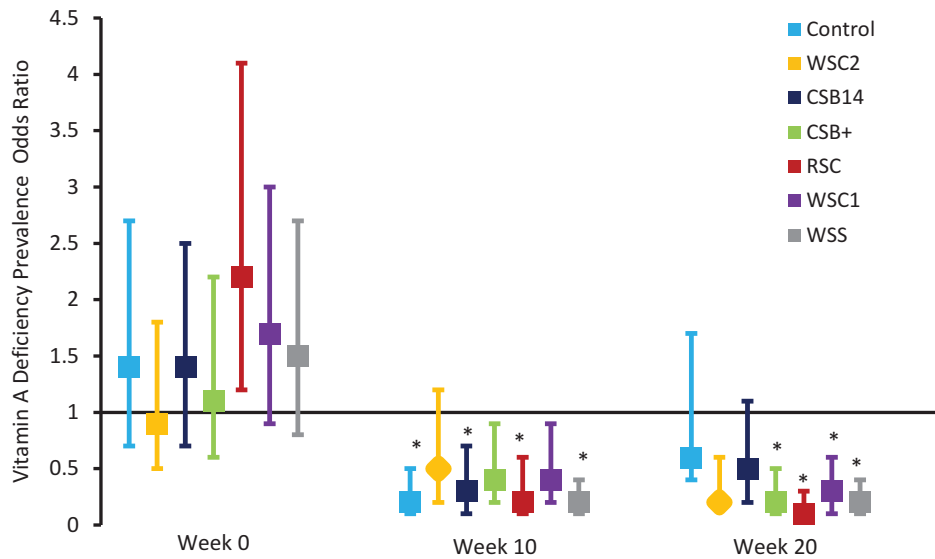

FIGURE 5 Adjusted vitamin A deficiency week 0, week 10, and week 20 ORs for the groups aged 24–53 mo. Week 20 vitamin A deficiency prevalence adjusted for week 0 vitamin A deficiency prevalence, week 0 and week 20 health and illness. *Significantly different compared with week 0 (*P* < 0.05). Different letters indicate significant differences between groups (*P* < 0.05). CSB14, corn-soy blend 14; CSB+, corn-soy blend plus; RSC, red sorghum-cowpea; SSB, sorghum-soy blend; WSC1, white sorghum-cowpea 1; WSC2, white sorghum-cowpea 2.

because the increased cost of the newly formulated FBFs compared with CSB+ brings the expectation that they should be significantly more effective at improving outcomes.

Replacement of ionically charged ferrous and ferric iron with EDTA iron has been proposed for use in FBFs because EDTA iron may not be subject to antinutritional factor chelation (10). Recent evidence suggests that individuals may adapt to antinutritional factor consumption, such as tannins (45–46), thus questioning whether forms such as sodium iron EDTA will be as efficacious as originally believed. Interestingly, we found decreased anemia OR in the 6–23-mo, but not in the 24–59-mo age groups that consumed newly formulated FBFs compared with CSB+ (2 mg/100 g compared with 2.5 mg/100 g) but much higher ferrous fumarate concentrations (11 mg/100 g compared with 4 mg/100 g). Taken together, this may suggest that iron quantity is more important than iron form. Studies that have compared EDTA with ionized iron forms have not reported improved iron bioavailability (47–49), although 1 study found that EDTA bioavailability was greater than ferrous sulfate in a single sorghum-containing polyphenol-rich meal (50). Similarly, most studies have not found iron status (ie hemoglobin) outcome differences between sodium iron EDTA and ionized iron fortification (51–56). It is possible that the higher iron needs of the faster growing 6–23-mo groups may have made these participants more sensitive to the higher iron quantity provided by the newly formulated FBFs, or other factors could have contributed to the differences between the age groups.

Equally interesting to iron deficiency anemia recovery rates among groups were vitamin A trends in CSB14 compared with other FBFs, and especially CSB+. In the in vitro digestion/Caco-2 cell model (57), rats (18), and broiler chickens (58) no differences have been observed in vitamin A bioavailability and status, respectively, between CSB14 and sorghum-based FBFs. CSB+ contains more vitamin A than CSB14 and the other newly formulated FBFs, and the greater quantity of vitamin A likely contributed to the improved vitamin A outcomes. Although CSB+ contains more vitamin A than CSB14, the 6–23-mo RBP concentrations were not significantly greater than in CSB14. In contrast, sorghum-cowpea and sorghum-soy FBF consumption trended toward consistent improvement in vitamin A deficiency during the study. Although this finding has not been verified in other models, it suggests that corn-soy FBFs may not be as conducive to improving vitamin A status for some unelucidated reason.

Although the no-intervention group's robustness in all outcome measures, but particularly anthropometrics, was an unexpected finding, this phenomenon has been cited elsewhere. In a cluster, randomized control trial ($n = 5536$) that followed Bangladeshi children from age 6 to 18 mo, there was a significantly greater rate of stunting and underweight with consumption of 2 ready-to-use foods (RUSFs) compared with the no-intervention group (38). In contrast to our findings, in children 6–23 mo old ($n = 4685$), super cereal plus (corn, soy, skim milk, sugar, oil, vitamin, and mineral premix) significantly improved moderate or severe acute malnutrition recovery compared with cash provision without nutritional supplementation, although cash and supplementary nutrition intervention combined were found to be most effective in treating moderate and severe acute malnutrition (40). It is somewhat surprising that consumption of newly reformulated FBFs with enhanced lipid content and animal-source protein did not result in improved anthropometric outcomes compared with CSB+, which adds to mixed effects of RUSFs, etc. In an 8-wk study, Malawian children ($n = 1362$) consuming RUSFs (both with or without animal protein) had significantly improved WHZs and WAZs compared with CSB+ consumption (41), which was attributed to the lipid content of the RUSFs. Conversely, in a Cameroonian cohort ($n = 833$), 73% of CSB+-supplemented and 85% of RUSF-supplemented children recovered from moderate acute malnutrition after 50% kcal/d supplementation for 56 d with no statistical difference in interventions (42). In addition, in Nigerians ($n = 2712$) moderate acute malnutrition recovery was similar among those receiving CSB++ (corn, soy, skim milk powder, sugar, oil, vitamin, and mineral pre-mix), soy and soy-whey RUSFs (HR: 1.13; 95% CI: 0.88, 1.46 in soy or soy/whey RUSF compared with CSB++) (59). All study participants were consuming complementary food outside of breastfeeding before and throughout this study period, which may have blunted some benefits of the reformulated FBFs. A recent study suggested that consumption of complementary foods, rather than plant compared with animal protein, determined protein adequacy in children 6–19 mo old (36). The heterogeneity in anthropometric outcomes compared with the no-intervention and nonanimal-protein-consuming groups in the present study and others discussed suggest that factors outside of formulation are notable contributors that should not be overlooked in combating undernutrition.

Limitations

It is important to note that this study was underpowered to look at anthropometric outcomes; sample size estimates to power significant differences in CSB14 compared with no-intervention with an α of 0.05 and power of 0.90 are between 2634 (for underweight) and 5284 (for stunting) paired measurements. A longer duration might also be needed to see an impact on these outcomes. In comparison, estimated sample sizes to find significant differences in CSB+ compared with CSB14 effect sizes are between 10,000 and 17,000 paired differences for underweight and stunting, respectively. Further, limitations included potential reporter bias (60) for covariate adjustments, especially in dietary diversity, reported FBF consumption, and care practices, which have been previously reported (61), and may have limited statistical model adjustments. Although efforts were made to cluster intervention groups to minimize bias, this was an unblinded study to both researchers and participants. Although it is difficult to assess the degree of bias, it may be that this affected our study findings.

Conclusions

Newly formulated FBFs based on sorghum, cowpea, corn, and soy significantly improved anemia and vitamin A deficiency OR over the 20-wk intervention period in children aged 6–53 mo. Our findings support the use of sorghum and cowpea in reformulated FBFs. However, the lack of difference in outcomes between CSB+ and reformulated FBFs that contain components that make them more costly suggest that further refinement of FBFs is warranted to improve their cost-benefit ratio and also meet recipient expectations.

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CM: analyzed data; ND and BL: wrote the paper; BL: had primary responsibility for final content; and all authors: have read and approved the final manuscript. This is contribution no. 19-002-J of the Kansas Agricultural Experiment Station.

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