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Comparison of four supplementary foods in treating moderate acute malnutrition in Sierra Leone: an Ebola-constrained cluster-randomized, controlled clinic-based effectiveness trial

A Report from the Food Aid Quality Review

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This report is made possible by the generous support of the American people through the support of the US Agency for International Development (USAID) and the USAID Office of Food for Peace (FFP) of the Bureau for Democracy, Conflict and Humanitarian Assistance (DCHA), and the World Food Programme (WFP) under the terms of the Contract AFP-C-00-09-00016-00, managed by Tufts University, and Project Peanut Butter.

The contents are the responsibility of Tufts University and its partners in the Food Aid Quality Review (FAQR) and do not necessarily reflect the views of the United States Agency for International Development (USAID), the United States Government, or the World Food Programme (WFP).

The authors have no conflict of interest to declare.

April, 2015

Recommended Citation

Koroma, Aminata; Manary, Mark; Marron, Bethany; Green, Jamie; Rogers, Beatrice; Walton, Shelley; Chui, Kwan Ho Kenneth; Suri, Devika; Langlois, Breanne; Jayson, Lauren, Boiteau, Jocelyn; Rosenberg, Irwin; de Pee, Saskia; Vosti, Stephen; and Webb, Patrick. 2015. Comparison of four supplementary foods in treating moderate acute malnutrition in Sierra Leone: an Ebola-constrained cluster-randomized, controlled clinic-based effectiveness trial, Report to USAID. Boston, MA: Tufts University.

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Acknowledgments

This publication would not have been possible without the collaborative work between the Sierra Leone Ministry of Health and Sanitation Nutrition Directorate, Tufts University, Washington University in St. Louis, and Project Peanut Butter. The authors would like to thank Njala University and Memuna Sawi, as well as Alfred Yambasu who trained, coordinated, and supervised the field data collection in Kenema District, and the Data Manager, Ibrahim Koroma. Thanks also go to Mariama Mattia, Josephine Swarray, Abu Bakarr Sesay, and Mohamed Bah for collecting clinic data and managing study logistics.

Many thanks to the team at Project Peanut Butter in Freetown, including Amanda Maust, Frederick Amara, and Dr. Tabita Kamara for continuous logistical support throughout the project. The team is grateful to Linus Sarkor, Gon Myers, Marian Bangura, Naoe Yakiya, Tekle Moges, and Michael Stanley with the World Food Programme who were essential in the study planning, coordinating food storage, and program logistics. The Ministry of Health team in Kenema District, including Kadiatu Fofanah and Solade Pyne-Bailey, assisted in overall program coordination and dissemination of monthly reports.

The study could not have been undertaken without many volunteers from all over the world: Ellen Murray, Alina Cornelissen, Katharina von Cölln, Astrid Thompson, Marcus Fagan, Craig Healy, and Brianna Hickey.

Thanks also go to study supervisors, enumerators, and office managers for their dedication and hard work in the field. We would like to thank Suliaman Lansana and Mariatu Jalloh for their template building and data entry services.

The strong support provided by Judy Canahauti, Rufino Perez, Melanie Thurber, Violet Dancheck, USAID FFP, Saskia de Pee, WFP Rome, and their colleagues at USAID and WFP is gratefully acknowledged.

Finally, this research depended on the goodwill and patience of the families of Kenema District who sat through hours of survey questions, allowed the team to measure their children, and welcomed the researchers into their homes.

This report is dedicated to Massah Kallon, an enumerator, who passed away in January 2015. Her enthusiasm, dedication to her work and her loving spirit will always be remembered.

Contents

Acknowledgments.....	2
Abbreviations and Acronyms.....	5
Executive Summary.....	6
I. Introduction	9
1.1 Study Rationale.....	10
2. Methods	11
2.1 Study Setting	11
2.2 The World Food Programme Supplementary Feeding Program	11
2.3 Treatment Study Research Design	12
2.4 Study Methods	13
2.4.1 Sample Size.....	13
2.4.2 Sampling.....	14
2.4.3 Subjects	15
2.4.4 Study Foods.....	16
2.4.5 Data Collection	16
2.4.6 Field Work	17
2.4.7 Data Entry and Cleaning	20
2.4.8 Data Analysis.....	20
3. Ebola Virus Outbreak	21
4. Results	24
4.1 Objective 1: Effectiveness	24
4.2 Objective 2: Cost-Effectiveness	27
4.3 Objective 3: Determinants of Effectiveness/Process	29
5. Challenges	30
6. Conclusions and Next Steps.....	31
7. References.....	33
Appendix I. Food Aid Quality Review Summary	35
Appendix II. Tables and Figures	36

List of Tables and Figures

Table 1. Power and detectable differences.....	14
Table 2. Research outcomes by study group, n=1327	25
Table 3. Rates of recovery (MUAC \geq 12.5cm within 10 weeks) by study group, n=1135.....	26
Table 4. Logistic regression comparing study groups with respect to recovery from MAM, defined as MUAC \geq 12.5cm within 10 weeks, n=1135.....	26
Table 5. Time to recovery and weight gain velocity by study group among those who recovered from MAM, n=665	27
Table 6. Costs of supplementary food rations and transportation to country among the four treatment groups in the Sierra Leone field-based research project I	27
Appendix Table 1. PHU classification*	36
Appendix Table 2. Nutrient composition of rations of supplementary foods.....	37
Appendix Table 3. Ingredient composition of rations of supplementary foods	39
Appendix Table 4. Overview of data collection instruments	40
Appendix Table 5. Summary of enrollment characteristics by study group, n=1327	41
Appendix Table 6. Descriptive summary of determinants of effectiveness by study group, n=234.....	42
Figure 1. Map of Sierra Leone and Kenema District.....	12
Figure 2. SFP distribution and cooking instructions for study protocol.....	18
Figure 3. New MAM cases* at research clinics by month	23
Figure 4. Product costs, by treatment group and two metrics of program success, using actual program outcomes in Sierra Leone, based on modeled prices I from June 2014 of commodities and transportation to country (but excluding programming costs).....	28
Figure 5. Commodity and transportation to country costs actually paid in the Sierra Leone field-based research project per recovered child by treatment group, compared with modeled prices from June 2014 of commodities and transportation to country (but excluding programming costs) I	29
Appendix Figure 1. Flow chart of outcomes for enrolled children with MAM treated up to 10 weeks or suspended, n=1327	44
Appendix Figure 2. Cumulative recovery rates by week.....	45
Appendix Figure 3. Empirical distribution for time to recovery by study group among those who recovered from MAM, n=665	46
Appendix Figure 4. Weight gain velocity (g/kg/day) by study group among those who recovered from MAM, n=665	47

Abbreviations and Acronyms

BMC	Beneficiary's Mother/Caretaker
CHC	Community Health Center
CHV	Community Health Volunteer
CSB	Corn Soy Blend
CSB14	Corn Soy Blend 14
DHS	Demographic and Health Survey
FBF	Fortified Blended Food
FGD	Focus Group Discussion
FVO	Fortified Vegetable Oil
GEE	Generalized Estimating Equations
HAZ	Height for Age Z-score
HDC	Health and Development Committee Member
HHFIAS	Household Food Insecurity Access Scale
ICC	Inter-Cluster Correlation Coefficient
IYCF	Infant and Young Child
MAM	Moderate Acute Malnutrition
MCHP	Maternal Child Health Post
MoHS	Ministry of Health and Sanitation
MUAC	Mid-Upper Arm circumference
OTP	Outpatient Therapeutic Program
PHU	Peripheral Health Unit
PPB	Project Peanut Butter
RUSF	Ready-to-Use Supplementary Food
RUTF	Ready-to-Use Therapeutic Food
SAM	Severe Acute Malnutrition
SES	Socioeconomic Status
SFP	Supplementary Feeding Program
SC	Super Cereal
SC+	Super Cereal Plus
USAID	United States Agency for International Development
WFP	World Food Programme
WHZ	Weight for Height Z-score

Executive Summary

This intent-to-treat study was designed to compare the relative effectiveness and cost-effectiveness of four food aid products for the treatment of moderate acute malnutrition (MAM) in Sierra Leone. While several products exist to treat MAM, including various formulations of fortified blended foods (FBFs) and ready-to-use supplementary foods (RUSFs), studies to date have provided mixed evidence on effectiveness, and few studies have addressed the question of cost-effectiveness in any depth.

A cluster randomized effectiveness trial was started in Sierra Leone in January 2014. Inclusion criteria for the study were: age six months up to five years; mid-upper group circumference (MUAC) ≥ 11.5 cm and < 12.5 cm; and receiving food from only one supplementary feeding program (SFP). The study site was Kenema District, where participants received one of four supplementary foods designed to treat MAM from a supplementary feeding program (SFP) based in a clinic setting. Three of these foods—Super Cereal (SC), Super Cereal Plus (SC+), and a RUSF—are commonly used. The fourth food, Corn Soy Blend 14 (CSB14)¹, was developed based on nutritional recommendations of the Food Aid Quality Review Phase I (FAQR) [1].

SFP clinic sites were cluster randomized to receive one of the four foods. From January to July 2014, a total of 1,327 children with MAM were eligible for enrollment. Participating children received a ration every two weeks, for up to 10 weeks or until one of the following outcomes was reached: recovered from MAM; developed severe acute malnutrition (SAM); transferred to inpatient care; default²; or death. The study foods were similar in energy and protein with the exception of RUSF, which provided roughly half as much energy and protein. The foods were not isocaloric, but were consistent with normal programmatic standards of WFP. WFP provides larger quantities of foods that require preparation, as the foods are expected to be shared more than foods that do not require preparation.

The study originally planned to enroll participants until March 2015. However, due to an Ebola virus outbreak in the research area, the study was terminated in July 2014. Early termination of the study meant the target sample size of 5,000 was not reached, leaving 1,135 children who completed the study. Additionally, much of the planned data collection was truncated.

The primary outcome measure was “recovery,” which is defined as achieving MUAC ≥ 12.5 cm within 10 weeks, or failure defined as no improvement within 10 weeks, developing SAM,

¹ Corn Soy Blend 14 is also called Corn Soy Whey Blend (CSWB) as indicated in the commodity specifications.

² Default is defined as abandoning treatment before it has been carried out for a pre-determined time or outcome.

transfer to inpatient care, default, or death. Secondary outcome measures included weight gain velocity and time to recovery.

Recovery rates, determined by MUAC, were as follows: 63.3 percent for SC+ (comparison group); 61.6 percent for SC; 54.8 percent for RUSF; 55.7 percent for CSB14. While bivariate analysis suggested that the RUSF and CSB14 groups had significantly lower odds of recovery compared to the comparison group (SC+), such differences were no longer significant after controlling for other relevant factors.

Mean time to recovery in weeks was highest in the RUSF group and lowest in the SC group, with significant differences noted between RUSF and every other group. Additionally, there were significant differences in mean time to recovery between the SC and CSB14 groups. RUSF had significantly lower mean weight gain velocity than each of the other three foods; no other significant differences were noted.

Due to early study termination, it was not possible to collect required data to conduct a full cost-effectiveness assessment. Using modeled market costs of product ingredients and actual study outcomes, product and transportation costs per recovered child were lowest in the SC+ and SC groups, followed by CSB14, and highest in the RUSF group. The team was not able to collect cost data on in-country transportation and distribution of foods.

A total of 234 Household Questionnaires were completed. SC+ and SC participants reported that the food ration lasted an average of 12 days, while RUSF and CSB14 participants reported an average of nine days. Supplement consumption by someone other than the beneficiary child (i.e. "sharing") was reported to be lowest in the RUSF groups (3.2 percent) and highest in CSB14 (43.3 percent).

CSB14 preparation requires the addition of fortified vegetable oil during cooking, which was taught (and provided for) at a ratio of 30 g FVO to 100 g CSB flour. Among participants in the CSB14 group, the actual ratio reported was 30 g FVO to 165g CSB flour. Sources of drinking water, use of a latrine, and access to electricity varied among the groups, as did the proportion of respondents who were enrolled in other food aid programs.

Due to early termination, the study was limited in a number of important ways. The intended sample size was not met, thereby reducing its power. Bias was created among children with the 10-week time period of study suspension, as children that reached an outcome sooner were less likely to be suspended. Assessment of determinants of effectiveness was incomplete due to reduction in data collection.

Treatment of MAM with food remains a priority research issue. This study offers suggestive

findings that there may be differences in effectiveness and cost-effectiveness among the study foods. However, due to early termination of the study, it is not possible to provide strong evidence or make definitive recommendations. Cost-effectiveness of alternative foods should drive programming choices. In this study, we were unable to determine which food represents better value for money or better recovery rates. These issues should be the top priority for future research. It is hoped that this study can be reproduced to its full intended extent in another setting.

I. Introduction

This report presents the findings from a study designed to determine the relative effectiveness and cost-effectiveness of four supplementary foods used in the treatment of moderate acute malnutrition (MAM) in children 6-59 months of age. This was an intent-to-treat study, designed and implemented as a partnership among Tufts University, Washington University in St. Louis, Project Peanut Butter (PPB), and the Sierra Leone Ministry of Health and Sanitation Nutrition (MoHS) Department. The World Food Programme (WFP) and the United States Agency supported the study for International Development (USAID).

The treatment of children with MAM was conducted in the context of a pre-existing Peripheral Health Unit (PHU) level, Supplementary Feeding Program (SFP) model, in Kenema District, Sierra Leone. Prior to the study, WFP was distributing a Super Cereal (SC) with sugar and FVO added on site at all of their SFP clinics. In order to conduct the study and compare four supplementary foods, WFP agreed to distribute the four designated foods at twenty SFPs. WFP continued to manage transportation and storage of the supply into the district whereas Project Peanut Butter oversaw the delivery of foods for the SFP to treat MAM. The SFPs were carried out using one of four foods:

- 1. Super Cereal Plus (SC+) at 800 kcal/d, 215 g/day (comparison group)**
SC+ [2] is composed of maize (58.24 percent), dehulled soybeans (20 percent), sugar (9 percent), dried skim milk powder (8 percent), vegetable oil (3 percent), and vitamin & mineral premix (1.76 percent). The ration does not require the addition of fortified vegetable oil (FVO) and was distributed to beneficiaries in two pre-packaged bags of 1.5 kg each per two weeks.
- 2. Super Cereal (SC), distributed with FVO and sugar at 998 kcal/day – 200 g SC and 20 g fortified vegetable oil (FVO) [3] and 20 g sugar/day**
SC [4] contains maize (78.3 percent), whole soybeans (20 percent), vitamin & mineral premix (1.7 percent). The ration requires the addition of FVO-fortified with vitamin A and D- and sugar in order to increase caloric density of the porridge and aid the absorption of fat-soluble vitamins. The ration was pre-mixed by clinic staff on site and distributed as a single package to beneficiaries.
- 3. Corn Soy Blend 14 (CSB14) and FVO at 978 kcal/day – 150 g CSB14 and 45 g FVO/ day**
CSB14 [5] is composed of cornmeal (68.34 percent), soy flour (21.13 percent), vegetable oil (5.5 percent), whey protein concentrate (3 percent), and a vitamin and

mineral premix (2.03). Like SC blended with sugar + oil on site, CSB14 is programmed with FVO [3], but the amount of FVO provided is three times the amount that is added to SC (45 g/150 g, instead of 15 g/150 g). CSB14 was scooped out of a 25 kg bag into individual bags by the clinic staff on site and was distributed to beneficiaries as a single package of flour along with a bottle of FVO.

- 4. Ready-to-Use Supplementary Food (RUSF) [6] – 500 kcal/day, 92 g/day**
- RUSF, specifically the variant used in this study: Plumpy'Sup™, contains peanut paste, vegetable oil, soy protein isolate, whey, maltodextrin, sugar, cocoa, and micronutrients [7]. As a lipid-based product, it has higher energy density and fat content than the Corn Soy Blend (CSB) flours. It does not require any preparation and can be consumed directly from the sachet. RUSF was provided as an individually packaged daily ration.

The objectives of the study were to:

1. Compare the effectiveness of four supplementary foods in the treatment of MAM in normal programmatic settings in Sierra Leone;
2. Determine total costs of implementing the feeding program per treated child for each study group, and estimate the cost-effectiveness of each product using cost per child recovered from MAM; and
3. Compare the determinants of effectiveness by study group, including: consumption adherence, preparation compliance, sharing of supplement within and outside of the household, adverse effects of foods, hygiene and health behaviors, socioeconomic status (SES), food security, and perceived barriers to supplement use.

The report is structured as follows: Section 2 presents the study setting and methods, Section 3 explains the Ebola virus outbreak's impact on the study, Section 4 presents the results, Section 5 highlights the challenges faced when implementing the study, while Section 6 offers conclusions and outlines ways forward to achieve the findings originally sought by this study.

1.1 Study Rationale

Globally, there are an estimated 161 million stunted children (too short for their age) [8] and at least 51 million are severely or moderately wasted (weighing too little for their height) [9, 10]. Undernutrition underlies almost half of preventable deaths in children younger than five years of age [10]. Stunted and wasted children have an increased risk of death from diarrhea, pneumonia, measles, and other infectious diseases [10].

The World Health Organization classifies MAM as having weight/height z-score (WHZ) < -2 and ≥ -3 with absence of edema. These children have greater susceptibility to infectious disease, delayed cognitive development, and decreased adult stature and productivity [11-14].

Currently, the universal recommendation for food insecure settings is that both treatment and

prevention of MAM involve providing mothers/caregivers with supplementary foods (RUSF or fortified blended food, FBF) to feed to the target child.

The results of the study were to be disseminated to the Government of Sierra Leone in order to inform decisions on the most cost-effective supplement for treating MAM in their population. This study will give insight on the type of product and ingredients that achieve the best impact in normal programmatic settings.

The Sierra Leone Ethics and Scientific Review Committee, the Human Research Protection Office at Washington University in St. Louis, and the Tufts University Health Science Campus Institutional Review Board approved the study.

2. Methods

2.1 Study Setting

According to the 2013 Sierra Leone Demographic Health Surveys (DHS) [15], nine percent of children are wasted, and four percent severely wasted in Sierra Leone nationally. Wasting increases initially with the child's age from 10 percent at under age six months to a peak of 18 percent at age 9-11 months, before declining steadily to seven percent at age 48-59 months.

This study was conducted in Kenema District. According to the 2013 DHS [15] 39 percent of children in Kenema District (population 545,000) were stunted. Eight percent of children under five years of age in Kenema were wasted, and 2.6 percent were severely wasted. Twenty rural SFP clinic sites in Kenema District, Sierra Leone (**Figure 1**) were identified with the help of the Nutrition Directorate at the MoHS, the Kenema District Health Management Team, and the Kenema District WFP sub-office Nutrition Program Officer. The study sites included varying levels of Peripheral Health Units (PHU) across eleven chiefdoms (**Appendix Table 1**). Each PHU represented a SFP clinic site. The sites were divided into four groups based on geographic location in order to avoid crossover among the study foods. Groups were then randomly assigned to the four study groups.

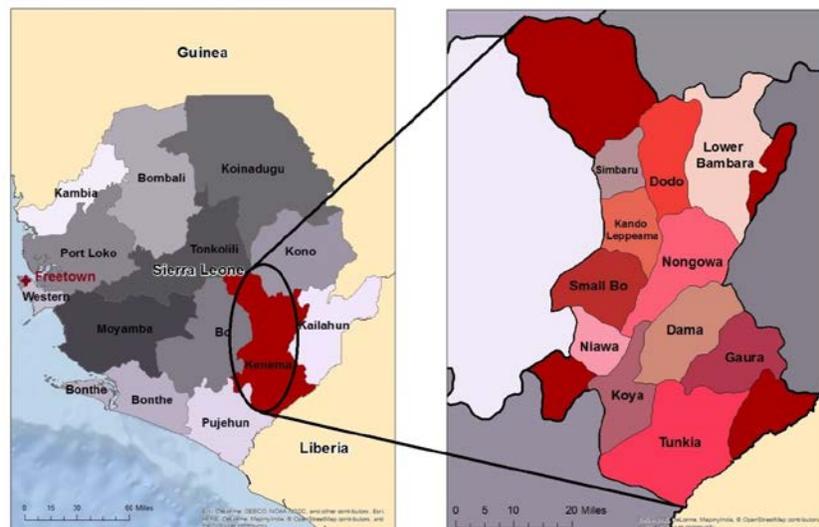
2.2 The World Food Programme Supplementary Feeding Program

The MAM SFPs are carried out through the Sierra Leone MoHS PHUs (referred to as SFP clinics throughout the report); the Sierra Leone WFP SFP protocol for children under age five is as follows:

- Children are screened for MAM in the community by Community Health Volunteers (CHV) and/or at a health facility during health visits, based on MUAC. If a child meets the SFP admission criteria, he/she is then referred to the nearest SFP, where he/she is then re-screened before receiving the supplementary food.

- According to WFP protocol, in order to be admitted into the MAM SFP, a child must meet at least one of the following criteria: WHZ of <-2 to -3; MUAC of 11.5 to 12.4 cm (only children referred through community screening); discharged from outpatient therapeutic (OTP) feeding (irrespective of their WHZ).
- A child is eligible to receive food for 60-90 days, depending on the rate of recovery. Caregivers also receive instructions on food preparation and positive infant and young child (IYCF) practices. The SFP provides two-week rations at a time for admitted children. Every two weeks the child's anthropometric measurements are taken and his/her growth is monitored.
- Discharge criteria for the SFP include: WHZ greater than or equal to -2 on two consecutive weightings; MUAC greater than or equal to 12.5 cm; Children admitted from OTP are discharged after receiving supplementary food for 60 days, irrespective of MAM status. The SFP provides two weeks of rations at a time for admitted children.

Figure 1. Map of Sierra Leone and Kenema District



2.3 Treatment Study Research Design

This was a cluster-randomized effectiveness study. The SFP clinic sites served as the clusters for randomization. Potential study participants were screened by community health volunteers (CHVs) and referred to the nearest SFP on the designated distribution day. Study participants were enrolled in the research for up to 10 weeks (or until an outcome was reached), but were eligible to receive the supplementary food for a total of 12 weeks. Data were collected biweekly, with up to a total of six data collection points for each participant (from start of

research to Week 10). If enrolled in the research for the full 10 weeks, participants received a supplementary food ration on their last research visit (up to a total of 12 weeks of supplementary food). Education on preparation and consumption of the food received was provided to caretakers at the SFP clinic site on the day of distribution. Study participants were treated with one of the designated supplementary foods for up to 10 weeks or until they met any of the discharge criteria. During the treatment period, CHVs visited households of enrolled beneficiaries to reinforce proper use of the study food. Children who successfully graduated from treatment (reached satisfactory MUAC within 10 weeks) were asked to return to the SFP clinic site for reevaluation at six months after graduation. Any children relapsing into MAM were treated according to Sierra Leone MoHS Integrated Management of Acute Malnutrition (IMAM) protocol.

2.4 Study Methods

2.4.1 Sample Size

The original sample size calculation was based on the outcome of percent of children who recover from MAM. Assuming a baseline recovery rate of 80 percent, to detect an improvement of six percentage points in recovery, a sample size of 1,028 children was needed for comparison of one treatment group to the comparison group, i.e. 514 children in the intervention and 514 in the comparison group³. To account for a cluster-randomized design, a correction factor was included, bringing the sample size to 1,250 children per treatment group⁴. Dropouts were not accounted for, as this was an intention to treat analysis.

Due to the early termination of the study, per-group sample size was capped at approximately 250 instead of the targeted 1,250. This drop in sample size decreased statistical power to about 30 percent, making it necessary for there to be larger differences in recovery rates among the study groups in order to find statistical significance. Based on a sample size of 250 per group, type I error rate of 5 percent, and using Fisher's Exact test, the power and new detectable differences are presented in **Table I**.

³ For a standard individually-randomized trial, with power of 80 percent and alpha of 0.05

⁴ Using an inter-cluster correlation coefficient (ICC) of 0.006 (a conservative estimate based on the possibility of different socioeconomic characteristics at SFP clinic sites) and the equation $m = n1(1-ICC)/((k-(n1*ICC))$ where m was the number of subjects per cluster after the ICC is incorporated, k is the number of clusters (sites) per treatment group, and $n1$ is the per group sample size if $ICC = 0$ (in this case the value explained above was used, where subjects are randomized individually, 514 per group). Using this equation and a k of five sites, the calculated sample size was about 250 subjects per site, or 1,250 children per treatment group.

Table I. Power and detectable differences

Group with the higher proportion recovered	Group with the lower proportion recovered	Power	Approximate detectable difference in percent point
90	80	86.1	10
85	74	84.1	11
80	68	84.5	12
75	63	80.4	12
70	57	83.6	13
65	52	81.8	13

The original plan for field data collection included cluster-randomized selection of a sub-sample of 1,600 (400 per group) beneficiary mothers/caretakers (BMCs) to participate in household questionnaires. This number allows detection of differences in continuous variables between any two groups with an effect size of 0.2 or larger, with a two-tailed and type I error rate = 5 percent and power of slightly more than 80 percent. The power of comparing proportions of two groups varies with different reference proportions and tested differences, but generally, with 400 per group, we can detect most proportion differences that are larger than 10 percent points.

The actual sample size for the field data collection was about 60 per group. Using the above criteria with 'n' per group of 60, the actual power to detect an effect size as small as 0.2 for continuous variables or a difference of 10 percent points for categorical variables was determined to be less than 20 percent.

2.4.2 Sampling

SFP Clinic data

SFP clinic sites were randomized to receive one of the four supplementary foods. There was no randomization at the individual level. Within each of the four groups, all children under age five meeting the inclusion criteria were eligible for participation in the study and were sampled using a convenience method⁵. SFP clinic data were collected from each participant upon his/her arrival on the day of food distribution every two weeks.

Field data

Additionally, it was planned to collect data from a subsample of participants for information on their use, preparation, and consumption of the assigned food aid product. This included household questionnaires, focus group discussions (FGD), and in-home observations. A pooled roster of enrolled beneficiary children was created for each group of the study using the

⁵ "Convenience sampling" is a non-probability sampling method by which subjects are selected based on their accessibility.

biweekly roster available per SFP clinic site. This was done every two weeks per SFP clinic site because all SFP clinic visits in one group are undertaken in the same week (e.g. all five SFP clinics receiving RUSF will have a distribution in the same week). These pooled rosters served as the sampling frames for field data collection in each group.

2.4.3 Subjects

All Beneficiary Mothers/Caretakers (BMCs) receiving food for their MAM-diagnosed children were considered part of the subject pool, as were all children receiving the food. Therefore, the study subjects were as follows:

1. Beneficiary children diagnosed with MAM at study SFP clinics and weighed and measured;
2. BMCs who participated in enrollment interviews, household questionnaires, FGDs, and in-home observations;
3. CHVs/Health and Development Committee Members (HDCs) who participated in individual interviews;
4. PPB and clinic staff members who participated in individual interviews; and
5. Village Elders/Headmen who participated in community interviews.

Beneficiary Children

The subjects in this study were children age 6-59 months old with MAM, defined as MUAC \geq 11.5 cm and $<$ 12.5 cm without bipedal edema who sought treatment at the study sites from January 2014 to July 2014. All eligible children were included, without regard to presence of chronic illness, permanent residence in the local community, or birth order in the household. Prior to enrollment all children were subject to an appetite test, which involved the child's caregiver feeding a sample of the supplementary food to the child. Eligible children who consumed the food were offered enrollment. Any children unable to consume the food or who presented with a medical complication preventing the child from eating were transferred to the closest Stabilization Center for inpatient care and treatment. Children exhibiting signs or symptoms of a peanut allergy were excluded from the study. No children showed any signs or symptoms of peanut allergy.

Beneficiary Mothers/Caretakers (BMC)

BMCs were eligible for selection to participate in household questionnaires and in-home observations when their child was diagnosed with MAM and enrolled to receive a ration from a study SFP clinic site. Interviews and observation included modules on birth and health history of the beneficiary child, household characteristics, and experiences with the food and SFP. There were no age restrictions for inclusion of BMCs. BMCs who participated in a household questionnaire, observation, or FGD once for this study were not eligible again for participation.

PPB & Clinic Staff Member

The PPB team consisted of two local nurses, two logistic coordinators, and anthropometrists. The clinic directors worked with the PPB team to screen children for MAM, enroll them into the SFP, distribute the food, complete a cooking demonstration/taste test, and give out instructions on preparation, handling/storage and feeding. The PPB anthropometrists were responsible for screening children for MAM upon arrival to the SFP clinic site and explaining details about the SFP.

Village Elders/Headmen

Village Elders/Headmen from every community served by the 20 SFP clinics were interviewed in order to understand basic community characteristics.

2.4.4 Study Foods

The nutrient content and ingredient composition of these foods is listed in **Appendix Table 2** and **Appendix Table 3**.

2.4.5 Data Collection

Three levels of data collection were planned: 1) SFP clinic data on beneficiary children using anthropometric measurements and enrollment questionnaires; 2) field data on beneficiary mother/caretaker, community members, and those involved in the SFP using questionnaires, observations, and focus group discussions; and 3) cost data on the time and costs associated with the SFP using cost matrices, program monitoring forms, and observations.

Data collection involved personal interviews in Krio or Mende language at each food distribution. The data collection instruments are listed in **Appendix Table 4**. The team also planned to complete FGDs with BMCs, and interviews with CHVs and Clinic staff members. In addition to FGDs and interviews, the team intended to conduct SFP observations. These were not completed due to study suspension.

Enrollment Questionnaire

Upon enrollment, weight, height and MUAC were measured; health history was obtained (current symptoms of fever, cough or diarrhea, previous treatment for MAM or Severe Acute Malnutrition (SAM), hospitalizations, tuberculosis exposure, and HIV status). The enrollment questionnaire collected data on demographic information (birth date, age, sex, and caretaker), household possessions, participation in other food assistance programs, and the household food insecurity access scale (HFIAS) was applied.

Community Questionnaire

Data were collected on a portion of communities in the study's catchment area through interviews with village headmen or elders. Data collected included information on basic community infrastructure, market access, and health services.

Household Questionnaire

The household questionnaire collected data on the BMC's experience of preparing and feeding the food supplement, instructions and training they received on the ration, sharing and leakage of the ration, accessibility and transport to the SFP clinic.

In-home Observation

In-home observations took place in the household over the course of five days. Observers recorded behaviors related to the storage, preparation, feeding, sharing, and consumption of the supplementary food.

Cost Matrix

In order to determine costs of each food product—including commodity/product, transportation, distribution, staff and beneficiary costs—data were collected from key informants from WFP and PPB, invoices, shipping records, budgets, and other cost data sources. Two data collection instruments were developed in order to capture time costs of transportation of the food to SFP clinics and distribution to beneficiaries. Due to the early study suspension, cost data were restricted to commodity and transportation costs to Kenema District.

2.4.6 Field Work

Clinic Team

The Clinic Research Team consisted of four national staff, including two Field Nurses and two Field Aides, one Clinic Research Manager, and two or three graduate interns. This team was divided into two. Each team visited one SFP clinic site per day, Monday-Friday, every 14 days. In order to ensure consistent delivery of service and implementation of the research protocol, staff was instructed to conduct SFPs and data collection uniformly. There were also one or two CHVs who assisted at clinics and performed recruitment/follow-up with patients in the villages.

The Clinic Research Team evaluated children presenting at the study sites with moderate malnutrition. Sierra Leonean nurses assessing and treating children were fluent in English, Krio, and the local tribal language, Mende, of the Kenema District. Study staff were given training prior to the start of the study, and also participated in a refresher training six months into the study. The staff was evaluated on their research knowledge and anthropometric measurements. Methodologies for standardizing anthropometric measurements were used.

Research personnel measured weight using a SECA 383 Electronic Baby Scale, on which the child could sit or stand. Length was measured on a SECA 417 Mobile Baby Measuring Station. Triplicate length measurements were taken, with all measurements falling within 0.5cm of each other. Study staff assessed each child for bilateral pitting edema (body tissue swelling due to fluid accumulation).

Caregivers of the children meeting enrollment criteria gave both verbal and written consent for participation in the study. As most caregivers were unable to write, a thumbprint was taken. Upon identification of MAM, children of mothers/caretakers who provided consent were admitted to the research and enrolled in the research study. All eligible children (regardless of research enrollment) were provided up to 12 weeks of food, distributed two weeks at a time, for the recovery from moderate acute malnutrition.

Research staff collected this information on site during each SFP clinic visit. Beneficiaries were instructed to return to the SFP clinic site every two weeks where they would be weighed, measured, and given their assigned food ration. Caregivers were instructed on proper food preparation, general health information messaging, return visits to the study clinic, and follow-up visits upon the child's graduation from treatment. Each caregiver was given a study identification card with the date of enrollment and dates for follow-up, including at six months after graduation from treatment. Differences in the study food preparation and consumption instructions are outlined in **Figure 2**. Children presenting to the SFP clinic site with fever, diarrhea, or other medical symptoms were referred to the local clinic staff for malaria, tuberculosis, and HIV testing and treatment, while they continued MAM treatment. The clinic research team and/or CHV followed up with children who missed their SFP clinic appointment by visiting them in their homes. If the child was found at home, anthropometric data was collected, but the beneficiary did not receive the food ration or any other services provided at the SFP clinic. Children who missed three consecutive visits were paid a home visit from the study team in order to assess the child and were classified with a default study outcome.

Figure 2. SFP distribution and cooking instructions for study protocol

SC+ (comparison group)
<p>Daily Ration 1 heaping cup SC+ 4 cups water</p> <p>Cooking Instructions</p> <ol style="list-style-type: none"> 1. Add water to pot and bring to boil 2. Keep at a rolling boil for at least 5 minutes to ensure sterilized water 3. Add SC+ and stir 4. Turn down heat (if possible). Simmer and continue to cook 5 minutes, stirring regularly to remove lumps and prevent sticking 5. After cooking, allow to cool for 10-15 minutes. Stir to eliminate as many lumps as possible <p>Two Week Supply 2 1.5 kg. packets SC+</p>
SC (Premix with FVO and Sugar)
<p>Daily Ration Premixed: 1 heaping cup 4 cups of water</p> <p>Cooking Instructions</p> <ol style="list-style-type: none"> 1. Add 4 cups of water to pot and bring to boil

<ol style="list-style-type: none"> 2. Keeping at a rolling boil for at least 5 minutes to ensure sterilized water 3. Add 1 butter cup of SC premix and stir 4. Turn down heat (if possible). Simmer or continue to cook 5 minutes, stirring regularly to remove lumps and prevent sticking. 5. After cooking, allow to cool for 10-15 minutes. Stir to eliminate as many lumps as possible. <p>Two Week Supply Premixed 2 pitchers* filled below the spout and shaken down plus 1 level cup *1 Pitcher holds approximately 2 quarts=8 cups</p>
<p>RUSF</p>
<p>Daily Ration 1 sachet No cooking required. Two Week Supply 14 sachets of Plumpy'Sup™</p>
<p>CSB14 (With FVO)</p>
<p>Daily Ration 1 level cup CSB14 (not shaken down) 2.5-3 cups water 4 Tablespoons FVO Cooking Instructions <ol style="list-style-type: none"> 1. Add 3 cups of water to pot and bring to boil 2. Keep at a rolling boil for at least 5 minutes to ensure sterilized water 3. Add 4 tablespoons FVO and 1 level cup of CSB14. Stir. 4. Turn down heat (if possible). Simmer or continue to cook 5 minutes, stirring regularly to remove lumps and prevent sticking. 5. After cooking, allow to cool for 10-15 minutes. Stir to eliminate as many lumps as possible. Two Week Supply 2 pitchers* filled below the spout and shaken down of CSB14 2 ½ cups FVO (fill to line on plastic container) *1 Pitcher holds approximately 2 quarts= 8 cups</p>

Field Team

In addition to the data collected by the clinic team, we also had a field study team who was responsible for all other data collection in the field. We contracted with local experts from Njala University to train, supervise, and collect data. The field team collected all survey data within the catchment communities and in beneficiary households. The field survey team consisted of sixteen enumerators, four field supervisors, and two data entry clerks with backgrounds in nutrition, medicine, behavior sciences, economics, or mathematics.

The four supervisors were trained first and completed the initial pretest of all data collection instruments. They were oriented to the study and learned how to supervise teams of four enumerators in the field. The supervisors were responsible for monitoring data collection, organizing completed data collection forms, reporting any issues to the field study director, and backstopping for their team. The supervisors traveled daily between the field and Kenema City where data were stored and entered.

Enumerators were trained over a 10-day period on the following topics: research integrity,

consenting procedures, questionnaire administration skills, facilitator skills, use of study materials (stopwatches, GPS units, and digital voice recorders), and how to fill out data collection forms. Each enumerator took a written and practical exam to demonstrate his/her understanding and ability to carry out field data collection. All data collection was pilot tested prior to field data collection, and enumerators were assessed on their competence to successfully collect data in the field (along with their test scores and basic understanding and engagement during training).

2.4.7 Data Entry and Cleaning

Data were entered in Microsoft Access, and discrepancies found via data cleaning were resolved by reexamination of data collection forms. Due to time constraints, data were not double entered. Enrollment and outcome characteristics were tabulated using Graph Pad; weight gain in g/kg/d and MUAC gain in mm/d were calculated for participants over the first four weeks (or less if they graduated earlier) of enrollment. Length gain in mm/d, was calculated over the entire duration of study participation.

Data analysis was conducted by teams at Tufts University and Washington University with collaboration on data cleaning, preparation and analysis plan. SFP clinic data were cleaned and prepared by teams at Washington University, while cleaning and preparation of field data were completed at Tufts. Each team was responsible for “locking” the data once cleaned and storing the locked data set on a password-protected computer. Locked data were accessible to both teams.

2.4.8 Data Analysis

The analysis plan reflects changes made after the early termination of the study. All data were analyzed using SAS 9.3 (SAS Institute, Cary NC). For all analyses, statistical significance was determined at the .05 level. Descriptive statistics were stratified by treatment group. Chi-square and ANOVA tests (Kruskal-Wallis if appropriate) were used to assess homogeneity of enrollment characteristics across groups.

Recovery from MAM (Objective 1)

The primary outcome for Objective 1 was recovery from MAM, defined as achieving MUAC \geq 12.5 cm within 10 weeks, or failure to recover. Failure to recover was classified as no improvement within 10 weeks, developed SAM, transfer to inpatient, default, or death. Due to early termination, those who were enrolled and suspended from the research prior to reaching an outcome were excluded from the primary analysis (n=192). Two logistic regression models were used to assess recovery from MAM among the study groups. First a simple, univariate logistic regression model was performed to compare each study group individually to SC+ (the comparison). Then a multivariate logistic regression model was fitted to control for potential confounders. Enrollment characteristics that were significantly associated with both the study group and recovery from MAM outcome were included in multivariate analysis as possible

confounders. Hosmer-Lemeshow test was used to assess goodness of fit. Additionally, rates of recovery were plotted over person-time to compare study groups.

Secondary outcome measures included mean time to recovery (in weeks) and weight gain velocity (g/kg/day). Time to recovery and weight gain velocity among those who recovered from MAM were assessed through ANOVA test. Pairwise comparisons were conducted using Duncan's Multiple Range Test. Additionally, an empirical distribution function was used to display the cumulative distribution of time to recovery for each study group. The metric used to assess weight gain velocity was of gram weight change per kilogram of body mass per day (g/kg/day).

While the criterion for this research was MUAC, we also calculated WHZ for all research visits using WHO child growth standards [16]. The two metrics (WHZ and MUAC) were compared through a correlation analysis, using a method to account for repeat measures [17].

Costs and cost-effectiveness (Objective 2)

To assess Objective 2, a comprehensive costing worksheet was developed with assistance from a cost-effectiveness expert from University of California, Davis. Using an ingredients/activities-based method, data for costs under the categories of commodity/product, transportation to country were entered into an Excel spreadsheet (Microsoft, 2013) for calculations. Other costs, including within country transportation, loading and unloading, storage and warehousing, personnel, distribution and beneficiary time were planned but not collected due to study suspension. Costs were collected in local currency and converted to US dollars. For each group of the study, we calculated: 1) the total operating costs of the treatment program; 2) the total cost per child treated; and 3) the cost per child recovered.

Determinants of effectiveness (Objective 3)

Due to lack of sufficient power to detect differences in key indicators across study groups, only descriptive statistics were reported for Objective 3. Findings from other field data collection instruments (In-home Observations and Community Questionnaires) were not reported, due to small sample size (fewer than 30 collected for each). For the Household Questionnaires, descriptive statistics were calculated for the following indicators and stratified by study group: supplement exposure from most recent food collection; sharing of supplement; adherence to consumption and food preparation instructions; KAP and self-efficacy; and SES factors.

3. Ebola Virus Outbreak

The onset of the Ebola virus in the Kenema District starting in June 2014 necessitated changes to the research protocol that affected measurement and food distribution as well as patient

follow-up and field data collection.

The Ebola virus entered Sierra Leone during February 2014. The neighboring Kailahun District reported the first case and was deemed a viral epicenter by the national Ministry of Health; Kailahun was quarantined (travel was suspended and public gatherings in the district were banned) in June 2014. Unfortunately, travel restrictions did not halt the spread of Ebola virus soon enough. By July 2014, an average of five indigenous positive cases were confirmed in Kenema Township per day. Subsequent fear that the outbreak would continue to worsen and reach the capital, Freetown, led to the inclusion of the Kenema District in the quarantine of late July 2014. Due to significant travel restrictions, the growing number of cases, and the overwhelmed health system in the Kenema District to treat the Ebola virus as well as trace cases and impacted areas, Kenema became an increasingly difficult and dangerous place to conduct research. Prevention and quarantine measures included screening checkpoints along major roads.

Starting in June 2014, clinic staff was subjected to Ebola virus screening (wherein all travelers were required to exit their vehicles and wait to be checked for fever and complete a questionnaire about their travel intentions and history of illness). Travel restrictions did not affect intra-village movement, i.e. caregivers going to SFP clinic sites. However, sporadic enforcement measures (checkpoints, screening), poor messaging and false messaging generated lack of understanding, belief, and trust toward health personnel and government among many local people.

Likewise, SFP clinic attendance and enrollment decreased dramatically following Ebola virus sensitization campaigns—the number of those seeking clinical care and/or feeding programs—fell in direct relation to growing “awareness” about the disease. Rumors and fear existing among caregivers were difficult to overcome. For example, it was believed that children would be screened and removed from their care or deliberately injected with Ebola virus. Such distrust posed serious security risks to aid workers, ambulances, and NGO vehicles, which, in some cases, were threatened and attacked. These circumstances led the research team to halt all travel to catchment villages (including all field research), unfortunately limiting their interaction with participants and minimizing opportunities to provide households with accurate information about the Ebola virus as well as recruit MAM patients for the feeding program.

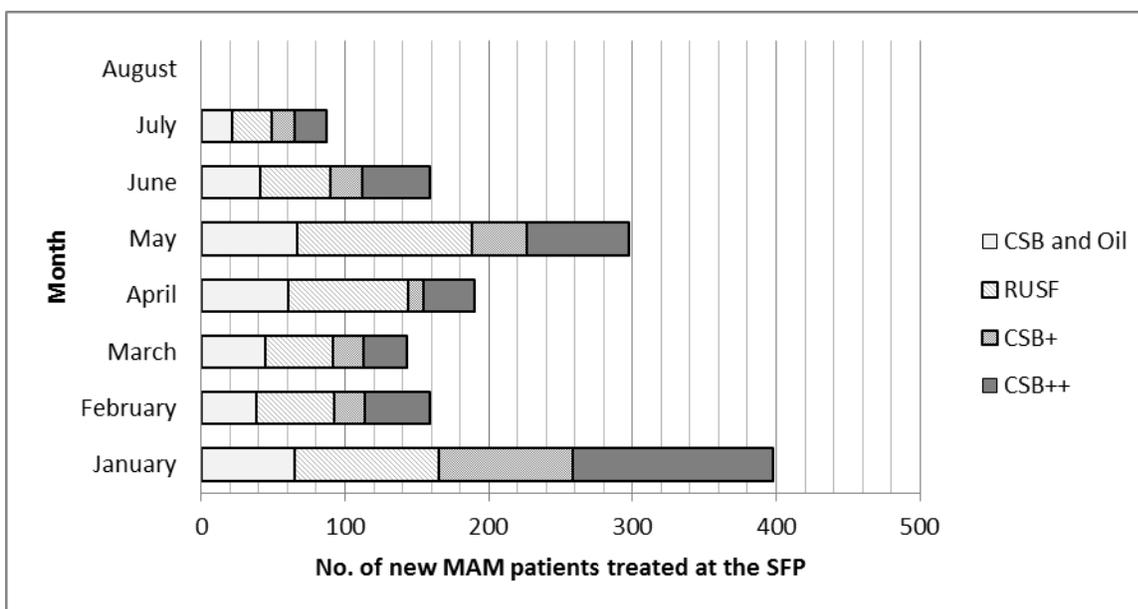
In addition to suspending travel into the villages, the research protocol was adapted to minimize contact and potential infection from enrollees. Prior to June 2014, children were weighed without clothing or diapers, whereas following concerns over the transmission of the Ebola virus, caregivers were instructed to clothe children with diapers before measurement. Also, in mid-June 2014 all SFP clinic sites programming the CSBI4 and SC were given a four-week supply of food; height, weight, MUAC and child health indicators were not assessed according

to the two-week protocol.

Travel restrictions, risk of infection in the clinic environment, security concerns, and low SFP clinic usage (low enrollment and high default) affected research communities and research protocol. The change in conditions from May to June 2014 led Washington University, Tufts University, and PPB to suspend data collection in July 2014 and to cancel all research activity in October 2014.

Figure 3 shows the number of new MAM cases treated at the SFP for January through August 2014, which decrease after Ebola virus reached Kenema district in June. Research was officially suspended in July at all SFP clinics. To determine the effect of potential bias (children not completing a full treatment), an analysis of the primary outcome was performed in two separate ways: 1) with suspended children included, and 2) with suspended children not included. Results are presented with suspended children not included; further discussion on this can be found in the challenges and limitations sections.

Figure 3. New MAM cases* at research clinics by month



*Not all MAM cases presenting at the clinic were enrolled in the research program. Exclusion criteria included: Transfer from OTP program with MUAC >12.5, recipient of other supplementary food within the last month, twin of sibling receiving RUTF, no consent from caregiver.

4. Results

4.1 Objective 1: Effectiveness

A total of 1,327 children were enrolled in the study from January 2014 to July 2014 (**Appendix Figure 1**). Of these, 192 were suspended due to early termination of the study. Suspension rates differed slightly among the study groups, but these differences were not significant ($p=0.62$). A total of 1,135 children enrolled and completed the study and were included in the primary analysis for Objective 1. RUSF had the highest enrollment followed by SC+, CSBI4, and SC. Throughout the study, the team monitored adverse reactions to study foods and none were reported.

A summary of enrollment characteristics for the whole study sample ($n=1,327$) by study group is displayed in **Appendix Table 5**. There were differences in enrollment characteristics among the study groups. Children had similar anthropometry (MUAC and WHZ) at enrollment, but differed in age, weight, and length. Distributions of sex among children and caretakers were similar across the four food groups. All groups had prevalence of concurrent illness, with 55 percent of children reported to have had a fever, 27 percent reported to have diarrhea and 36 percent reported to have cough within two weeks prior to enrollment; the difference in prevalence of these symptoms varied significantly among the study groups at enrollment. Other significant differences in enrollment characteristics among the study groups included caregiver's age, Mende ethnicity, caregiver's years of education, number of live births and number of people in the household. The following variables were identified as potential confounders and included in multivariate analysis of the primary outcome (recovery from MAM): weight (kg) at start, breastfeeding, presence of fever, diarrhea, and cough in prior two weeks. In addition, demographic characteristics of beneficiary child and indicator of OTP start were included.

A descriptive summary of the outcome measures is displayed in **Table 2**. Overall recovery from MAM as defined as $MUAC \geq 12.5\text{cm}$ within 10 weeks was 50 percent; the percent recovered was highest in the SC+ (comparison group). The distribution of other research outcomes among all children was as follows: 14 percent of children developed SAM, one child (0.08 percent) was transferred to inpatient care, 6.8 percent of children defaulted, 0.9 percent died, 13.6 percent showed no response after 10 weeks, and 14.5 percent did not reach a study outcome prior to study suspension due to Ebola virus.

Table 2. Research outcomes by study group, n=1327

	SC + (comparison)	SC	RUSF	CSBI4	Total
	<i>n</i> (col%)	<i>n</i> (col%)	<i>n</i> (col%)	<i>n</i> (col%)	<i>n</i> (%)
Recovered from MAM	212 (54.9)	109 (53.7)	183 (46.5)	161 (46.8)	665 (50.1)
Developed SAM	46 (11.9)	23 (11.3)	61 (15.5)	56 (16.3)	186 (14.0)
Transfer to inpatient	0	0	1 (0.3)	0	1 (0.1)
Default	26 (6.7)	16 (7.9)	25 (6.4)	23 (6.7)	90 (6.8)
Death	3 (0.8)	3 (1.5)	4 (1.0)	2 (0.6)	12 (0.9)
Fail	48 (12.4)	26 (12.8)	60 (15.2)	47 (13.7)	181 (13.6)
Suspension	51 (13.2)	26 (12.8)	60 (15.2)	55 (16.0)	192 (14.5)
Total, <i>n</i> (%)	386 (29.1)	203 (15.3)	394 (29.7)	344 (25.9)	1327 (100.0)

The rate of recovery, expressed over person-time, was highest in the SC group (**Table 3**), with a recovery rate of 126.2 per 1,000 child-weeks. In comparison, rate of recovery was 123, 94.8 and 105 per 1,000 child-weeks in the SC+, RUSF and CSBI4 groups, respectively. In bivariate analysis, the RUSF and CSBI4 groups had significantly lower odds of recovery than the comparison, SC+. However, after controlling for potential confounders in multivariate analysis, these differences were no longer significant (**Table 4**). Child's age, and OTP start were negatively associated with recovery, while weight (kg) and having diarrhea in the two weeks prior to enrollment were positively associated with recovery in the multivariate model. We suspect the dehydration and water losses caused by diarrhea which were then restored during treatment caused these children to move from MAM to recovered status, thus confounding the relationship between diarrhea and recovery.

Mean time to recovery was 4.5 weeks in the SC+ (comparison) group, 4.1 weeks in the SC group, 5.5 weeks in the RUSF group and 4.9 weeks in the CSBI4 group, with significant differences among the groups (**Table 5**). Significant differences in time to recovery were noted between RUSF and each other group, and between CSBI4 and SC. Cumulative recovery rates by week are displayed in **Appendix Figure 2**. **Appendix Figure 3** displays the empirical distribution for time to recovery by study group among those who recovered from MAM.

There were significant differences in weight gain velocity across study groups (g/kg/day) among those who recovered from MAM (**Table 5**). When compared individually, RUSF had significantly lower weight gain velocity than each of the other study groups (SC+, SC, CSBI4). Mean weight gain velocity in g/kg/day was 2.7 in the SC+ (comparison group), 3.0 in the SC group, 2.2 in RUSF, and 2.9 in CSBI4. A boxplot of weight gain velocity by study group is displayed in **Appendix Figure 4**.

Correlation analysis of the two metrics, WHZ and MUAC, yielded significant evidence of a positive, weak-to-moderate linear association ($r=0.38$, $p<.0001$).

Table 3. Rates of recovery (MUAC \geq 12.5cm within 10 weeks) by study group, n=1135

	SC+ (comparison)	SC	RUSF	CSB14	Total
Recovered, <i>n</i> (col%)	212 (63.3)	109 (61.6)	183 (54.8)	161 (55.7)	665 (58.6)
Failure, <i>n</i> (col%)	123 (36.7)	68 (38.4)	151 (45.2)	128 (44.3)	470 (41.4)
Total (%)	335 (29.5)	177 (15.6)	334 (29.4)	289 (25.5)	1135 (100)
<i>Rates over person-time</i>					
Recovered, <i>n</i>	212	109	183	161	665
Child-weeks, <i>n</i>	1724	864	1930	1534	6052
Rate/1,000 child-weeks	123	126.2	94.8	105	109.9

Table 4. Logistic regression comparing study groups with respect to recovery from MAM, defined as MUAC \geq 12.5cm within 10 weeks, n=1135

	OR (95% CI)	p-value
<i>Model 1: Univariate model</i>		
Study group		
SC+ (comparison)	Ref	
SC	0.93 (0.64, 1.35)	0.71
RUSF	0.70 (0.52, 0.96)	0.03
CSB14	0.73 (0.53, 1.01)	0.05
<i>Model 2: Multivariate model</i> (57 observations deleted due to missing values, n=1078)		
Study group		
SC+ (comparison)	Ref	
SC	0.93 (0.62, 1.41)	0.73
RUSF	0.74 (0.52, 1.06)	0.10
CSB14	0.77 (0.54, 1.11)	0.16
Female gender ('male' is ref)	1.03 (0.79, 1.35)	0.84
Child's age, mos.	0.95 (0.92, 0.97)	<0.001
OTP start ('no' is ref)	0.38 (0.2, 0.71)	0.00
Breastfeeding	1.07 (0.66, 1.72)	0.79
Weight (kg) at start	2.62 (2.12, 3.25)	<0.001
Fever in prior 2 weeks ('none' is ref)	0.79 (0.57, 1.10)	0.16
Diarrhea in prior 2 weeks ('none' is ref)	1.61 (1.15, 2.25)	0.01
Cough in prior 2 weeks ('none' is ref)	1.16 (0.83, 1.61)	0.39
Hosmer-Lemeshow: $\chi^2=14.5$, df=8		0.07

Note: Recovery outcome is defined as 1='recovered', 0='not recovered'

Table 5. Time to recovery and weight gain velocity by study group among those who recovered from MAM, n=665

	Total	SC+ (comparison)	SC	RUSF	CSB14	p-value
<i>mean ± SD</i>						
Weeks to recovery	4.8 ± 2.6	4.5 ± 2.5 ^{cb}	4.1 ± 2.3 ^c	5.5 ± 2.8 ^a	4.9 ± 2.7 ^b	<0.001
Weight gain velocity (g/kg/day)	2.7 ± 2.2	2.7 ± 2.0 ^a	3.0 ± 2.5 ^a	2.2 ± 1.7 ^b	2.9 ± 2.5 ^a	0.001

Note: Means with the same superscript are not significantly different from each other.

4.2 Objective 2: Cost-Effectiveness

Due to early study termination, we were unable to collect enough information to conduct the full cost-effectiveness assessment. Cost data for food supplements and transportation to Sierra Leone were collected, as shown in **Table 6**.

Table 6. Costs of supplementary food rations and transportation to country among the four treatment groups in the Sierra Leone field-based research project¹

Costing Component	Treatment Group			
	SC+	SC ¹	RUSF	CSB14 ²
Supplementary Food Ration, USD/MT	1,278	700	2,621	2,745
Transport costs of food rations imported to Sierra Leone, USD/MT	241	211	520	580
Total costs, USD/MT	1,519	911	3,141	3,326

¹ Cost per MT is calculated per MT ton of the ration as distributed which includes SC, FVO, Sugar; transport costs are similarly calculated as MT of the ration.

² CSB14 was purchased on a small volume, custom production basis and consequently was significantly more expensive than other products and then one would reasonably expect to pay if CSB14 were to become commercially available. Cost per MT is calculated per MT ton of the ration as distributed which includes CSB14 and FVO; transport costs are similarly calculated as MT of the ration.

CSB14 was purchased on a small volume, custom production basis and consequently was significantly more expensive than the other products and more expensive than one would reasonably expect to pay if CSB14 were to become commercially available. Therefore, we also modeled the costs for the program using a beta-costing tool developed for FAQR by Kassahun Melese and Stephen Vosti based on market costs of product ingredients and average transportation costs from June 2014. The modeled cost is a more reliable metric for what the cost of CSB14 will be when produced at scale, and once it reaches equilibrium price level, based on the costs of the ingredients, similar to foods such as SC.

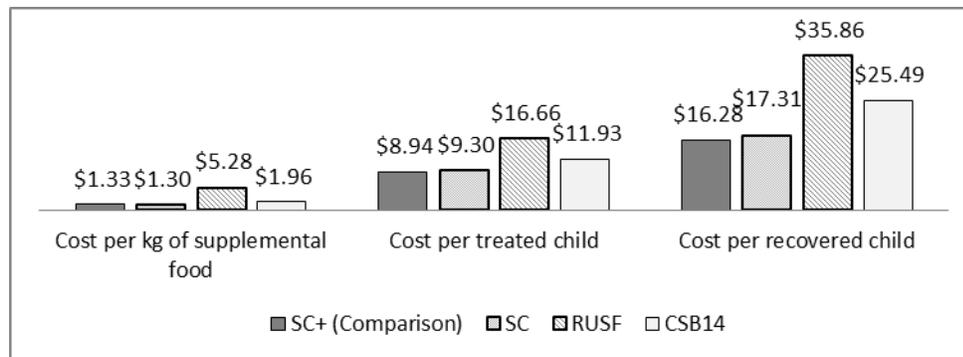
It should be emphasized that these results do *not* reflect true cost-effectiveness due to lack of complete cost data. However, using modeled product and transportation costs to country and based on the actual study outcomes, **Figure 4** shows, for each of the study groups, the cost

per kg of supplementary food rations, the cost per treated child, and the cost per recovered child. Modeled product and transportation costs per recovered child were lowest in the SC+ and SC groups, followed by CSB14, and highest in the RUSF group.

Figure 5 shows a comparison between the use of the modeled costs and actual study costs, in which the inflated cost of CSB14 results in almost double the modeled cost per recovered child.

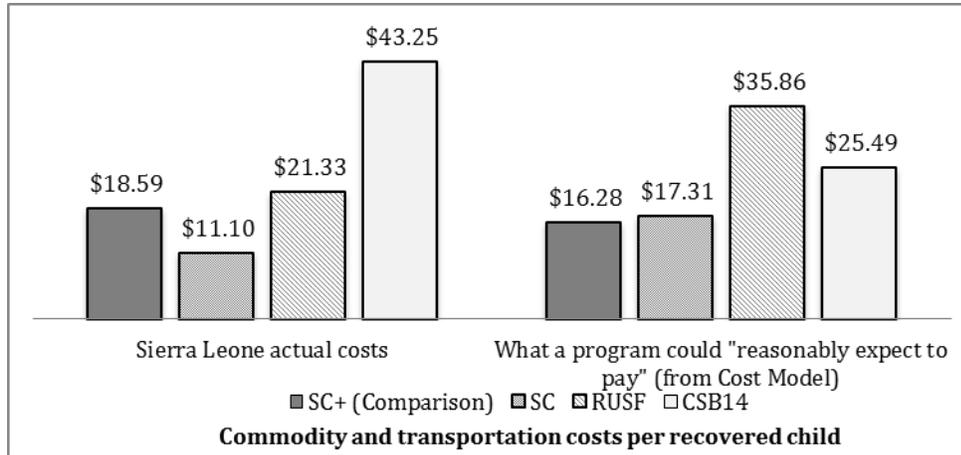
Due to early study suspension, we were unable to collect cost data on in-country transportation and distribution of foods. It will be up to future studies to collect such data, in addition to costs of product and transportation to country, and calculate cost-effectiveness. Anecdotal data from clinic staff and field researchers indicate that SC+ seemed to be the easiest food to distribute, as it required handling just two 1.5 kg pre-packaged bags of product. Next, RUSF distribution involved providing all beneficiaries 14 pre-packaged sachets. Clinic staff and/or CHVs easily completed these tasks. In contrast, CSB14 and SC required a knowledgeable point person to mix and/or measure quantities of CSB14 and FVO (CSB14 group) or SC, FVO, and sugar (SC group). Although measurements were converted to match the volumes of local mixing tools, only trained field aides were permitted to prepare the premix.

Figure 4. Product costs, by treatment group and two metrics of program success, using actual program outcomes in Sierra Leone, based on modeled prices¹ from June 2014 of commodities and transportation to country (but excluding programming costs)



¹ Modeled using beta FAQR Costing Tool v.1.0, Kassahun Melese and Stephen Vosti, 2015

Figure 5. Commodity and transportation to country costs actually paid in the Sierra Leone field-based research project per recovered child by treatment group, compared with modeled prices from June 2014 of commodities and transportation to country (but excluding programming costs)¹



¹ CSB14 was purchased on a small volume, custom production basis and consequently was significantly more expensive than other products and than one would reasonably expect to pay if CSB14 were to become commercially available.

4.3 Objective 3: Determinants of Effectiveness/Process

Appendix Table 6 displays a descriptive summary of determinants of effectiveness, stratified by study group. A total of 234 household questionnaires were collected: 66 in SC+, 45 in SC, 63 in RUSF, and 60 in CSB14. The following results are descriptive, as significance tests were not performed due to the small sample size. All SC+ participants reported that their entire food ration reached the beneficiary child’s home, while this figure was lowest in the RUSF group (93.7). SC+ and SC participants reported that the food ration lasts an average of 12 days while RUSF and CSB14 participants reported an average of a little over nine days, indicating that some consumed more than one per day. The median number of times per day participants reported to have prepared the study food for the beneficiary child was 1.0 in the SC+, SC, and CSB14 groups, while this figure was 3.0 in the RUSF group. Although only intended in the RUSF group, all four groups indicated consumption directly from the packet. Median number of times per day participants reported the beneficiary child consumed directly from the packet was 3.0 in the RUSF and CSB14 groups and 1.0 in the SC and SC+ groups.

Supplement consumption by someone other than the beneficiary child (i.e. “sharing”) was reported to be lowest in RUSF group (3.2 percent) and highest in CSB14 (43.3 percent). Of the total sample, “sharing” was reported with mothers of the beneficiary child (8.2 percent) and other children within the household (15.9 percent); none reported consumption by the father of the beneficiary child. Only one participant (0.4 percent) indicated that other children outside the household had consumed the ration. Nine participants (3.9 percent) reported having ever

given the ration away to anyone outside of the HH, while all participants (100 percent) reported they have never sold the ration. When asked why the beneficiary child was receiving the supplement, over two-thirds of respondents in the SC+ and RUSF groups gave “treatment of malnutrition” as a reason, compared with only 20 percent in the SC and CSB14 groups. Over 50 percent of respondents in SC and CSB14 groups thought the food would help the child gain weight.

CSB14 preparation requires addition of fortified vegetable oil during cooking; beneficiaries are taught to add FVO in a ratio of 30 g FVO to 100 g CSB flour. Among participants in the CSB14 group, the average ratio of CSB flour to FVO used during household questionnaires when the enumerator asked the BMC to demonstrate her cooking procedures was 30g FVO to 165g CSB flour.

Respondents reported they were “very confident” in their knowledge of how to feed the study food correctly to the beneficiary child more than 97 percent of the time in the SC+, SC, and CSB14 groups, while this figure was slightly lower at 86 percent in the RUSF group. The portion of porridge fed to the beneficiary child during the last meal was reported to be highest in the SC+ group (350 mL), followed by 280 mL in the SC group and 260 mL in the CSB14 group. Median number of RUSF sachets served to the beneficiary child at the most recent meal was one sachet. The mean number was slightly higher (1.1), since more than one sachet was occasionally consumed.

Sources of drinking water, use of a latrine, and access to electricity varied among the groups, as did the proportion of respondents who were enrolled in other food aid programs.

5. Challenges

The research trial encountered several challenges that affected the results. The first problem related to SAM treatment capacity in the Kenema District. Despite verbal confirmation of *operational* OTP to treat children suffering from SAM, programs were found to be inadequate almost immediately after the start of research enrollment. The problem presented both a research protocol and ethical dilemma. It was inappropriate to run a feeding program for moderately malnourished children without also accepting and treating those children in more dire health identified as SAM, yet such patients could not be eligible for research enrollment.

Starting in February 2014, PPB and USAID procured and administered ready-to-use therapeutic food (RUTF) to SAM patients. Still, the long and medium-term impact of deficient OTP programming prior to the start of the trial is unknown. The data show that failure rate via development of SAM among research participants was quite high (14 percent). About 8 percent of children in our sample graduated “up” into MAM from SAM (designated “OTP start”), which

was associated with a lesser recovery rate.

Due to a supply chain delay at the beginning of the trial, five RUSF designated research sites received a two-week provision of SC+ at the first distribution. This affected only 46 participants in the study, who received SC+ for their first provision instead of the designated research food, RUSF. Of these 46 in the RUSF group who received SC+ at start, two never received RUSF throughout their enrollment in the research: one developed SAM; one defaulted. To assess the potential effect this group may have on results, the RUSF-SC+ start group was assessed as a separate research group: RUSF with RUSF-SC+ start not included (n=348) vs. RUSF-SC+ start (n=46). It was concluded that the two groups were similar enough to retain within the overall sample. Thus, the 46 children who received SC+ start are included as part of the RUSF group in analysis. The effect of changing food supplements on caregiver adherence to feeding instructions as well as the impact of giving both foods in one group is unknown, but is something to consider for future studies (e.g. starting with RUSF and ending with CSB, etc.).

An additional challenge in analysis was the study suspension. Those children who started within 10 weeks of their clinic's suspension date were at risk of being suspended. If a child reached an outcome prior to that date, he or she was assigned a research outcome; however, if that child did not have time to reach a research outcome due to study suspension, then it is unknown what that outcome would have been. Thus, the suspension created a bias between children who reached an outcome *sooner* and children who would have had the same outcome given more time. An assessment was conducted on potential bias due to study suspension. First, suspension rates were assessed between the study groups, and no significant differences appeared. Second, analysis of the primary outcome was performed in two ways: 1) with suspended children included, and 2) with suspended children not included. Ultimately, we decided a bias may be present and therefore excluded those who were suspended from the analyses of the primary outcome. However, it is important to note that recovery rates may be slightly overestimated as a result of excluding those who were suspended.

6. Conclusions and Next Steps

Overarching study conclusions indicate that:

- This study offers suggestive findings that there may be differences among the study foods. However, due to early termination of the study, it is not possible to provide strong evidence or make definitive recommendations.
- Cost-effectiveness of alternative foods should drive programming choices. In this study, we were unable to determine which food represents better value for money or better recovery rates. These issues should be the top priority for future research.
- Treatment of MAM with food remains a priority research issue.

It is hoped that this study can be reproduced to its full intended extent in another setting.

Based on experience in Sierra Leone, the team is considering collecting additional data on relapse to MAM post-exit from treatment. In addition, the team is considering adding two sub-studies: 1) Data collection on beneficiaries' body composition as a measure of lean mass accretion during MAM treatment; and 2) Data collection on the presence of environmental enteropathy of beneficiaries upon enrollment as a predictor of recovery.

1. Body Composition

Greater lean body mass is believed to have an impact on health outcomes in children recovering from moderate acute malnutrition (MAM). The body composition sub-study will compare lean body mass accretion among four food assistance products. The results will contribute to the understanding of product effectiveness in terms of total body mass vs. lean body mass accretion. The study will contribute to building evidence on the “quality” of recovery and potential relationships to preventing relapse.

2. Environmental Enteropathy

Presence of environmental enteropathy (EE) may affect the effectiveness of supplementary feeding in promoting recovery from MAM. The environmental enteropathy substudy will assess EE in the study subjects. The resulting information would provide a basis for assessing the role of EE in determining the effectiveness of the supplementary food, and whether EE differentially affects the effectiveness of the four foods. The study will add to the body of evidence on the link between EE and strategies for the treatment of wasting.

7. References

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Appendix I. Food Aid Quality Review Summary

The study falls under the auspices of the Food Aid Quality Review Phase II.

The United States Agency for International Development's (USAID) Office of Food for Peace awarded a two-year extension contract (FAQR Phase II) to Tufts University's Friedman School of Nutrition Science and Policy in October 2011 and a third-year extension in 2013 for a total of five years. FAQR Phase I, conducted from 2009 to 2011, examined the nutritional needs of beneficiary populations across the developing world and the nutritional quality of commodities currently available to meet those needs, with the objective of improving the quality of Title II food aid commodities and programming. The findings of FAQR Phase I were published as a report, *Delivering Improved Nutrition: Recommendations for Changes to US Food Aid Products and Programs* (USAID, April 2011), which is available at www.foodaidquality.org and at <http://www.usaid.gov/what-we-do/agriculture-and-food-security/food-assistance/resources/research-and-policy-papers>.

The FAQR is part of a series USAID and United States Department of Agriculture (USDA) activities aimed at enhancing product choice under Title II of Public Law 480 (PL480), improving quality control and assurance (of both processes and products), and updating technical guidance and the evidence base for programming approaches. The present contract builds on work performed under the original FAQR and will focus on implementing recommendations made in Phase I for changes in food aid products, programming, and processes.

FAQR Phase II activities include advancing the evidence base through production and testing of improved food products, their packaging and delivery methods, and comparative studies of products' nutritional effectiveness and cost-effectiveness, implementation research and pilot projects, and facilitation of interagency and multi-sectoral coordination. FAQR Phase II continues its consultative process to interact with and solicit input from a wide range of stakeholders.

The work of the FAQR Phase II continues to address three areas of focus: products (development and testing of new or modified nutritionally-enhanced food aid commodities); programs (the uses of such foods to meet nutritional goals in the context of Title II programs); and processes (e.g., safety and quality assurance in the supply chain, harmonization of processes among donor agencies, and coordination among agencies within the US Government).

Appendix II. Tables and Figures

Appendix Table I. PHU classification*

Clinic	Level of PHU	Chiefdom	No. of Catchment Villages	Distance from Kenema Town
SC				
Foindu	CHC with no SFP support	Lower Bambara	8	1 hr 30 mins
Largo	CHC	Nongowa	13	42 mins
Dodo	CHC	Dodo	21	2 hrs
Mbowohun	CHP	Dodo	21	1 hr 45 mins
Baoma	CHC	Koya	7	1 hr 40 mins
CSB14				
Potehun	CHC with no SFP support	Nongowa	6	45 mins
Hanga	CHC	Nongowa	9	15 mins
Perrie	MCHP	Guara	3	1 hr 50 mins
Joru	CHC	Guara	7	1 hr 35 mins
Ngegbwema	CHC	Tunkia	11	2 hr 30 mins
SC+				
Kornia Kpindima	CHC with no SFP support	Lower Bambara	10	1 hr 15 mins
Levuma	CHC	Kandu Leppiama	15	1 hr
Baoma Oilmill	CHP	Kandu Leppiama	13	1 hr 20 mins
Boajibu	CHC	Simbaru	33	2 hrs
Nyangbe-BO	MCHP	Small Bo	8	1 hr
RUSF				
Bandawor	CHC with no SFP support	Niawa	5	1 hr
Geima Dama	CHC	Dama	15	45 mins
Kpandebu	CHC	Dama	11	42 mins
Sundumie	MCHP	Niawa	3	1 hr 30 mins
Blama	CHC	Small Bo	14	35 mins

* PHUs are the primary delivery point for primary health care in Sierra Leone. There are three types: (1) The Community Health Center carries out health prevention measures, curative and health promotion activities and is in charge of overseeing other PHUs in the area. Each Chiefdom, which is the unit of local government in Sierra Leone below the level of district, has at least one community health center. (2) Community Health Posts perform a similar function to Community Health Centers but have fewer facilities and are used to refer patients to the health center or the district hospital. (3) Maternal and Child Health posts are the first level of contact on the ground and are located in smaller towns of with populations between 500-2000.

Appendix Table 2. Nutrient composition of rations of supplementary foods

Nutrients	Units	Super Cereal Plus (SC+) [2] (Comparison)	Super Cereal (SC) with Fortified Vegetable Oil (FVO) and Sugar [3, 4, 18]	Corn Soy Blend 14 (CSB14) and Fortified Vegetable Oil (FVO) [3, 5]	Ready-to-Use Supplementary Food (RUSF) [6]		WHO Technical Standards for Management of MAM for children 6-59 months of age [19]		
			200 g SC, 20 g FVO, 20 g sugar/day	150 g CSB14, 45 g oil/day	92 g/day		Minimum	Maximum	Min
Serving (grams)		215 g/day							
Energy minimum	kcal	881.50	998.00	978.00	500.00	506	1000	1000	
Protein	g	34.40	28.00	21.00	11.59	14.168	20	43	
Fat	g	19.35	32.00	54.00	27.60	35.512	25	65	
Vitamin A	IU	3,577.60	7,400.00	6,273.80	1,840.00	3220	6666	10,000	
Niacin	mg	10.32	16.00	12.00	4.88	13.8	>25	–	
Pantothenic acid	mg	14.41	3.20	2.40	2.30	4.14	>5	–	
Vitamin B6	mg	3.66	2.00	1.50	0.55	1.38	>5	–	
Folate	mcg	129.00	220.00	165.00	193.20	233.68	>400	–	
Vitamin B12	mcg	4.30	4.00	3.00	1.20	2.3	>5	–	
Vitamin C	mg	215.00	180.00	135.00	48.76	121.44	>150	–	
Vitamin D	mcg	8.60	1.20	2.70	6.44	21.16	20	60	
Vitamin D3	IU	–	883.20	662.40	–	–	–	–	
Vitamin E	mg	17.85	16.60	12.45	14.72	27.6	>30	–	
Vitamin K	mcg	215.00	60.00	45.00	19.32	34.96	>50	–	
Vitamin B1 (Thiamine)	mg	0.28	0.40	0.30	0.55	1.196	>1	–	
Vitamin B2 (Riboflavin)	mg	0.96	2.80	2.10	0.74	2.024	>4	–	
Iron (Ferrous fumarate)	mg	8.60	8.00	6.00	7.36	11.96	18	30	

Nutrients	Units	Super Cereal Plus (SC+) [2] (Comparison)	Super Cereal (SC) with Fortified Vegetable Oil (FVO) and Sugar [3, 4, 18]	Corn Soy Blend 14 (CSB 14) and Fortified Vegetable Oil (FVO) [3, 5]	Ready-to-Use Supplementary Food (RUSF) [6]		WHO Technical Standards for Management of MAM for children 6-59 months of age [19]	
Iron (Iron-sodium EDTA)	mg	5.38	5.00	3.75	–	–	–	–
Zinc	mg	10.75	10.00	7.50	10.12	13.8	20	35
Iodine	mcg	86.00	91.00	84.75	78.20	138	150	350
Potassium	mg	860.00	280.00	210.00	699.20	1113.2	1500	2200
Phosphorus	mg	430.00	560.00	420.00	276.00	450.8	850	1400
Calcium	mg	279.50	724.00	543.00	276.00	501.4	1000	1400
Biotin	mcg	–	16.40	0.00	11.04	78.2	>20	–
Copper	mg	–	–	–	0.51	1.84	1	3.5
Magnesium	mg	–	–	–	73.60	138	280	420
Manganese	mg	–	–	–	0.63	–	1	2
Selenium	mcg	–	–	–	7.36	34.04	35	90
Sodium	mcg	–	–	–	266.80	–	–	500

Appendix Table 3. Ingredient composition of rations of supplementary foods

	SC+ [2]	SC and FVO and Sugar [3, 4, 18]	CSBI 4 and FVO [3, 5]	RUSF [6]
Raw Materials	<u>SC+ Ingredients:</u> maize, soya beans, dried skim milk powder, refined soya bean oil, sugar vitamin/mineral premix, monocalcium phosphate, potassium chloride	<u>SC Ingredients</u> maize, soya beans, vegetable oil, sugar, vitamin/mineral premix, dicalcium phosphate anhydrous, potassium chloride <u>FVO Ingredients</u> palm oil fortified vitamins (A,D)	<u>CSB I4 Ingredients</u> maize, soya beans, whey protein concentrate, vegetable oil, vitamin/mineral premix, potassium monophosphate, tricalcium phosphate, sodium chloride <u>FVO Ingredients</u> palm oil fortified vitamins (A,D)	<u>RUSF Ingredients</u> peanut paste, vegetable fat, soy protein isolates, whey, maltodextrin, sugar, cocoa, vitamin/mineral premix

Appendix Table 4. Overview of data collection instruments

Subject Category	Collection Point	Instrument Name (No.)	Target	Actual Forms Collected				
				SC	CSB/4	SC+	RUSF	Total
Elders/Headsmen	Field	Community quest. (02)	271	10	8	0	9	27
Children	SFP Clinic	Anthropometry form (03)	1,250/group	352	177	286	284	
BMCs	Field	Household quest. (04)	436/group	45	60	66	63	234
	Field	FGD* (05)	5/group	0	0	0	0	0
	Field	In-home obs. (06)	36/group	5	6	6	6	23
Health Volunteers	Field	In-depth int.** (07)	15/group	0	0	0	0	0
Various Sources	Field, clinic, KIs	Costing sheet (08)	2/group	0	0	0	0	0
Clinic, PPB Staff	Field	Individual int. (09)	45	0	0	0	0	0
PHU	Field	PHU obs.,*** (10)	10/group	0	0	0	1	1
Truck Drivers	Field	Ride along quest./ obs. (11)	40	0	0	0	0	0

* 8-10 participants per FGD, **3 Interviews per 20 SFPs, ***Observe 6 women per PHU observation

Appendix Table 5. Summary of enrollment characteristics by study group, n=1327

	Total n=1327	SC + (comparison) n=386	SC n=203	RUSF n=394	CSB14 n=344	p-value
<i>mean ± SD, or % (n)</i>						
Caregiver						
Caregiver's age, years (23 missing)	26.1 ± 6.8	26.7 ± 6.9	25.9 ± 6.7	26.4 ± 7.5	25.2 ± 5.8	0.02
Female gender	99.6 (1322)	99.7 (385)	99.0 (201)	99.8 (393)	99.7 (343)	0.50
Caregiver is mother (3 missing)	93.7 (1243)	92.5 (357)	94.1 (191)	93.4 (366)	95.9 (329)	0.26
Mende ethnicity (3 missing)	97.7 (1294)	95.6 (368)	97.0 (197)	98.7 (388)	99.4 (341)	0.00
Farmer occupation (9 missing)	78.9 (1040)	80.0 (308)	80.4 (160)	76.9 (300)	79.1 (272)	0.69
Married (13 missing)	92.9 (1220)	91.6 (351)	92.5 (186)	94.9 (369)	92.1 (314)	0.32
No. years of education (14 missing) ^{†‡}	0 (0, 5)	0 (0, 6)	0 (0, 6)	0 (0, 0)	0 (0, 5)	0.00
No. of live births (6 missing)	3.2 ± 2.0	3.7 ± 2.3	3.5 ± 2.3	2.8 ± 1.7	2.7 ± 1.5	<0.001
No. people in household (37 missing)	12.9 ± 6.1	15.0 ± 6.3	14.4 ± 6.8	11.7 ± 5.6	11.2 ± 4.8	<0.001
Breastfeeding (11 missing)	83.5 (1099)	83.6 (321)	84.1 (169)	80.1 (313)	87.1 (296)	0.09
Beneficiary child						
Child's age, mos. (53 missing)	13.3 ± 8.2	12.7 ± 7.6	13.4 ± 8.4	14.5 ± 9.2	12.7 ± 7.5	0.01
Female gender (1 missing)	57.6 (764)	53.3 (205)	59.1 (120)	59.4 (234)	59.6 (205)	0.23
Long-term disease (20 missing) [§]	2.0 (26)	3.7 (14)	3.5 (7)	0.3 (1)	1.2 (4)	0.00
Anthropometry at start of research						
MUAC (cm)	12.0 ± 0.3	12.0 ± 0.3	12.0 ± 0.3	12.0 ± 0.3	12.0 ± 0.3	0.26
WHZ (14 missing)	-1.7 ± 0.8	-1.7 ± 0.8	-1.7 ± 0.8	-1.8 ± 0.8	-1.7 ± 0.8	0.21
Weight (kg) (3 missing)	6.9 ± 1.1	6.8 ± 0.9	6.9 ± 1.0	7.0 ± 1.2	6.8 ± 1.1	0.02
Length, average (cm) (1 missing)	68.9 ± 6.3	68.3 ± 5.5	69.2 ± 6.5	69.8 ± 7.1	68.2 ± 6.1	<0.001
Fever in prior 2 weeks (1 missing)	55.6 (737)	69.4 (268)	62.6 (127)	43.2 (170)	50.2 (172)	<0.001
Diarrhea in prior 2 weeks (1 missing)	27.1 (359)	42.8 (165)	34.5 (70)	14.5 (57)	19.5 (67)	<0.001
Cough in prior 2 weeks (1 missing)	36.6 (485)	53.1 (205)	44.8 (91)	20.1 (79)	32.1 (110)	<0.001
OTP start	8.8 (117)	8.0 (31)	8.4 (17)	10.9 (43)	7.6 (26)	0.36

† Median and interquartile range presented

‡ Kruskal-Wallis test used

§ Cerebral palsy, seizures, HIV, TB, or Down syndrome

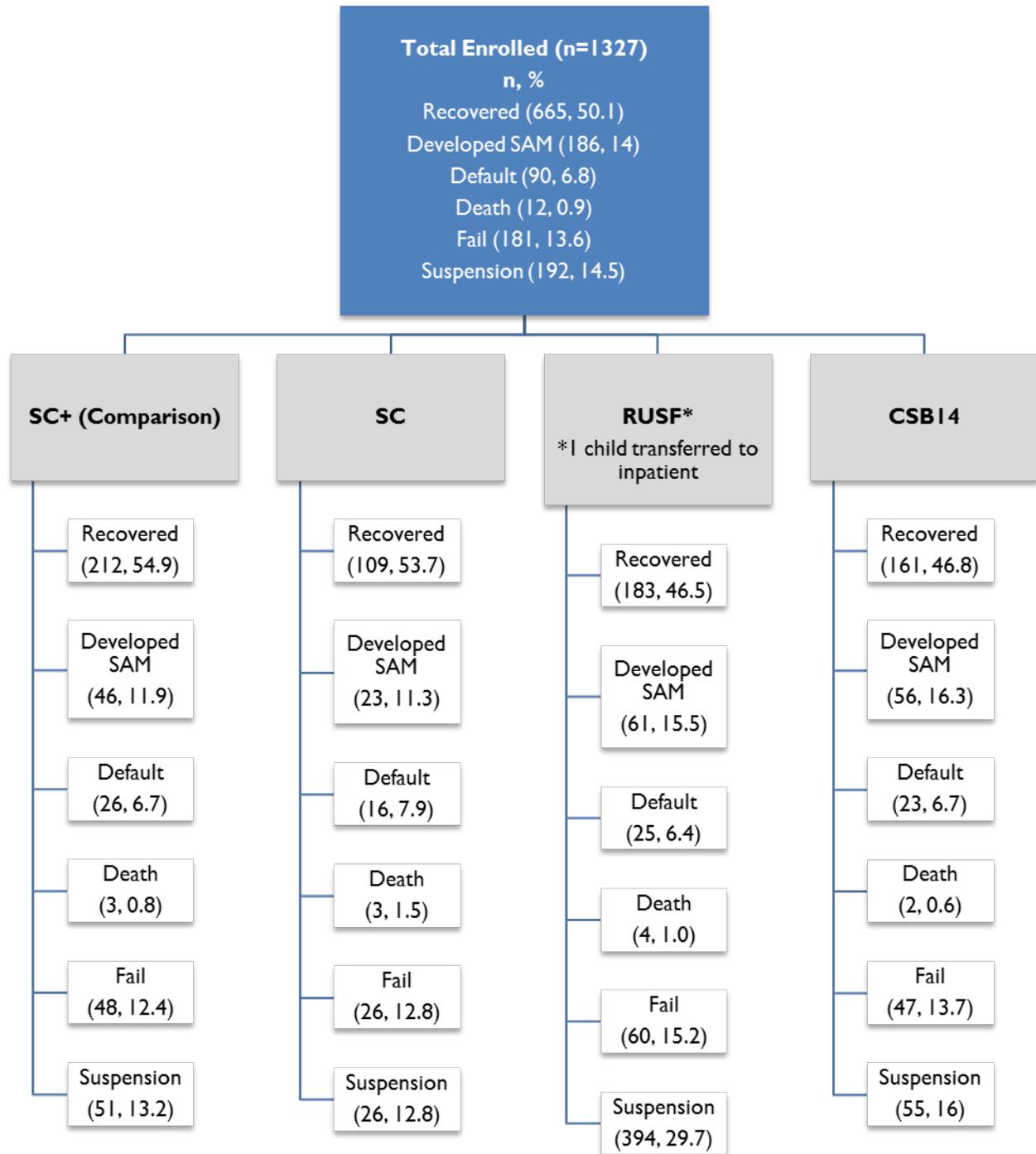
Appendix Table 6. Descriptive summary of determinants of effectiveness by study group, n=234

	Total n=234	SC+ (comparison) n=66	SC n=45	RUSF n=63	CSB14 n=60
<i>mean ± SD, median (min, max), or % (n)</i>					
Supplement exposure (most recent food collection)					
Entire food supply reached the home	97 (227)	100 (66)	97.8 (44)	93.7 (59)	96.7 (58)
Fortified oil (CSB14 group)	98.3 (59)	N/A	N/A	N/A	98.3 (59)
No. days study food lasted	11.2 ± 3.5	12.2 ± 3.6	12.5 ± 2.3	9.5 ± 2.7	9.3 ± 3.7
No. times per day child is fed the ration	1.0 (1, 3)	1.0 (1, 3)	1.0 (1, 3)	3.0 (1, 3)	1.0 (1, 3)
No. times per day beneficiary child normally consumes study food directly from packet	3.0 (1, 4)	1.0 (1, 4)	1.0 (1, 4)	3.0 (1, 3)	3.0 (2, 4)
Sharing of supplement					
Has ever given study food away	3.9 (9)	6.1 (4)	0	1.6 (1)	6.7 (4)
Fortified oil (CSB14 group)	0	N/A	N/A	N/A	0
Has ever sold study food	0	0	0	0	0
Fortified oil (CSB14 group)	0	N/A	N/A	N/A	0
Since last received, study food has been consumed by others	20.9 (49)	16.7 (11)	22.2 (10)	3.2 (2)	43.3 (26)
KAP and compliance					
Belief of why child is receiving food supply					
Help child grow	53.8 (121)	31.8 (21)	60 (24)	69.5 (41)	58.3 (35)
Keep child healthy	40.9 (92)	28.8 (19)	27.5 (11)	71.2 (42)	33.3 (20)
Give child nutrients	13.3 (30)	6.1 (4)	17.5 (7)	27.1 (16)	5 (3)
Treat illness	25.3 (57)	34.9 (23)	27.5 (11)	23.7 (14)	15 (9)
Treat malnutrition	49.3 (111)	74.2 (49)	20 (8)	69.5 (41)	21.7 (13)
Help child gain weight	69.8 (157)	51.5 (34)	90 (36)	88.1 (52)	58.3 (35)
Confidence in knowledge of how to correctly feed study food to the child					
Very confident	95.3 (223)	98.5 (65)	97.8 (44)	85.7 (54)	100 (60)
Somewhat confident	3.9 (9)	0	2.2 (1)	12.7 (8)	0
Not confident	0.9 (2)	1.5 (1)	0	1.6 (1)	0
Demonstrations of most recent time study food was prepared					
Amount of flour used (ml)	278.0 ± 63.4	252.0 ± 55.2	287.9 ± 74.4	N/A	298.7 ± 53.1

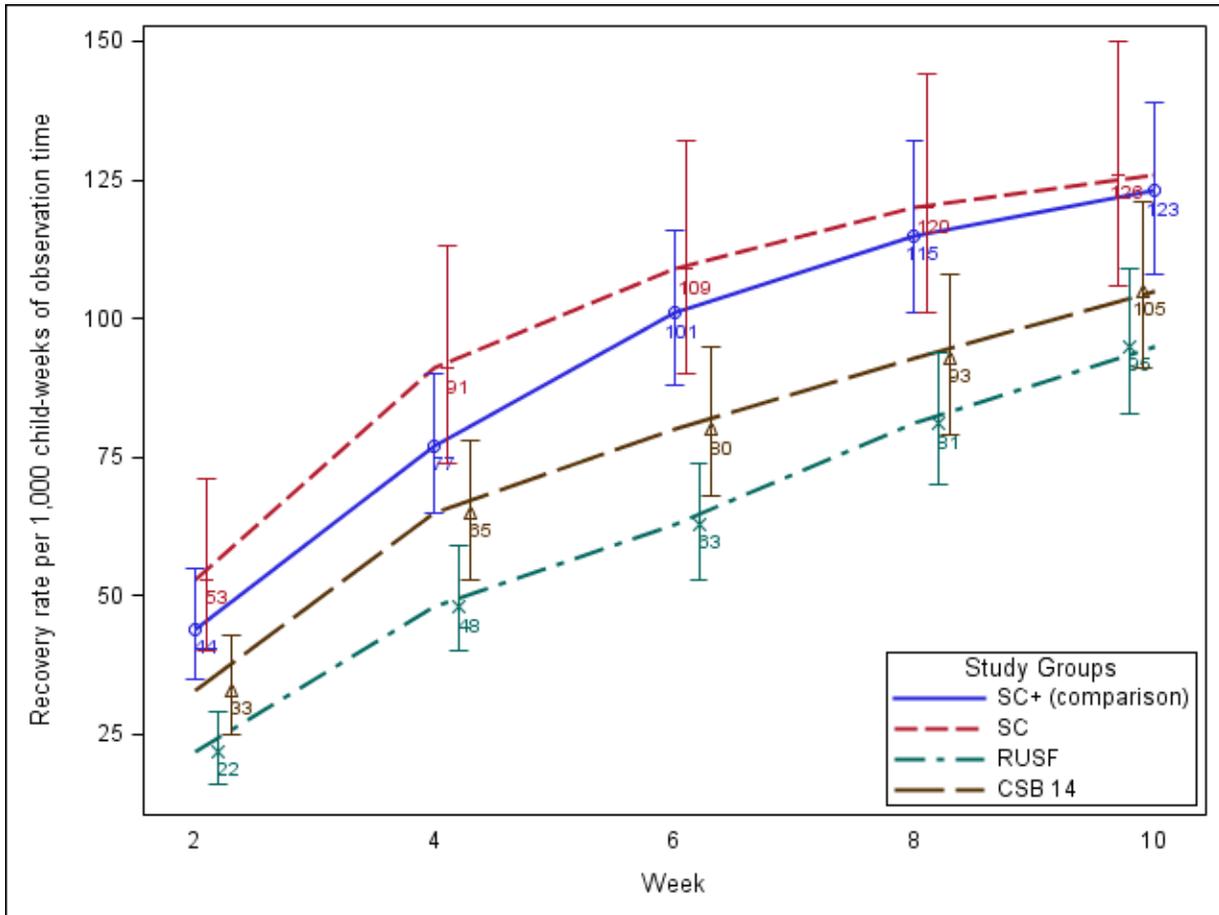
Comparison of Four Supplementary Foods for treatment of MAM-Sierra Leone

Amount of fortified oil used (ml)	35.7 ± 10.4	N/A	N/A	N/A	35.7 ± 10.4
Amount of water used (ml)	1045.1 ± 265.7	1129.7 ± 146.4	1215.2 ± 318.5	N/A	825.8 ± 156.5
Amount beneficiary child consumed per feeding (ml)	300.1 ± 112.8	350.5 ± 119.7	279.8 ± 117.4	N/A	259.6 ± 75.9
No. sachets served to beneficiary child (RUSF group)	1.0 (0.5, 3.0)	N/A	N/A	1.0 (0.5, 3.0)	N/A
Food was consumed by others	18 (42)	12.1 (8)	15.6 (7)	3.2 (2)	41.7 (25)
Other					
Source of drinking water					
Piped	22.2 (52)	1.5 (1)	33.3 (15)	6.4 (4)	53.3 (32)
Tube well or bore hole	46.6 (109)	60.6 (40)	28.9 (13)	49.2 (31)	41.7 (25)
Protected dug well	15 (35)	13.6 (9)	33.3 (15)	12.7 (8)	5 (3)
Unprotected dug well	2.1 (5)	0	0	7.9 (5)	0
Protected spring	3.9 (9)	3 (2)	0	11.1 (7)	0
Unprotected spring	1.7 (4)	3 (2)	2.2 (1)	1.6 (1)	0
Surface water	8.6 (20)	18.2 (12)	2.2 (1)	11.1 (7)	0
Use a latrine	85.9 (201)	78.8 (52)	82.2 (37)	87.3 (55)	95 (57)
Access to electricity in home	3 (7)	0	6.7 (3)	4.5 (3)	1.7 (1)
Enrolled in other food aid program	8.1 (19)	4.6 (3)	13.3 (6)	14.3 (9)	1.7 (1)

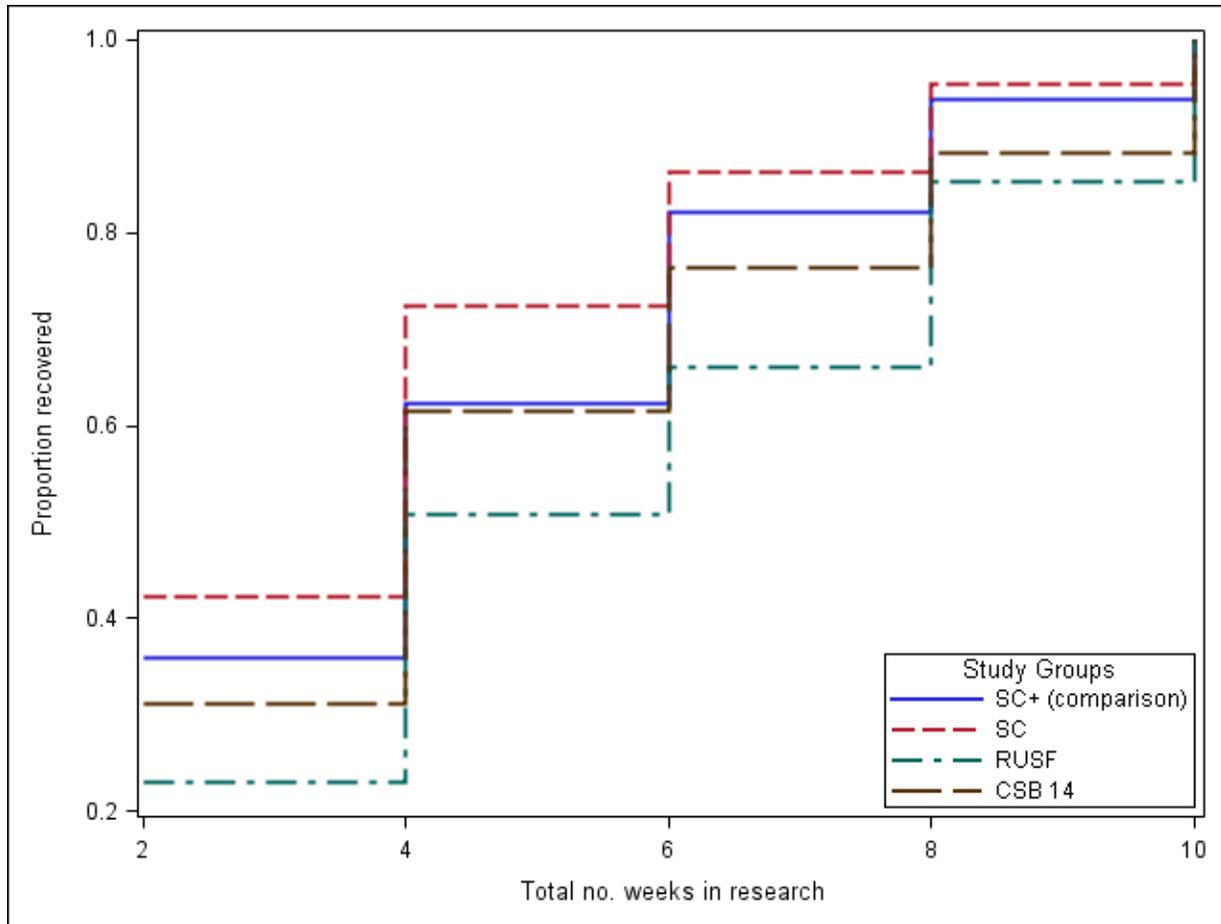
Appendix Figure I. Flow chart of outcomes for enrolled children with MAM treated up to 10 weeks or suspended, n=1327



Appendix Figure 2. Cumulative recovery rates by week



Appendix Figure 3. Empirical distribution for time to recovery by study group among those who recovered from MAM, n=665



Appendix Figure 4. Weight gain velocity (g/kg/day) by study group among those who recovered from MAM, n=665

