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Effectiveness of Chickpea-Based Ready-to-Use-Supplementary Foods for Management of Moderate Acute Malnutrition in Ethiopia: A Cluster-Randomized Control Trial

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Abstract

Background: Children with moderate acute malnutrition have nutritional requirements that differ from non-malnourished and severely malnourished children. They require increased intake of energy and essential nutrients over and above those required by non-malnourished children and, when necessary, treatment for any associated medical conditions. The study was aimed to evaluate chickpea only (Formula 1) and chickpea-maize-soya (Formula 2) ready-to-use food against two other widely-used supplementary foods: Super Cereal and the improved product, Super Cereal PLUS, for their effectiveness in the supplementary feeding programs.

Method: The design of the study was a cluster-randomized controlled effectiveness trial that was conducted in four regions of Ethiopia from 9th June 2014 to 22nd October 2014. According to Disaster Risk Management and Food Security Sector (DRMFSS) Hotspot Priority Report of April 2014, Oromia had 75 hotspot Priority 2 woredas, followed by Somali with 55; Amhara with 26; Tigray with 13 and SNNPR, 5. The study subject was taken from HHs based in hotspot priority 2 woreda.

Result: Statistically significant higher overall recovery rate (42%) was observed in children fed Super Cereal PLUS. Children in the lower age group (< 24 months) were more likely to recover than children in the higher age group (> 24 months). Super Cereal PLUS had a statistically significant higher rate of recovery compared to Super Cereal, Formula 1, and Formula 2. There was no significant difference among Super Cereal, Formula 1, and Formula 2 in terms of recovery rate. However, taking into account the result of cost effectiveness along with recovery rates, Formula 2 proved to be the most efficient in treatment of moderate acute malnutrition.

Recommendation: Therefore, Formula 2 is recommended for the treatment of MAM in Ethiopia for the pilot study under close follow-up to minimize all the limitations observed in current effectiveness trials study.

Keywords: *Effectiveness Trial; Supplementary Products; Moderate Acute Malnutrition*

Background

Acute malnutrition or wasting is a measure of thinness defined by Weight-For-Height (WFH) or Mid Upper Arm Circumference (MUAC) measurements. Wasting is characterized by rapid weight loss usually due to illness and/or reduced food intake. It leads to changes in the body related to cellular composition and tissue and organ functions. Acute malnutrition can either present itself as severe or moderate [1]. Moderate acute malnutrition in children is defined as weight-for-height between > –3 and < –2 z-scores of the WHO child growth standards without oedema [1]. Specific to Ethiopia, the definition encompasses MUAC ≥ 11.0 cm to < 12.0 cm for children aged 6 - 59 months

[1]. Globally, moderate acute malnutrition affects a total of 11% of children under the age of 5 years [3]. In Ethiopia, overall 10% of children aged 6 - 59 months are wasted and 9.7% are moderately wasted [4].

Acute malnutrition is estimated to contribute to about one third of under-five deaths annually in developing countries [5]. According to the 2013 Lancet series about 45% of deaths are caused by malnutrition. It is estimated that moderately malnourished children have a three-fold increased risk of death as compared to well-nourished children [6]. Proper treatment of moderate acute malnutrition can reduce or prevent the progression towards severe acute malnutrition. Ultimately, this has the potential to reduce child mortality and morbidity [7].

The dietary management of moderate acute malnutrition should be based on the optimal use of locally available nutrient-dense foods to improve the nutritional status of children and prevent severe acute malnutrition or failure to thrive [8]. Intake of nutrients present in inadequate amounts in the habitual diet can be increased through a number of approaches, including dietary diversification and fortification of certain staple foods with vitamins and minerals [9].

In situations of food shortage, or where some nutrients are not sufficiently available through local foods, caregivers may not be able to provide infants and young children recovering from moderate acute malnutrition with a diet that meets their nutritional needs. This risk of nutrition insecurity may be aggravated in emergencies, droughts, and/or displacement situations. In such conditions, specially formulated supplementary foods are usually required to supplement the regular diet and contribute to an improved intake of the required nutrients [10]. Supplementary foods with varying nutrient compositions have been used to facilitate the recovery of children with moderate acute malnutrition. The WHO has recently recommended different nutrient densities for foods used to treat moderate acute malnutrition [9].

In order to address chronically food insecure populations in Ethiopia, the Enhanced Outreach Strategy (EOS) was designed jointly by Federal Ministry of Health (FMOH) and United Nations Children's Fund (UNICEF). This program provides specific health interventions, including rapid screening for acute malnutrition, for children less than 5 years of age and for pregnant and lactating women, in campaigns every 6 months in targeted areas of need. In some areas of Ethiopia, the nutrition-screening component has been taken over by the Community Health Days (CHD), in which nutritional screening is carried out every 3 months [11].

The Targeted Supplementary Food (TSF) Program, managed by the World Food Programme (WFP) and jointly supported by UNICEF, support Ethiopia's Enhanced Outreach Strategy (EOS) for Child Survival. The goal is to rehabilitate moderately malnourished children under five years of age as well as pregnant and lactating women [11].

The conventional food distributed in supplementary feeding programs is Super Cereal (SC), a blended flour made of corn and soy and fortified with vitamins and minerals. Overall, SC is a good food option for these programs because of its decent nutritional value for limited cost. Additionally, it can be locally produced and procured and is well-accepted by most beneficiaries in developing countries [10]. For these reasons, it has become the food ration of choice in most supplementary and complementary feeding programs for malnourished pregnant and lactating women, children under 5 years of age, and people living with HIV/AIDS [12].

According to Golden, 2009, the nutrient requirements of children suffering from MAM are different compared to both children with SAM and normal, healthy children. This led to the conclusion that SC was nutritional inappropriate and inadequate for the treatment of MAM in terms of energy density of prepared porridge (around 0.5 kcal/g, whereas the recommendation is to have at least 0.8 kcal/g). Therefore, SC requires the addition of vegetable oil in order to meet the requirements for essential fatty acids and energy [10]. Furthermore, SC contains a relatively high amount of anti-nutrients and fibre, which impact mineral absorption. In addition to nutritional inadequacies, SC flour requires preparation and cooking before it can be consumed. Therefore, there is an additional need for firewood (or a cooking fuel), safe water, and cooking equipment.

According to Karakochuk, 2010, the recovery rate from malnutrition (MUAC value ≥ 12.0 cm) in programs using SC in Ethiopia is 67%, which is below the sphere standard of 75% recovery for programs providing supplementary foods [13,14]. According to the cond of conduct for international red cross and red crescent and non-governmental organization in disaster response, sphere standard is a humanitarian charter and minimum standard in disaster response. This result has led to the development of a new generation of fortified blended flours with revised micronutrient profiles (super-cereals) or the addition of milk to suit the macronutrient requirements of children aged 6 to 23 months of age (Super Cereal PLUS). Super Cereal PLUS (SC+) aligns with the WHO technical note for treating MAM because it has milk powder, oil, sugar, and the updated micronutrient premix. Super Cereal, on the other hand, has the same updated premix (since Oct 2010) but not the milk powder, oil, and sugar and therefore has lower energy density when prepared (0.5 kcal/g vs, 0.7 kcal/g). Thus, although it has an improved micronutrient profile, Super Cereal is not appropriate for treating MAM among young children.

The nutrient-profile limitation of Super Cereal, limited funding, an inadequate supply, and significant increases in the number of malnourished women and children screened as eligible for these programs have put tremendous strain on the implementation of these WFP supported programs using Super Cereal [15]. This has encouraged WFP to investigate and evaluate other possible treatment foods besides SC that could be more effective at treating malnutrition in this population group [16]. Furthermore, the overall demand for Super Cereal has increased in Ethiopia, local production has been able to keep up with the demand, and WFP has been able to procure Super Cereal PLUS in Ethiopia at a fast enough rate to meet the current needs for all food distribution operations. In order to continue meeting the requirements for programming and to scale-up emergency programs as required, the investigation of alternative sources of treatment foods is necessary [13].

The use of ready-to-use food (RUF) has become increasingly popular for the treatment and prevention of moderate and severe acute malnutrition. This energy-dense fortified food is packaged conveniently so it is "ready-to-eat" and does not require cooking or preparation [16]. Ready-to-use therapeutic food has now been accepted in the international community as an effective community-based treatment food for severe acute malnutrition [17]. The success of RUF has been attributed to: its specialized formula that meets the nutritional needs of severely malnourished children, reduced susceptibility to bacterial growth and contamination because it is oil-based, and the ability to consume it at home instead of having to reside in specialized in-patient feeding centers [18]. The efficacy and effectiveness of ready-to-use therapeutic food (RUTF) for the treatment of severe acute malnutrition has been well documented [19] and its use accepted by the international nutrition community as part of a proven successful approach of community-based therapeutic care [18]. The considerable evidence supporting the use of RUTF for the treatment of severe acute malnutrition has led to consideration of using RUTF for the treatment of moderate malnutrition in supplementary feeding programs [10]. A new class of product, ready-to-use supplementary food (RUSF) is also now being introduced in the field of international feeding programs. RUSF is not meant to replace a meal, but to be used as a supplement to locally available age-appropriate foods provided in a child's regular diet [16]. RUSF is indicated for use in supplementary feeding programs as a treatment for moderate acute malnutrition and an alternative to fortified blended flour (SC). Although the nutrient content of RUTF and RUSF are very similar, the taste of RUSF is different from RUTF as is the color of the packaging. But the major difference is its intended use. The dosage of RUSF is a standard 500-kcal/day ration, regardless of the child's weight, to provide a supplement in addition to the regular daily intake. However, due to their similarity in nutritional content per 100g, RUTF has also been used for supplementary rations with an adjusted dosage quantity to about 500 kcal/day [20].

The cost of RUSF remains an important factor given the high number of children to be reached and the limited available budget globally and at country level for addressing MAM [10]. Also, with the great variability of the price of ingredients such as whey proteins and peanut, it is important to have other versions of RUSF that do not contain these ingredients and that are specifically designed for children with MAM [21].

The new chickpea-based RUSF, which was initially modeled after a similar product, "Acha Mum" developed by WFP in Pakistan, is now locally-sourced, locally-manufactured, and seen as a cost-effective RUSF. A total of four products were developed and produced: (i) Chick-

pea-Soy; (ii) Chickpea-Maize; (iii) Chickpea-Maize-Soy; and (iv) Chickpea only. Although the 4 formulae have almost the same amount of chickpeas, there are noted differences in the ingredients of the Chickpea-Soy, Chickpea-Maize, and Chickpea-Maize-Soy RUSF compared to the Chickpea only. The basis for the development of the formulae was the need to develop an "optimized" formula that complies with WHO standards, relies more on local unit costs, and is based on chickpeas.

WFP worked with manufacturers to produce samples that were taken through an acceptability trial among Ethiopian children. The results of the trial indicated that the developed and produced formulae were rated as highly acceptable among children and their mothers [22]. The recommendations of the study indicated that the chickpea-based RUSF formulae be taken through an effectiveness trial on children to evaluate impact on nutritional status and to assess potential for wider utilization in addressing malnutrition in the country. Given the above information, a study was designed to evaluate the new generation of fortified blended flour (Super Cereal PLUS) and two chickpea-based RUSF (Chickpea-RUSF and Chickpea-Maize-Soy-RUSF) against the widely used Super Cereal (SC) for their effectiveness in the supplementary feeding programs in Ethiopia.

About Study Food

The supplementary food products that were tested in the study included 2 Lipid-Based Nutrient Supplements (LNS) and 2 Fortified Blended Foods (FBFs). The LNS included Chickpea-RUSF (C-RUSF) and Chickpea-Maize-Soya-RUSF (CMS-RUSF) while the FBFs included Super Cereal (SC) with oil and Super Cereal PLUS (SC+). For effective quality control and supervision of the trial, only 2 products [Super Cereal (SC) with oil and Super Cereal PLUS (SC+)] were chosen among several being used in different nutrition programmes as well as the developed chickpea-based products. Chickpea only will be referred to as Formula 1 and Chickpea-Maize-Soya will be referred to as Formula 2.

Method

The study was a cluster randomized controlled effectiveness trial that was conducted in the four regions of Amhara, Oromia, Southern Nations, Nationalities, and People's Region (SNNPR), and Tigray using the 4 study food products (C-RUSF, CMS-RUSF, SC, SC+). The study was implemented from 9th June 2014 to 22nd October 2014.

According to Disaster Risk Management and Food Security Sector (DRMFSS) Hotspot Priority Report of April 2014, Oromia had 75 hotspot Priority 2 woredas, followed by Somali with 55; Amhara with 26; Tigray with 13 and SNNPR, 5. From each region, one zone was randomly selected and subsequently three woredas from each zone were selected. Based on the above criteria, a total of 12 woredas were randomly selected for the study from the 4 regions.

From each woreda, two Health Centers were randomly selected based on Woreda Health Office (WOHO) report on the incidence of child malnutrition. Underneath each Health Centre is 5 to 7 Health Posts. For each of the selected Health Centres, four Health Posts (clusters) were selected based on the number of malnourished children identified in the 3 months prior to the study.

All children aged 6 to 59 months were mobilized and screened for moderate acute malnutrition from the communities. Those meeting the admission criteria for enrollment in the study had a Mid Upper Arm Circumference (MUAC) of between greater than or equal to 11cm and less than 12.5 cm (≥ 11 AND < 12.5) with no bilateral oedema. Therefore the primary indicator used for admission was MUAC 11 - 12.5 cm. The primary indicator for discharge was percent weight gain. The study was followed with 3 intervention arms that included C-RUSF; CMS-RUSF; SC-PLUS (SC+) and a comparator SC (SC). This involved a total of 2,425 Ethiopian children with MAM, aged 6 to 59 months, in four regions. From each region, one zone with three Food Security Priority 2 Hotspot woredas (districts) was randomly selected based on information from DMRFSS. In each woreda, two health centers were selected based on information from the WOHO reports on incidence of child under-nutrition rate. From each health centre, four health posts were selected as clusters. From each of the selected woreda, 152 study subjects were recruited and for each health center, 4 health posts were selected and each therefore contributed an average of 25 study subjects.

Cluster randomization was done at the field level. There were 24 clusters per region, 8 per woreda, and 4 clusters per health centre. Each of the 4 clusters within the health centre was randomly assigned to one of the study arms (products).

The eligible children participated in the study until they reached discharge criteria using percentage of weight gain and/or after 12 weeks of supplementation without recovery. Each study participant received a weekly ration for a maximum of 12 weeks depending on how fast or slow the child recovered from MAM. Children were assessed upon enrollment and after that, on a weekly basis. They were provided with sufficient ration of the allocated food supplement to cover the time between two visits. If the child remained wasted after 12 weeks or developed SAM during the study period, then such a child was referred to an Outpatient Therapeutic Program (OTP) and no study food was given. Monitoring of adherence included regular verification of stock during home visits conducted at least 6 times per child in the course of the study. The study outcomes were documented as shown in table 2.

Sample Size

The sample size and power for comparing two binomial proportions in Bernard Rosner's fundamentals of biostatistics was used. A sample size of 2,425 children aged 6 to 59 months, with 606 in each of the four arms, is sufficient to detect a clinically important difference of 8% or more between groups in recovering from MAM using a one-tailed z-test of proportions between two groups with 80% power and a 5% level of significance. This 8% difference represents a 64.4% recovery rate using Super Cereal and expecting a higher recovery rate of C-RUSF, CMS-RUSF and SC by 8%. Level of significance

Formula of calculating sample size was:

$n = [(Z\alpha + Z\beta)^2 \times \{(p1\ (1-p1) + (p2\ (1-p2)\}]/(p1 - p2)^2$

Where: n = sample size required in each group; p1 = proportion of subject recovered by SC/oil = 0.644; p2 = proportion of subject cured by RUSF = 0.724; p1-p2 = clinically significant difference = 0.08; Zα: Level of significance, for 5% which is 1.64; and Zβ: Power, for 80% which is 0.84= 5%, Power for 80% which is 0.84.

Based on above formula, the sample size required for each arm was 606 with a design effect of 1.25 including the assumption of 10% drop out rate. Hence total sample size required of 2,425 was used (Table 1 and 2).

	Overall	Region	Woreda	Kebele (Clusters)
Sample size	2,425	606	152	19
Study sites		4	12	96

Table 1: *Sample size for the study.*

Study outcome	Description
Recovered	Children weight gain > 13% from the baseline weight for two consecutive weeks
Non-response	Child did not recover after 12 weeks of treatment using the percentage of weight gain criteria
Defaulted	Child was absent for 3 visits or did not return
Transferred	Child's nutrition status deteriorated and/or developed SAM, required transfer to in-patient care or OTP (WHZ < -3 and/or bilateral oedema)
Died	Child died during trial or died during follow up in community or health facility after referral

Table 2: *Study Outcome for each Study Subject.*

Other indicators assessed during the trial included: target weight gain of 13% of admission weight, MUAC > 12.5, time to recover, amount of nutrient/food child consumed per day, rate of adverse events (allergic reactions, vomiting and diarrhoea), length of treatment, cost per product per beneficiary, and length of treatment. Reasons for defaulting, death, transferred and non-response were documented for each child. Other measurements included weight gain/day and length/height gain/day.

Inclusion

All children aged 6 to 59 months identified as moderately malnourished based on MUAC screening measurement of > 11 - < 12.5 cm without bipedal pitting oedema were eligible for the study.

Exclusion

Those exclused from the study included: children identified as severely malnourished based on MUAC screening <11cm and/or bilateral oedema; children with any illness or clinical condition that would have prevented them from safely ingesting the study food. Children were therefore assessed upon enrollment for any complicated clinical condition such as oedema, malaria, ARI, vomiting, diarrhoea (defined as 3 or more watery stools in 24 hours), and lack of appetite that would require medical attention; chronic debilitating illness including congenital or acquired malformations; children in an Outpatient Therapeutic Programme (OTP); and children already enrolled and participating in the TSF programme.

Results and Discussion

Characteristics of study participants

The sex composition across all the food products was similar; there was a higher percentage of girls (55.6%) than boys. Children were classified using the WHO age categories. Across the products, 41% of the children were in the age range of 12 - 23 months. This age category is very important because it is characterized by active physical activity and weening. The mean MUAC of the children ranged from 11.6 - 11.7 cm with an average of 11.6 cm. The average weight of the children was 7.9 kg. There was no significant difference between the mean weight and MUAC of the children across the products (P > 0.05).

Out of the participant children about 3.1% were twins. As presented in table 3, nearly one fifth (18.5%) of the children had a good appetite at baseline as reported by their care-givers. There was no significant difference (P > 0.05) between the children across the products in terms having twins and having a good appetite.

Characteristics		TSF									
	SC+		SC		Formula-1 (chickpea only)		Formula-2 (chickpea-maize-soya)		Total		
	N	Percent (%)	N	Percent (%)	N	Percent (%)	N	Percent (%)	N	Percent (%)	
Sex	Male	289	46.5	253	43.5	247	44.3	251	43.1	1040	44.4
	Female	333	53.5	329	56.5	310	55.7	332	56.9	1304	55.6
Age of child	6 - 11 Months	119	19.1	132	22.7	114	20.5	131	22.4	496	21.2
	12 - 23 Months	263	42.3	256	44.0	218	39.3	223	38.2	960	41.0
	24 - 35 Months	121	19.5	97	16.7	102	18.4	119	20.4	439	18.7
	36 - 59 Months	119	19.1	97	16.7	121	21.8	111	19.0	448	19.1
Mean MUAC (cm)		622	11.6	582	11.7	557	11.6	584	11.7	2345	11.6
% MUAC (11-12.5cm)		577	97.2	547	98.9	552	99.6	559	99.3	2235	98.7
Mean weight (kg)		622	7.9	582	7.8	557	8.0	584	7.9	2345	7.9
Is the child a twin?	No	577	95.1	561	97.1	537	98.0	558	97.4	2233	96.8
	Yes	30	4.9	16	2.8	11	2.0	14	2.4	71	3.1
Reported to have good appetite	No	383	78.2	385	80.2	348	81.7	377	86.7	1493	81.5
	Yes	107	21.8	95	19.8	78	18.3	58	13.3	338	18.5
Fever prior 2 weeks	No	577	99.5	517	95.9	506	99.6	535	98.2	2135	98.3
	Yes	3	0.5	22	4.1	2	0.4	10	1.8	37	1.7
Cough prior 2 weeks	No	567	100.0	513	95.7	502	99.6	524	98.5	2106	98.5
	Yes	0	0.0	23	4.3	2	0.4	8	1.5	33	1.5
Diarrhea prior 2 weeks	No	544	99.3	497	96.7	434	96.7	483	94.2	1958	96.7
	Yes	4	0.7	17	3.3	15	3.3	30	5.8	66	3.3
Vomiting prior 2 weeks	No	582	100.0	511	95.3	492	98.6	525	97.6	2110	97.9
	Yes	0	0.0	25	4.7	7	1.4	13	2.4	45	2.1

Table 3: *Characteristics of Moderate Acute Malnourished children during enrollment in the four regions (Ahmara, Oromia, SNNPR, and Tigray) of Ethiopia, 2015.*

The morbidity status of the children 2 weeks prior to the assessment was determined for fever, cough, diarrhea, and vomiting by using questionnaires as reported by care-givers. Overall, 1.7% of the children had fever of unexplained source, 1.5% had a cough, 3.3% had diarrhea, and 2.1% reported vomiting. There was a significant difference ($P < 0.05$) among children assigned to the different products in terms of morbidity prior to the trial.

Recovery rates of children with MAM

There was statistically significant ($P < 0.05$) recovery rate (42%) observed in Super Cereal PLUS (SC+) compared to the other three products (SC, Formula 1, and Formula 2). The recovery rate was higher in males than females across all products except Formula 1 (chickpea only). Of all the age groups, children in the age range 6 – 11 months had the highest recovery rate except those who ate Formula 2 (Chickpea–Maize-Soya) as treatment. The difference might be attributed to the variation of daily calorie requirement across the age categories. The recovery rate of all products was very low, compared to the sphere standard (almost half of the sphere standard cut-off). This might be due to the limitations stated above on product quality, seasonality (data collection during hunger season), and site selection.

The highest recovery rate with SC+ was obtained at the age group 6 - 11 months, whereas the highest overall recovery 52.5% was scored by this age group. The age group 12 - 23 months and 36 - 59 months showed the second and third highest overall recovery rates, with 41.2% and 40.2% respectively. For children with MAM of all ages (0 - 59 months), who were fed Formula 2 (Chickpea-Maize-Soya) only 33.5% recovered. The 6 - 11 months age group had the highest recovery percentage (42.6%), whereas the 36-59 months age group was the lowest recovery percentage (22.7%) after 12 weeks of intervention (Table 4 and 5).

Variable		Recovery rate by product type			
SC+		SC	Formula-1 (chickpea only)	Formula-2 (chickpea-maize-soya)	
Recovery rate by sex	Male	42.9	37.2	31.1	34.3
	Female	41.3	32.7	33.9	33.0
Recovery rate by age	6 - 11 Months	52.5	36.4	37.7	28.7
	12 - 23 Months	40.2	36.9	34.3	32.6
	24 - 35 Months	36.4%	33.3%	28.7%	32.6%
	36 - 59 Months	41.2%	27.8%	28.1%	22.7%
	Total	42.0%	34.7%	32.6%	33.5%

Table 4: *Distribution of recovered children by sex and age.*

Variable		Type of products			
SC+		SC	Formula 1 (chickpea only)	Formula 2 (chickpea-maize-soya)	
Mean time of recovery in week		7.87	8.02	7.76	7.65
95% CI	Lower bound	7.48	7.59	7.38	7.21
	Upper bound	8.25	8.45	8.15	7.69

Table 5: *Mean time of recovery by product.*

Binary Logistic Regression Model of Factors Associated with Recovery from Moderate Acute Malnutrition After Supplementray Feeding

On multivariable logistic regression after adjusting for explanatory variables, having a cough 2 weeks before enrollment and age of the child were positively related to recovery rate when fed Formula 2 (CMS-RUSF). Similarly, children vomiting during study period and

caretaker reports of child eating well at time of enrollment were positively related with recovery when fed SC. It was found that children aged 6 - 11 months and 24 - 35 months were 2.5 and 1.6 more likely to recover, respectively, when fed Formula 2 (CMS-RUSF) than those aged 36 - 59 months. Children vomiting during study period were 2.4 times more likely to recover by eating SC than those children who did not experience vomiting. Mother or caretaker reports of children eating well at time of enrollment were 37% less likely to recover when fed SC than those who are not eating well during enrollment (Table 6).

Independent variables	SC+			SC			Formula-1 (chickpea only)			Formula-2 (chickpea-maize-soya)		
	N	OR	P-value	N	OR	P-value	N	OR	P-value	N	OR	P-value
Mother as primary caretaker	599	0.66	0.287	562	1.18	0.72	516	1.81	0.297	544	0.82	0.66
Caretaker reports child eating well at time of enrollment	489	0.77	0.243	480	0.63	0.043	426	0.92	0.760	434	1.39	0.296
Vomiting in 2 week period before enrollment	612	0.71	0.291	580	0.52	0.198	545	1.14	0.710	566	1.14	0.773
Cough in 2 week before enrollment	613	0.53	0.036	580	0.86	0.704	543	0.22	0.640	566	0.52	0.050
Diarrhea in 2 week before enrollment	617	0.74	0.216	579	0.59	0.156	548	0.70	0.162	566	0.74	0.283
Height for Age Z-score (stunted)	619	0.92	0.621	580	0.71	0.067	554	1.00	0.973	579	1.13	0.497
Sex of child	619	1.07	0.689	580	1.22	0.266	554	0.88	0.498	578	1.06	0.754
Age difference	619		0.065	580		0.429	552		0.331	579		0.014
		1.58	0.080		1.48	0.175		1.55	0.117		2.53	0.001
		0.96	0.862		1.51	0.112		1.33	0.246		1.64	0.065
		0.82	0.444		1.30	0.408		1.03	0.920		1.85	0.038
Vomiting during study period	619	0.87	0.815	580	2.39	0.059	554	1.14	0.795	579	1.22	0.603
Cough during study period	619	1.46	0.541	580	1.64	0.213	554	0.64	0.566	579	1.27	0.693
Diarrhea during study period	619	0.87	0.715	580	1.61	0.153	554	1.17	0.589	579	1.04	0.902
Fever during study period	619	0.84	0.760	580	1.56	0.291	554	1.07	0.902	579	1.14	0.833

Table 6: *Binary logistic regression model of factors associated with recovery from moderate acute malnutrition after supplementary feeding.*

Rate of weight gain of children with MAM

There was no statistically significant mean weight change across all the products. During the whole intervention period the mean weight gain per kilogram of body weight was highest for super cereal plus (SC+) followed by Formula 2 (chickpea-maize-soya). Super Cereal (SC) showed the lowest mean weight gain per kilogram of body weight compared with the other supplementary food products. However, these differences were not statistically significant. Comparing these results to the sphere standard, the rate of weight gain per

kilogram of body weight across all products is very low. This might be due to the limitation stated above on product quality, seasonality, and site selection (Table 7).

Follow up Weeks	Product Type							
	SC+		SC		Formula-1 (chickpea only)		Formula-2 (chickpea-maize-soya)	
	N	Mean Wt. gain/kg	N	Mean Wt. gain/kg	N	Mean Wt. gain/kg	N	Mean Wt. gain/kg
Week1	589	.20	554	.14	517	.14	552	.16
Week2	590	.32	542	.25	510	.24	536	.26
Week3	591	.40	543	.31	505	.33	534	.36
Week4	590	.51	540	.37	491	.42	524	.43
Week5	602	.56	528	.43	480	.49	508	.50
Week6	584	.63	540	.51	470	.56	512	.57
Week7	574	.68	523	.57	459	.64	486	.64
Week8	567	.75	510	.61	458	.68	464	.69
Week9	563	.79	492	.65	436	.75	472	.75
Week10	542	.85	479	.72	431	.80	457	.80
Week11	533	.88	485	.79	425	.84	434	.85
Week12	517	.95	485	.87	419	.89	434	.89

Table 7: *Average change of anthropometric measurements by products.*

Rate and time of recovery of children with MAM

The highest rate of moderately acute malnutrition was observed in the age group 12 - 23 months (Table 3). However as demonstrated in Figures 2 - 5, it is observed that children in this age category (12 - 23 months) have the highest rate of recovery across all products. From this observation, we can conclude that this age group is more vulnerable to moderately acute malnutrition and thus will have the highest probability of improvement with timely treatment (Figures 1-4).

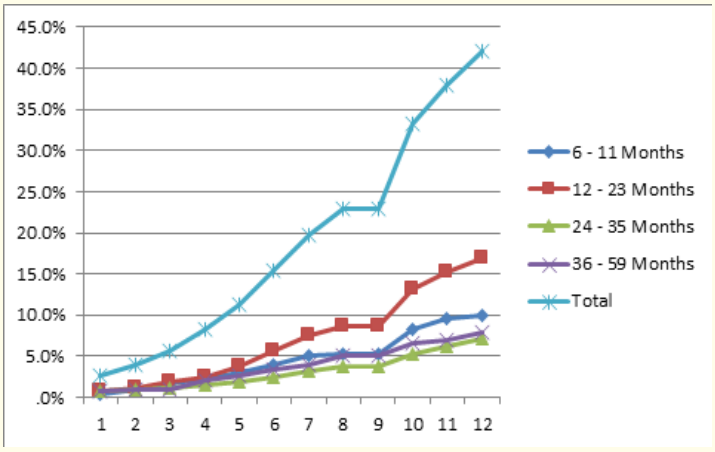

Figure 1: *Percentage of children fed SC+ who recovered by age and recovery time in weeks.*

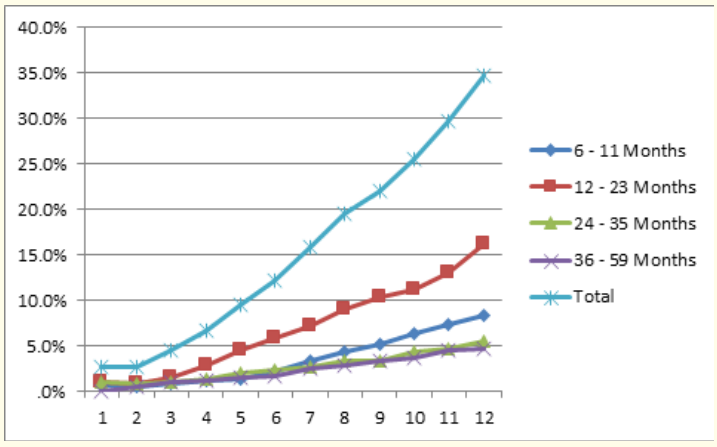

Figure 2: *Percentage of children fed SC who recovered by age and recovery time in weeks.*

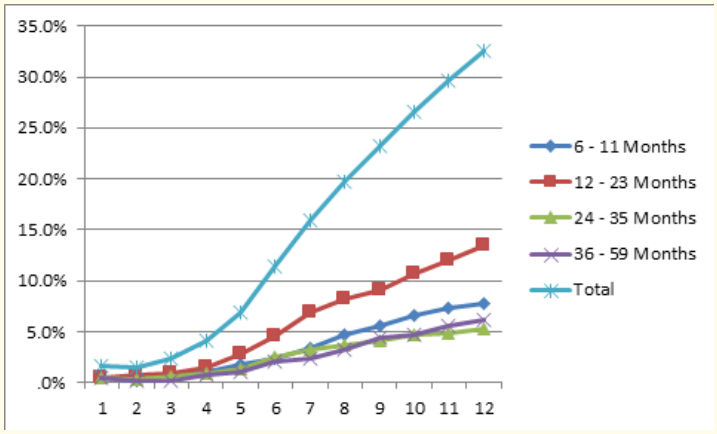

Figure 3: *Percentage of children fed Formula-1 who recovered by age and recovery time in weeks.*

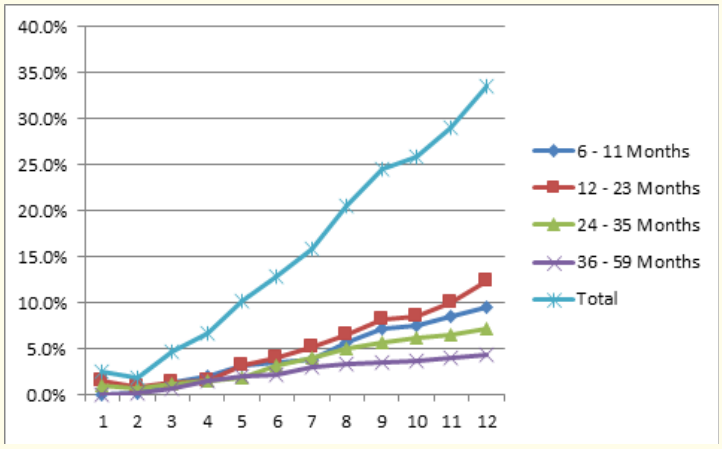

Figure 4: *Percentage of children fed Formula-2 who recovered by age and recovery time in weeks.*

Over time, the rate of recovery was increased for all products. SC+ show relatively higher recovery rate than the other three supplementary food products. For SC+ and Formula 2, the trend of recovery showed some inconsistency at the 9th and 10th weeks. This might be due to interruption of food supplies during the intervention period (Figure 5).

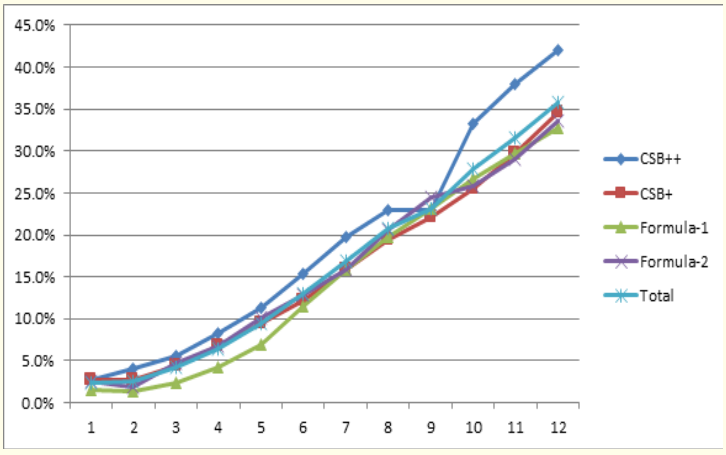

Figure 5: *Percentages of recovery by recovery time and product type.*

Diarrhea was the most common illness and vomiting the second most common illness reported during the study. The frequency of diarrhea and vomiting were increased from the start to the end of the study. The study tried to assess the illness by product types. The occurrence of diarrhea in Formula 1 (2.7%) and Formula 2 (2.9%) is almost double with compared to Super Cereal (SC), (1.3%). Once a child is malnourished, he/she is more likely to suffer from infections and diseases due to lower body defenses. Many illnesses, including diarrhea, vomiting, cough, fever and respiratory infections can make the effects of malnutrition worse (Table 8 and 9).

Illnesses	Follow up time in weeks											
	1	2	3	4	5	6	7	8	9	10	11	12
Diarrhea	3.3%	3.0%	1.8%	2.2%	1.7%	1.5%	1.2%	1.4%	.6%	.7%	.7%	.4%
Vomiting	2.1%	2.0%	1.8%	1.5%	1.6%	1.1%	1.5%	1.7%	1.2%	1.1%	1.0%	1.1%
Fever	1.7%	1.7%	1.3%	1.2%	1.6%	1.0%	1.4%	1.6%	1.2%	1.1%	1.1%	1.1%
Cough	1.5%	1.5%	1.3%	1.4%	1.5%	1.0%	1.1%	1.4%	1.1%	1.2%	1.2%	1.3%
Appetite	18.5%	17.2%	17.8%	17.8%	17.7%	17.7%	18.0%	18.0%	18.3%	18.3%	18.2%	18.2%

Table 8: *Proportion of child illness by week.*

Illness	Product type				Total
	SC+	SC	Formula-1 (chickpea only)	Formula-2 (chickpea-maize-soya)	
Diarrhea	31	51	64	67	213
	1.3%	2.2%	2.7%	2.9%	9.1%
Vomiting	11	32	20	34	97
	.6%	1.4%	.9%	1.4%	4.2%
Fever	13	31	16	13	73
	.6%	1.3%	.7%	.6%	3.1%
Cough	12	36	7	14	69
	.5%	1.5%	.3%	.6%	3.0%

Table 9: *Occurrence of selected illness during the follow-up period by product type.*

Program performance rates for each food product

Of all children enrolled in the study, the total development of SAM across all food products was 7.8%. The development of SAM by food group during the intervention was as follows: SC+ (9.5%), SC (6.0%), Formula 1 (6.0%), and Formula 2 (9.4%). There was no death reported at any sites during the intervention period. However, there was a relatively high default rate of 4.5% reported in children who took Formula 1 and Formula 2. Compared with sphere standard, the death and default rate of all products are better (Table 10).

Outcomes		Product Type				Total
		SC+	SC	Formula-1	Formula-2	
Recovery	N	618	580	554	579	2331
	(%)	42.1	34.7	32.7	33.5	35.9
	95% CI	[38.2,46.0]	[30.9, 38.6]	[28.9, 36.7]	[29.8, 37.5]	[33.9, 37.8]
Development of SAM	N	609	571	551	576	2307
	(%)	9.5	6.0	6.0	9.4	7.8
	95% CI	[7.4, 12.1]	[4.3, 8.2]	[4.3, 8.3]	[7.2, 12.0]	[6.7, 8.9]
Non-Recovery	N	618	580	554	579	2331
	(%)	57.9	65.3	67.3	66.5	64.1
	95% CI	[54.0, 61.8]	[61.4, 69.1]	[63.3, 71.1]	[62.5, 70.2]	[62.2, 66.1]
Death	N	621	582	557	584	2344
	(%)	0.0	0.0	0.0	0.0	0.0
Default	N	621	582	557	584	2344
	(%)	1.3	1.7	4.7	4.5	3.0
	95% CI	[0.7, 2.6]	[0.9, 3.2]	[3.2, 6.8]	[3.0, 6.5]	[2.4, 3.8]

Table 10: *Program performance indicator by product type.*

Discussion

There was significant recovery rate (42%) observed in Super Cereal PLUS (SC+) compared to the other three products (SC, Formula 1, and Formula 2). The highest recovery rate with SC+ was obtained at the age group 6 – 11 months, whereas the highest overall recovery 52.5% was scored by this age group. Comparing these results to the sphere standard, the rate of weight gain per kilogram of body weight across all products is very low. SC+ shows relatively higher recovery rate than the other three supplementary food products. Taking into account cost effectiveness along with recovery rates, Formula 2 proves to be the most efficient in treatment of moderate acute malnutrition.

Our study showed that higher recovery rate in children who received Super Cereal Plus. In contrast to our study, the study conducted in southern Ethiopia showed that the MAM children who received RUSF (Supplementary Plumpy: Nutriset) showed higher recovery rate compared to MAM children who received CSB [23]. But this study is similar to our study in case of lower rate of recovery compared to sphere standard recovery rate of greater than 75%. Similarly, the study conducted in Malawi showed that the MAM children who received RUSF had higher recovery rate than those who received CSB. Hence, RUSF are superior to CSB for moderately malnourished children [20]. The other study conducted in the same country (Malawi) showed that children with MAM who received CSB++ had more or less the same recovery rates compared to those who received RUSF products which is comparable to our study. This study demonstrated that CSB++ is the first fortified-blended flour to not be inferior to an RUSF product in the treatment of MAM [24].

Study Limitation

- Withdrawal of Somali region due to unable to find enough eligible MAM children without TSF program.
- One of the inclusion criteria to select woreda was no TSF program currently exists in the area. The study woreda don't have a system of implementing TSF program and behavioral change communication is require longer time than what was given during the study period (3 months).
- The study was done during the huger season. Hence, this condition increases the probability of sharing and not providing additional food for the study subjects.

Implication

Chickpea based ready to use supplementary food products can be used as an alternative food for MAM treatment.

Unanswered Question and Future Study

Study with very small sample size eliminating all the limitation mentioned above limitations.

Conclusion and Recommendation

The study revealed that SC+ produces a statistically significant higher rate of recovery compared to SC, Formula 1, and Formula 2. However, there is no significant difference among SC, Formula 1, and Formula 2 in terms of recovery rate. Taking into account cost effectiveness along with recovery rates, Formula 2 proves to be the most efficient in treatment of moderate acute malnutrition. Therefore, Formula 2 is recommended for the treatment of MAM in Ethiopia for the pilot study under close follow-up to minimize all the limitations observed in current effectiveness trials study.

Conflict of Interests

The author(s) declare that they have no competing interests.

Authors' Contributions

TH, MT, BT and BT initiated the research and designed the study protocol, coordinated data collection, performed analyses, and drafted the manuscript. AK, GA, DZ designed the study protocol, and participated in preparing the manuscript. YB, TA, DK, MG, MW and BW designed the study protocol, helped the data collection instrument, and participated in preparing the manuscript. MT and TG designed the study protocol, and participated in preparing the manuscript. All authors gave approval for the final version to be published.

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