

# The MFFAPP Tanzania Efficacy Study Protocol: Newly Formulated, Extruded, Fortified Blended Foods for Food Aid<sup>1–4</sup>

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## Abstract

Fortified blended foods (FBFs) are micronutrient-fortified blends of milled cereals and pulses that represent the most commonly distributed micronutrient-fortified food aid. FBFs have been criticized due to lack of efficacy in treating undernutrition, and it has also been suggested that alternative commodities, such as sorghum and cowpea, be investigated instead of corn and soybean. The Micronutrient Fortified Food Aid Pilot Project (MFFAPP) Tanzania efficacy study was the culmination of economic, processing, sensory, and nutrition FBF research and development. MFFAPP Tanzania was a 20-wk, partially randomized cluster design conducted between February and July 2016 that enrolled children aged 6–53 mo in the Mara region of Tanzania with weight-for-height z scores >–3 and hemoglobin concentrations <10.3 mg/dL. The intervention was complementary feeding of newly formulated, extruded FBFs (white sorghum cowpea variety 1, white sorghum-cowpea variety 2, red sorghum-cowpea, white sorghum-soy blend, and corn-soy blend 14) compared with Corn Soy Blend Plus (CSB+), a current US Agency for International Development–distributed corn-soy blend, and a no-FBF-receiving control. Screened participants ( $n = 2050$ ) were stratified by age group (6–23 and 24–53 mo) and allocated to 1 of 7 FBF clusters provided biweekly. Biochemical and anthropometric data were measured every 10 wk at weeks 0, 10, and 20. The primary objectives of this study were to determine whether newly formulated, extruded corn-, soy-, sorghum-, and cowpea-based FBFs result in equivalent vitamin A or iron outcomes compared with CSB+. Changes in anthropometric outcomes were also examined. Results from the MFFAPP Tanzania Efficacy Study will inform food aid producers and distributors about whether extruded sorghum- and cowpea-based FBFs are viable options for improving the health of the undernourished. This trial was registered at [clinicaltrials.gov](http://clinicaltrials.gov) as NCT02847962. *Curr Dev Nutr* 2017;1:e000315.

## Introduction

Protein-energy malnutrition, iron, and vitamin A are among the most common nutritional deficiencies worldwide (1); and although global rates of stunting and wasting have declined in the past 25 y (2), >200 million children are stunted or wasted and 45% of deaths in children <5 y old globally have been attributed to undernutrition (3). Contributing to morbidity and mortality rates, only 21% of children aged 6–23 mo consume a “minimally acceptable diet” (2). Iron deficiency affects an estimated 2 billion people, nearly half of whom suffer from iron deficiency anemia (4), and rates of decline have only neared 10% in the past 15 y (5). Vitamin A deficiency remains the leading cause of preventable childhood blindness, and 33% of preschool-aged children have inadequate daily intakes of vitamin A (6). Low-income countries bear the majority of the burden of undernutrition, where reductions in stunting, wasting, and micronutrient deficiencies lag behind their wealthier counterparts



**Keywords:** fortified blended food, extrusion, sorghum, cowpea, vitamin A, iron, protein, food aid, undernutrition

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<sup>3</sup> Project Concern International coordinated the efficacy study, conducted screening, organized and collected efficacy study sensory and nutrition data, distributed fortified blended foods, and designed and conducted nutrition education.

<sup>4</sup> Supplemental Materials 1–5 are available from the “Online Supporting Material” link in the online posting of the article and from the same link in the online table of contents at <http://cdn.nutrition.org>.

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(2). UNICEF recommends the use of locally available fortified foods to prevent and treat stunting and undernutrition in children aged 6–23 mo and beyond (6).

Fortified blended foods (FBFs)<sup>9</sup> are micronutrient fortified, partially precooked blends of milled cereals and pulses that are the most commonly distributed micronutrient-fortified food aid. Among FBFs, the primary forms distributed are corn-soy blends (CSBs), of which hundreds of thousands of metric tons are distributed annually (7). FBFs have been used in supplementary feeding programs as complementary food for >4 decades because of their low cost compared with other food aid options (8). FBFs are easy to prepare; however, they have been criticized due to their limited efficacy in treating malnourished children (9, 10). The most widely distributed FBF by the US Agency for International Development (USAID) is Corn Soy Blend Plus (CSB+), a roasted whole-corn and soy blend (11). A review commissioned by USAID encouraged the development of new cereal-based FBFs and specifically pointed out that sorghum “could be well suited, given its acceptability in Africa, relatively low price, and its acceptability among host governments. A sorghum-soy (or indeed sorghum-pea or other pulse) blend could be envisaged” (7). Sorghum and cowpea are drought-tolerant, can withstand water-logging during rainy seasons, and can be procured locally and regionally in most of Africa (12, 13). The use of sorghum in FBFs does have its potential challenges. Sorghum iron bioavailability (14) and protein digestibility are poorer than for most grains, especially when wet-cooked (15). Despite potentially poorer nutritional quality in sorghum, there is evidence that extrusion cooking, a mechanical food-processing technique, can decrease the contents of the antinutritional factors, like phytic acid and tannins (16), potentially improving iron bioavailability and protein digestibility (17).

To develop sustainable, economically viable, efficacious, and acceptable FBFs, an interdisciplinary Micronutrient Fortified Food Aid Pilot Project (MFFAPP) team was created at Kansas State University (KSU) through the collaboration of nutrition, agricultural economics, sensory analysis, and grain science. The overarching aim of this project was to create FBFs meeting all goals of food security (18), including availability and access to safe, sufficient, and nutritionally adequate foods that are physically and economically available, and that meet the dietary and food preference needs of their consumers. From blends developed, 6 FBFs were selected for a field efficacy study in Tanzania. Priority for receiving project funding was working with a current McGovern-Dole program to maximize project cost-effectiveness. To this end, KSU partnered with Project Concern International (PCI)–Tanzania, a nongovernmental organization that was implementing a

USDA-funded Food for Education program. PCI-Tanzania was able to use its infrastructure, relationships, and local knowledge to facilitate and implement in-country project activities.

## Methods

### Objectives and design

This study was designed to determine whether newly formulated, extruded corn-, soy-, sorghum-, and cowpea-based FBFs result in the same or better anthropometric, vitamin A, or iron outcomes than a currently used FBF. A partially randomized noninferiority cluster efficacy study with a 1-way treatment structure was designed to test the hypothesis that newly formulated, extruded FBFs result in equal or better nutritional efficacy (by anthropometric, vitamin A, or iron status outcomes) than a traditionally prepared corn-soy FBF in 2 age groups (6–23 and 24–53 mo) over a 20-wk study period. During the study, all sites followed a written protocol, and identical equipment and supplies are used. Common data forms were transmitted to KSU for collation, analysis, and storage.

### Ethics approval and consent to participate

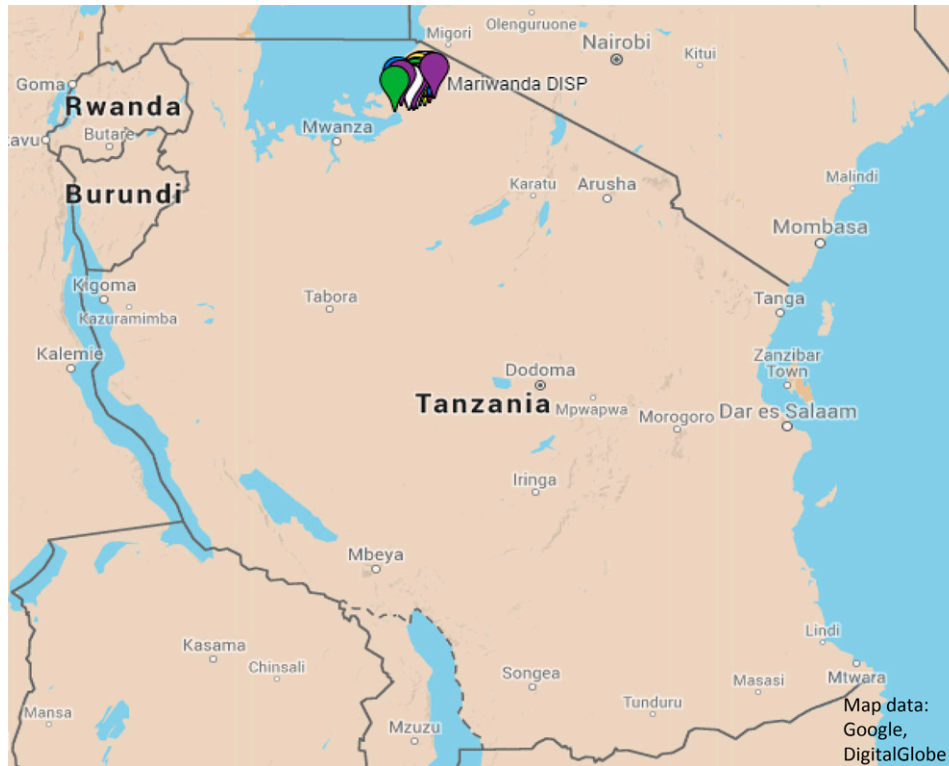
This study was approved by the Institutional Review Boards at KSU (no. 7147) and the National Medical Research Institute of Tanzania (NMRI). The protocol was reviewed annually per institutional review procedures, and all protocol changes were reported to Institutional Review Board institutions. All of the participants' guardians gave written and verbal consent before study enrollment; if guardians could not read or write, they provided verbal consent. All of the participants were given unique numeric identifiers anonymizing them during data analysis at KSU, all data files were locked on password-protected computers, and paper forms were stored in locked file cabinets. This trial was registered at [clinicaltrials.gov](http://clinicaltrials.gov) as NCT02847962.

### Study location, site selection and assessment

The study was conducted in the Bunda district located in the Mara region of Tanzania where current reports indicate that 37%, 26%, and 57% of children aged 6–59 mo are stunted (19), vitamin A deficient (20), or anemic (19), respectively. In addition, half the population is estimated to be food insecure (20, 21).

Twenty-one health facilities were assigned into 7 clusters, stratified by 2 age groups (1 group aged 6–23 mo and 1 group aged 24–53 mo) for a 20-wk intervention (**Figures 1 and 2**). Health facilities were selected on the basis of 1) their willingness and ability to support the study and 2) regional vitamin A and iron deficiency estimates. All of the health facilities underwent a basic initial assessment to determine their suitability for the study by the end of 2014. A detailed health facility assessment focused on services, infrastructure, staffing, and target populations was undertaken during April–June 2015 by community mobilizers and a commodity logistics management team. The commodities team used these data to determine the storage and safety updates needed at each facility (repairs, padlocks, grills, etc.) to ensure that each facility was in proper condition before the first distribution. PCI also provided training and materials necessary to carry out their scope of work, as well as the health facilities' responsibilities related to

<sup>9</sup>Abbreviations used: CRP, C-reactive protein; CSB, corn-soy blend; CSB14, corn-soy blend 14; FBF, fortified blended food; HAZ, height-for-age z score; KSU, Kansas State University; MFFAPP, Micronutrient Fortified Food Aid Products Pilot Project; MUAC, midupper arm circumference; NMRI, National Institute for Medical Research; PCI, Project Concern International; RBP, retinol binding protein; RSC, red sorghum-cowpea variety; USAID, US Agency for International Development; WAZ, weight-for-age z score; WHZ, weight-for-height z score; WSC1, white sorghum-cowpea variety 1; WSC2, white sorghum-cowpea variety 2.



**FIGURE 1** Map of the Tanzanian region for the efficacy study. The Mara region was chosen due to the prevalence of stunting, wasting, and vitamin A and iron deficiency. DISP, dispensary. Map data: Google, DigitalGlobe.

recruitment, screening, sensitization, data collection, reporting, and product distribution. Other prescreening and household observations are described in **Supplemental Materials 1**.

### Screening

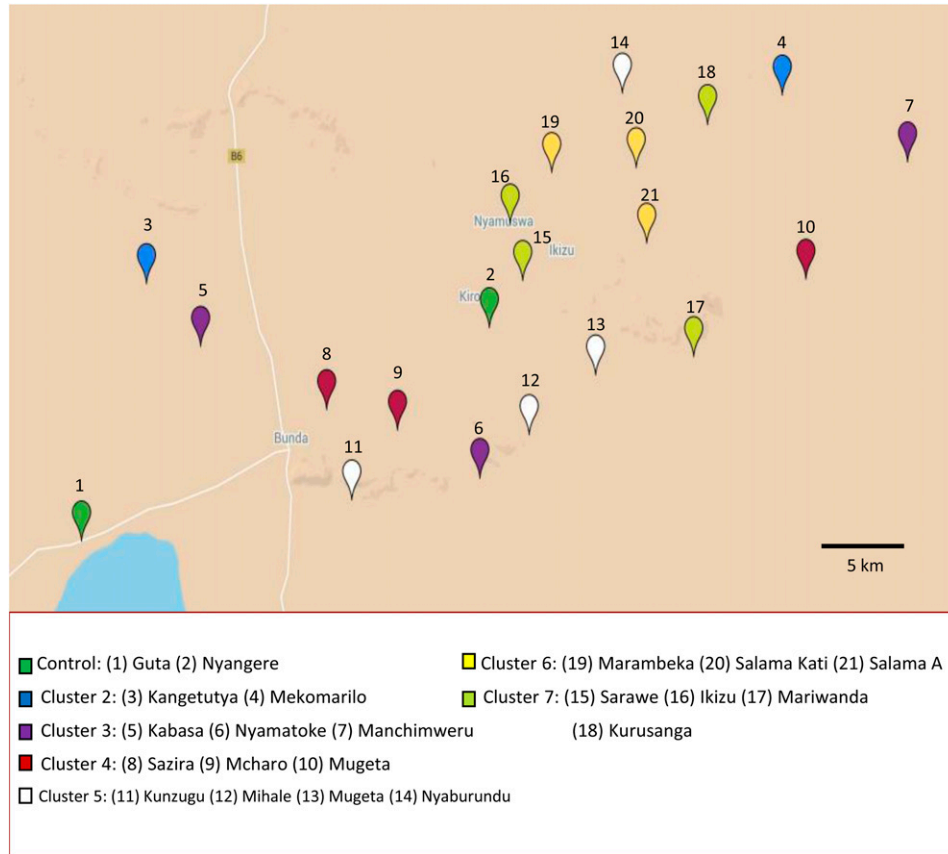
Community mobilizers and trained enumerators conducted screenings at local health facilities (Figures 1 and 2), where parents or guardians of participant children provided written and verbal informed consent. Selection criteria were satisfied when participants aged 6–53 mo met the following: 1) weight-for-height  $z$  scores (WHZs)  $> -3$  [severe undernutrition (22); these children were referred to health facilities for follow-up care] and 2) hemoglobin concentrations  $< 10.3$  mg/dL [indicating mild, moderate, or severe anemia (23)]. The age criterion allowed participants to complete the 20-wk study before their fifth birthday.

**Noninvasive hemoglobin assessment.** For screening, hemoglobin concentrations were measured by using noninvasive Massimo Pronto-7 hemoglobin monitors (Massimo Inc, Irvine, California). Measuring hemoglobin noninvasively for screening avoided blood collection from many potential participants who would not be included in the study and reduced discomfort for both mothers and children. At the beginning of screening, a subsample of participants screened with both HemoCue 201+ (HemoCue America, La Brea, California) and Massimo Pronto-7 monitors were followed ( $n = 419$ ) to correlate estimated hemoglobin concentrations between the measurements. Hemoglobin concentrations measured by using

Massimo Pronto-7 monitors were lower in the lowest tertile and higher in the top 2 tertiles compared with HemoCue (**Table 1**). Underestimation of hemoglobin by HemoCue 201+ monitors in anemia has been reported (24); and thus, instead of the use of concentrations  $< 11$  mg/dL to diagnose children as being mildly anemic,  $< 10.3$  mg/dL was used as the inclusion criterion (**Figures 3 and 4**). In addition, with the criterion at  $< 10.3$  mg/dL, there was better agreement between the 2 methods than at  $< 11$  mg/dL, giving greater confidence that those enrolled were anemic.

Difficulties with Massimo Pronto-7 monitors included long reading times at high temperatures, failed readings with too much light exposure, the need for daily battery replacement, poor sensitivity with child movement, issues taking measurements because of small child finger size (used the thumb in many cases), and difficulty measuring very low hemoglobin concentrations ( $< 6.5$  mg/dL).

**Nonhematologic screening and exclusion.** Vitamin A deficiency was indirectly assessed by a combination of noninvasive methods, including xerophthalmia classification, assessed by trained eye screeners, and reported night-blindness. Participants were excluded from participation in the study for exclusive breastfeeding, unwillingness of participant family to travel to health facilities, enrollment of the child in school during the study period, anticipated relocation of the family during the study, or allergy to the FBF product ingredients. Screening results are summarized in **Figure 5**.



**FIGURE 2** Location of health facilities and clusters in the Mara region. Clusters were grouped by age and geographic location of health facilities to avoid crossover of treatments. Map data: Google, DigitalGlobe.

**Additional screening.** Due to a delay in the start of the study after screening, some families moved out of the study area or were not easily relocated. To obtain the participant numbers, targeted, additional screening was conducted by revisiting communities with low week 0 enrollment, and nonenrolled, eligible children were encouraged to be screened as part of an extended week 0 evaluation. Children were first screened for age, anthropometric, and hemoglobin eligibility; and if inclusion criteria were met, they were taken through the entire week 0 data collection and FBF distribution procedures.

**Study design and activities**

Sensitization and post-trial nutrition education are described in **Supplemental Materials 2**.

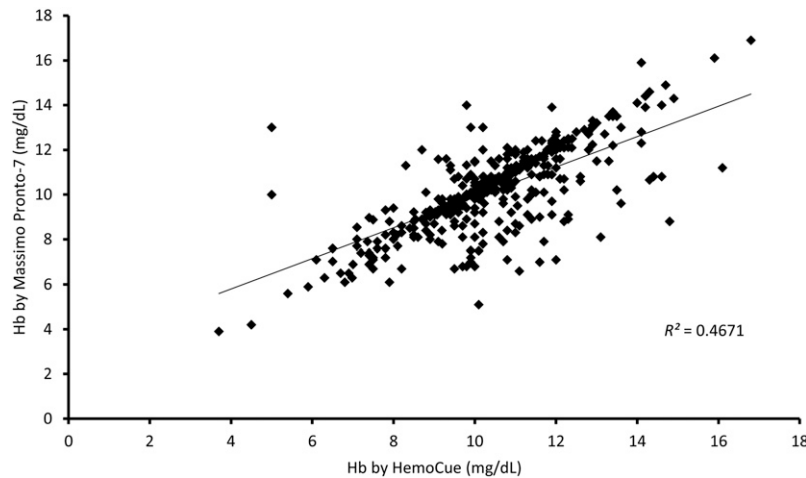
**Fortified-blended foods.** Sorghum-, cowpea-, corn-, and soy-based FBFs were formulated according to USAID food aid recommendations (7) and later reformulated to meet viscosity requirements by replacing 15% of extruded grain and legume flours with sugar, whey protein concentrate and oil [Tables 2–4 (25)]. CSB+ was an FBF formulated according to USDA recommendations (26). Non-genetically modified corn and soy were used in preparing FBFs, a requirement of the Tanzanian government.

**Clustering and randomization.** Sample size ( $n = 135/\text{treatment age group}$ ) was calculated by using a paired  $t$  test calculator (<http://www.biomath.info/power/prt.htm>), with a power of 0.8,  $\alpha$  of 0.05, and mean differences calculated from results from efficacy studies assessing hemoglobin (27) and serum retinol (28). The larger hemoglobin sample size was used; an estimated 25% drop-out rate was then added to this number (rounded up to the nearest whole number). Participants were stratified into 2 age groups (6–23 mo and 24–53 mo). The younger age group was chosen as an age group of particular interest due to recommendations and evidence suggesting that catch-up linear growth is minimal in undernourished children after age 2 (29) and an emphasis on linear growth

**TABLE 1** Tertile average hemoglobin concentrations for the Massimo Pronto-7 and Hemocue 201+ and differences between the device averages<sup>1</sup>

Hemoglobin measurement technique	Tertile		
	1: <10.0 mg/dL (n = 150)	2: 10.0–13 mg/dL (n = 230)	3: >13.0 mg/dL (n = 39)
Massimo Pronto-7, mg/dL	8.55 ± 1.30	11.12 ± 0.82	14.05 ± 0.92
HemoCue, mg/dL	8.79 ± 1.59	10.74 ± 1.39	12.34 ± 2.26
Difference, mg/dL	-0.24 ± 1.53	0.38 ± 1.22	1.713 ± 2.12

<sup>1</sup>Values are means ± SDs.



**FIGURE 3** Correlation between invasive (Hemocue 201+) and noninvasive (Massimo Pronto-7) Hb monitoring used for screening procedures ( $n = 419$ ). Correlation was poor ( $R^2 = 0.46$ ; all data) in the upper and lower tertiles of Hb values, prompting lower Hb inclusion criteria. Hb, hemoglobin.

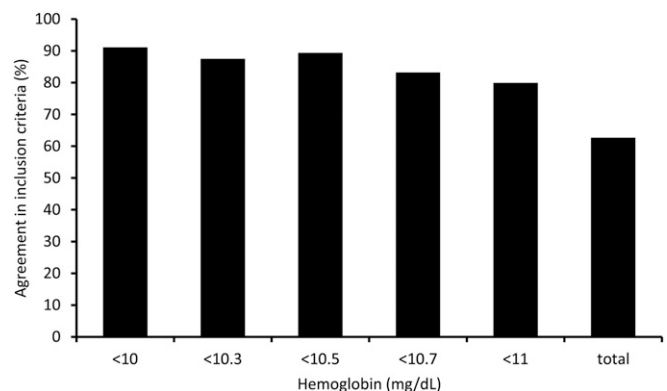
as a marker of nutritional status rather than underweight (30). The older group was important because there were no applicable studies that had examined iron and vitamin A outcomes to calculate a sample size for the study. Twenty-one health facilities were allocated to 7 clusters (stratified by age) on the basis of geographical location and sample size, and then randomly assigned to 1 of 7 treatments by KSU (**Table 5**).

Clusters (divided into groups: 6–22 mo and 23–53 mo) received variants of extruded sorghum cowpea blends [2 white: white sorghum-cowpea variety 1 (WSC1) and white sorghum-cowpea variety 2 (WSC2); 1 red: red sorghum-cowpea variety (RSC)], a white sorghum soy blend, an extruded CSB (CSB14), or a traditionally prepared CSB (CSB+); the last cluster did not receive any FBF during the study period and served as the control. This group was provided an equal amount of CSB14 for 20 wk after study conclusion. Community mobilizers distributed FBFs from health facilities and outreach stations, which were organized to decrease the distance that participants had to travel every 2 wk. The FBFs are weighed biweekly into bags provided by the study, and participant collection was monitored and documented. Blends were distributed with the expectation that infants and children aged 6–12, >12–24, and >24–60 mo consume 65, 130, and 230 g, respectively, of FBF daily (>50% of daily nutrient requirements), consistent with the Food Aid Quality Report recommendations (7). All of the groups that received FBFs were provided with enough for 3 other children or family members (an additional 500 g/d, 14 d total/collection) to increase the likelihood that the participant child consumed the FBF. Control participants were given foam balls and laundry soap to incentivize participation at week 0 and week 10. At week 20, control participants received their first FBF distribution. Parents and guardians were instructed to feed respective FBFs to children 3 times/d for a duration of 5 mo, and were encouraged to continue breastfeeding. Instructions with regard to the preparation of FBFs were given, but parents and guardians were not provided nutritional advice during the study. FBFs were produced at KSU; the USDA seal of

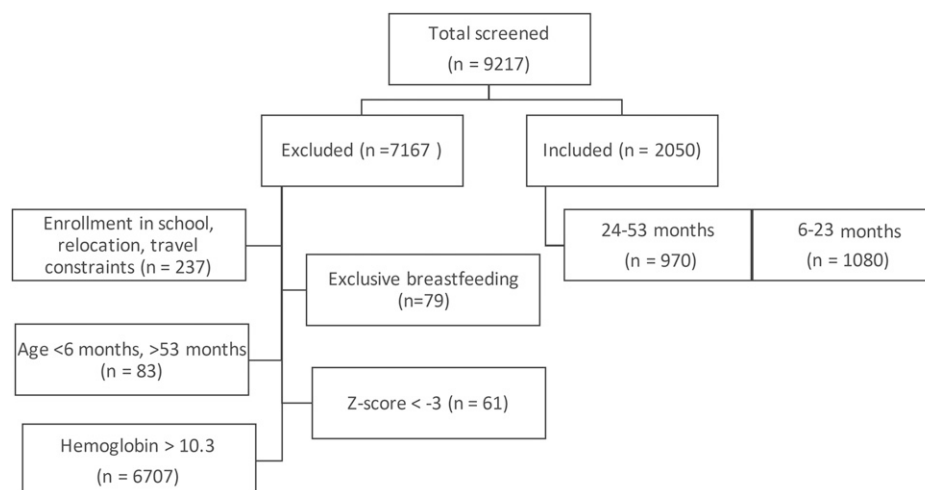
certification was on all packages along with a description of their contents and expiration date.

**Data collection.** Trained staff from the Tanzania NMRI conducted standardized assessments of study participants at study weeks 0, 10 (10 wk), and 20 (20 wk) at local health facilities. Assessments included anthropometric measurements, biochemical indicators of micronutrient status, infectious disease data, supplementation and health care data, and food variety and intake data (**Supplemental Materials 3**). Acceptability and paired preference testing methods are described in **Supplemental Materials 4**.

**Anthropometric measurements.** Measurements were made according to WHO guidelines (31), including weight, recumbent or



**FIGURE 4** Agreement between invasive (Hemocue 201+) and noninvasive (Massimo Pronto-7) monitoring for inclusion criteria at different hemoglobin cutoffs ( $n = 419$ ). Values are presented as the percentage of agreement in participants below a given hemoglobin cutoff value. Inclusion criteria agreement between the 2 hemoglobin measurement tools improved with cutoffs <10.3 mg/dL (91% agreement) compared with 11 mg/dL (65% agreement).



**FIGURE 5** Screening, exclusion, and inclusion criteria for randomization. Participants within study age ranges were excluded for restrictions in travel, relocation, and exclusive breastfeeding. Other participants were excluded if they had a weight-for-height z score  $< -3$  or hemoglobin  $> 10.3$  mg/dL.

standing length, midupper arm circumference (MUAC), and pitting edema. Weights were measured by using a SECA digital scale accurate to the nearest 10 g, taking the difference between mother and child. Recumbent length was measured with an adaptable recumbent and standing stadiometer accurate to 1 mm. Children who were able to stand on their own were measured via standing stadiometer, whereas recumbent lengths were measured for nonstanding infants. MUAC was measured by flexible measuring tape to the nearest 1 mm. Measurements were made in duplicate, and anthropometric instruments were calibrated regularly. Clinical signs of malnutrition, including bilateral pitting edema, were assessed by trained medical staff. WHZs and z scores for weight-for-age (WAZs) and length-for-age were calculated on the basis of WHO guidelines (31) with 2011 ENA SMART software (Action Against Hunger Canada).

**Micronutrient and inflammatory status.** At weeks 0, 10, and 20, to assess vitamin A, iron, and inflammatory status, retinol binding protein (RBP), hemoglobin, and C-reactive protein (CRP) were used to assess vitamin A, iron, and inflammatory status. Dried blood spots were collected for RBP and CRP assessment. RBP, a surrogate marker of retinol (32), was assessed by SCANLISA (SCIMEDX) enzyme immunoassay. Measurement of SCANLISA RBP has been verified with dried blood spot assessment (33). High-sensitivity CRP

enzyme immunoassay (Biocheck, Inc.) measurement was used for acute-phase inflammatory response RBP and iron correction (34–36). RBP:CRP correction was adjusted via multiple linear regression (33, 34). RBP and CRP would be transformed, if needed, for regression analysis; and vitamin A deficiency was defined by an RBP  $< 17.325$  ng/dL, a previously defined cutoff (37).

Adjusted RBP was calculated as follows:

$$\{\text{unadjusted RBP} - (\text{regression coefficient for CRP}) \times [\text{CRP} - (\text{maximum CRP in lowest 10\% of CRP})]\} \quad (1)$$

as defined previously (34). Hemoglobin was assessed by using HemoCue 201+ monitors, and anemia defined according to WHO definitions (23).

**Confounding health and other factors.** Data on complementary feeding and breastfeeding, vitamin A or iron supplementation, health maintenance, acute illness, and hygiene were collected at weeks 0, 10, and 20 in health facilities. Health facility vitamin A supplementation efforts were monitored, and caregivers were asked about the last time they received iron or vitamin A supplementation.

Deworming was provided by the District Medical Officer at week 10 due to the confounding effect of helminths on iron status

**TABLE 2** Newly formulated, extruded FBF CSB+ formulations<sup>1</sup>

	Sorghum flour	Cowpea flour	Soy flour	Corn flour	Sugar	Whey protein	Vegetable oil	Micronutrient premix
WSC1, WSC2, RSC	24.7	38.6	0	0	15	9.5	9.0	3.2
WSS	47.6	0	15.7	0	15	9.5	9.0	3.2
CSB14	0	0	15.2	48.1	15	9.5	9.0	3.2

<sup>1</sup>Values are calculated percentages formulated for blends. CSB+: whole corn (78.4%), whole roasted soy (20%), vitamins and minerals (0.2%), tricalcium phosphate (1.16%), and potassium chloride (0.17%). CSB+, Corn Soy Blend Plus; CSB14, corn-soy blend 14; FBF, fortified blended food; RSC, red sorghum-cowpea; WSC1, white sorghum-cowpea variety 1; WSC2, white sorghum-cowpea variety 2; WSS, white sorghum-soy. Adapted from reference 25 with permission.



**TABLE 3** Analyzed FBF macronutrient, micronutrient, and antinutrient content<sup>1</sup>

	WSC1 blend (WSC1 + WPC)	WSC2 blend (WSC2 + WPC)	RSC blend (RSC + WPC)	WSS blend (WSS + WPC)	Extruded corn-soybean blend (CSB14 + WPC)	CSB+ blend
Total energy, kcal/100 g	394.6	396.5	397.1	392.19	392.4	361.64
Carbohydrate, g/100 g (%)	60.8 (61.6)	59.6 (60.1)	60.7 (61.1)	60.7 (61.9)	61.1 (62.3)	64.7 (71.6)
Protein, g/100 g (%)	19.0 (19.2)	19.7 (19.9)	19.5 (19.6)	19.4 (19.8)	19.3 (19.7)	14.7 (16.3)
Fat, g/100 g (%)	8.4 (19.2)	8.8 (20)	8.5 (19.2)	8.0 (18.3)	7.7 (18)	4.9 (12.1)
Lysine, mg/g	74.1	70.9	72.2	69.5	68.3	52.9
Cysteine + methionine, mg/g	33.1	30.9	32.2	35.0	35.7	35.3
Available lysine, mg/g	72.0	67.9	68.6	67.4	66.2	52.2
Iron, mg/100 g	15.2	15.9	15.2	15.6	15.6	8.2
Vitamin A, µg/100 g	598.9	496.9	527.7	553.7	462.6	846.0
Phytates, mg/100 g	832.0	561.0	689.0	557.0	318.0	1885.0
Tannins, mg/100 g	0.00	0.00	0.00	0.00	0.00	0.00

<sup>1</sup>FBFs were analyzed by using AOAC methods by the University of Missouri Agricultural Chemical Laboratories. Macronutrient and micronutrient contents were analyzed in duplicate. CSB+, Corn Soy Blend Plus; CSB14, corn-soy blend 14; FBF, fortified blended food; RSC, red sorghum-cowpea; WPC, whey protein concentrate; WSC1, white sorghum-cowpea variety 1; WSC2, white sorghum-cowpea variety 2; WSS, white sorghum-soy. Adapted from reference 25 with permission.

(38, 39). Participants aged 12–53 mo were given a one-time dose of mebendazole (500 mg). If children were not able to swallow tablets, the medication was crushed and administered after mixing with water. Data collection monitors watched for gastrointestinal upset, and hygiene measures were taken during administration. Interviewers asked about home toilet and water sources, cooking conditions, and home livestock. Caregivers were also asked about fever, cough, flu, diarrhea, vomiting, or loss of appetite. Medical staff assessed children for acute illness (weakness, sick appearance) after anthropometric measurement.

### Data analysis

Data will be analyzed by using SAS statistical software (SAS Studio, version 3.6), with significance set at  $P < 0.05$ . Before analysis, all data will be analyzed for normality and homogeneity in Q-Q plots and with Levene's tests. Variables that are non-normal will be transformed before analysis. Log-transformed variables will be included in stepwise variable selection in adjusted model building (see below). All log-transformed data will be back-transformed for results presentation.

**Week 0 demographic characteristics.** Week 0 differences in covariate factors, including socioeconomic, food intake, and other categorical data, obtained during data collection will be analyzed by using chi-square testing by cluster and age group. Numerical covariate data will be analyzed by multivariate ANOVA by cluster and age group.

**Defining covariates for regression-adjusted outcomes.** Improved and unimproved toilet and water sources, defined by the WHO, have previously correlated with WAZ, height-for-age z score (HAZ), and cognitive outcomes in children (40, 41) (**Supplemental Materials 5**). Composite score covariates, 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, were defined and analyzed from week 0 data as possible covariates for outcomes adjustments in addition to single covariates collected

during weeks 0, 10, or 20 (from survey collection; Supplemental Materials 3).

**Outcomes regression analysis.** Unadjusted raw outcomes data, including height, length, hemoglobin, RBP, MUAC, WAZ, HAZ, and WHZ, will be analyzed by Bonferroni-adjusted ANOVA at weeks 0, 10, and 20. Raw categorical data, including vitamin A deficiency, and anemia, will be analyzed by Bonferroni-adjusted binomial logistic regression analysis. Multiple regression will be used to adjust outcomes for repeated (health facility) and random covariates at week 20 for each outcome measure after backward regression for numeric (hemoglobin, RBP, WAZ, HAZ, MUAC, and WHZ) and categorical (anemia and vitamin A deficiency) variables.

### Discussion

The MFFAPP Tanzania efficacy study was designed to determine whether newly formulated, extruded corn-, soy-, sorghum-, and cowpea-based FBFs resulted in equivalent, or improved, vitamin A or iron outcomes compared with CSB+. Changes in anthropometric outcomes were also examined. So far, few research groups have explored the process of research and development of food aid (7); this efficacy study is the culmination of economic, processing, nutrition, and sensory collaboration to create sustainable, acceptable, and nutritionally sound FBFs.

There were challenges in conducting the efficacy study. Initially, the plan was to source CSB+ to use as a comparison from a vendor that produces it. However, given that it included genetically modified corn and soy we were not able to obtain approval to do so. Thus, non-genetically modified corn and soy were sourced, and CSB+ for the study was produced at KSU. Obtaining NMRI institutional review board approval took longer than anticipated, which delayed the start of participant screening, and changed the start of the study. There was also difficulty in screening as many participants as originally targeted, which led to an extended screening period. Once screening was completed, there was a delay before the start of the study due to several factors, including obtaining final approvals from the Tanzania food safety and

standards agencies and the finalization of the subagreement between partners for data collection during the trial. This delay led to a greater-than-anticipated time between screening and the start of the study and necessitated additional participant screening.

Regardless, the MFFAPP Tanzania efficacy study should provide food aid consumers and producers with information on the feasibility, acceptance, and nutritional efficacy of new FBF formulations for the undernourished. Future publications will detail

**TABLE 4** Newly formulated, extruded FBFs and CSB+ vitamin and mineral fortificant contents<sup>1</sup>

	mg/100 g
Newly formulated, extruded FBFs	
Vitamin A palmitate	0.488
Thiamin mononitrate (vitamin B-1)	0.652
Riboflavin (vitamin B-2)	0.933
Niacinamide (vitamin B-3)	9.07
Calcium D-pantothenate (vitamin B-5)	3.646
Pyridoxine hydrochloride (vitamin B-6)	0.752
Folic acid (vitamin B-9)	0.087
Vitamin B-12	0.0015
Vitamin D <sub>3</sub>	0.0292
Vitamin E	13.224
Vitamin K	0.033
Coated ascorbic acid	40.0
Calcium (tricalcium phosphate)	279.08
Iron*	13.0
Sodium iron EDTA	2.0
Ferrous fumarate	11.0
Iodine (potassium iodide)	0.23
Magnesium oxide	9.47
Phosphorus (tricalcium phosphate)	290.97
Potassium (potassium monophosphate)	163.19
Sodium chloride	225.67
Zinc sulfate	5.50
CSB+	
Vitamin A retinyl ester	1.04
Thiamin mononitrate (vitamin B1)	0.2
Riboflavin (vitamin B-2)	1.4
Niacinamide (vitamin B-3)	8
Calcium D-pantothenate (vitamin B-5)	1.6
Pyridoxine hydrochloride	1
Folic acid (vitamin B-9)	0.11
Vitamin B-12	0.002
Vitamin D <sub>3</sub>	0.011
Vitamin E	8.3
Vitamin K	0.03
Coated ascorbic acid	90
Calcium (tricalcium phosphate)	452
Iron*	6.5
Sodium iron EDTA	2.5
Ferrous fumarate	4.0
Iodine (potassium iodide)	0.04
Phosphorus (tricalcium phosphate)	290
Potassium (potassium chloride)	140
Zinc sulfate monohydrate	5
Sodium chloride	326

<sup>1</sup>Newly formulated FBFs include CSB14, CSB+, RSC, WSC1, WSC2, and WSS.

\*Amount of iron the fortificant is providing. CSB+, Corn Soy Blend Plus; CSB14, corn-soy blend 14; FBF, fortified blended food; RSC, red sorghum-cowpea; WSC1, white sorghum-cowpea variety 1; WSC2, white sorghum-cowpea variety 2; WSS, white sorghum-soy. Adapted from reference 25 with permission.

**TABLE 5** Cluster health facilities, sample size by age group, and allocated treatment<sup>1</sup>

Cluster	Treatment	Health facilities included	Age group, n		Total, n
			6–23 mo	24–53 mo	
1	Control	Guta and Nyangere	135	140	275
2	WSC2	Mekomarilo, Kangetutya	145	141	286
3	CSB14	Kabasa, Machimweru, Nyamatoke	138	154	291
4	CSB+	Sazira, Mcharo, Mugeta	196	142	338
5	RSC	Kuzungu, Mihale, Hunyari, Nyanburundu	154	141	295
6	WSC1	Marambeka, Salama A, Salama K	143	112	255
7	SSB	Sarawe, Ikizu, Kurusanga, Mariwanda	169	140	309
Total			1080	970	2050

<sup>1</sup>CSB+, Corn Soy blend Plus; CSB14, corn-soy blend 14; RSC, red sorghum-cowpea; SSB, sorghum-soy blend; WSC1, white sorghum-cowpea variety 1; WSC2, white sorghum-cowpea variety 2; WSS, white sorghum-soy.

efficacy study outcomes and elucidate acceptance and nutritional differences between FBFs.

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