

Severe and Moderate Acute Malnutrition Can Be Successfully Managed with an Integrated Protocol in Sierra Leone^{1–4}

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Abstract

Background: Global acute malnutrition (GAM) is the sum of moderate acute malnutrition (MAM) and severe acute malnutrition (SAM). The use of different foods and treatment protocols for MAM and SAM treatment can be cumbersome in emergency settings.

Objective: Our objective was to determine the recovery and coverage rates for GAM of an integrated protocol with a single food product, ready-to-use therapeutic food (RUTF), compared with standard management.

Methods: This was a cluster-randomized controlled trial in Sierra Leone conducted in 10 centers treating GAM in children aged 6–59 mo. The integrated protocol used midupper arm circumference (MUAC) as the criterion for admission and discharge, with a MUAC <12.5 cm defining malnutrition. The protocol included a decreasing ration of RUTF and health maintenance messages delivered by peers. Standard therapy treated MAM with a fortified blended flour and SAM with RUTF and used weight-for-height to determine admission to the treatment program. Coverage rates were the number of children who received treatment/number of children in the community eligible for treatment.

Results: Most of the children receiving integrated management had MAM (774 of 1100; 70%), whereas among those receiving standard management, SAM predominated (537 of 857; 63%; $P = 0.0001$). Coverage was 71% in the communities served by integrated management and 55% in the communities served by standard care ($P = 0.0005$). GAM recovery in the integrated management protocol was 910 of 1100 (83%) children and was 682 of 857 (79%) children in the standard therapy protocol.

Conclusion: Integrated management of GAM in children is an acceptable alternative to standard management and provides greater community coverage. This trial was registered at clinicaltrials.gov as NCT01785680. *J Nutr* doi: 10.3945/jn.115.214957.

Keywords: moderate acute malnutrition, severe acute malnutrition, ready-to-use therapeutic food, malnutrition treatment, Sierra Leone

Introduction

Childhood global acute malnutrition (GAM)⁹, the sum of severe acute malnutrition (SAM) and moderate acute malnutrition (MAM), is common in developing countries and is found in

~8% of children worldwide (1). Management of malnutrition is often assisted by the UN agencies; UNICEF has developed treatment protocols for SAM and provides the poorest countries with appropriate therapeutic foods (2, 3). The World Food Programme has codified management strategies for MAM and provides supplementary food to treat MAM children (4, 5). The result of this division of labor and responsibility by the UN agencies is that MAM and SAM are often managed through different programs that operate out of different physical locations and may use discordant anthropometric criteria and different foods.

In humanitarian emergencies, such as drought, war, or ethnic violence, childhood malnutrition often escalates; and the separation of the treatment of MAM and SAM can become administratively cumbersome and redundant. A caregiver might well recognize that her child is malnourished but not know whether

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⁴ Supplemental Tables 1 and 2 and Supplemental Figure 1 are available from the "Online Supporting Material" link in the online posting of the article and from the same link in the online table of contents at <http://jn.nutrition.org>.

⁹ Abbreviations used: GAM, global acute malnutrition; MAM, moderate acute malnutrition; MUAC, midupper arm circumference; PSU, primary sampling unit; RUTF, ready-to-use therapeutic food; SAM, severe acute malnutrition; WHZ, weight-for-height z score.

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to seek care at the MAM or the SAM clinic. Treatment locales need to stock multiple foods supplied by different agencies and use different documentation schemes for MAM and SAM. Transitioning between MAM and SAM treatment programs is disjointed for patients, and children may be at risk of dropping out of treatment programs prematurely. An integrated management scheme for GAM using the same anthropometric criteria and the same food might have particular advantages in such crises.

We conducted a cluster-randomized clinical trial in postconflict Sierra Leone before the advent of the Ebola outbreak of 2014 to test the hypothesis that integrated MAM and SAM treatment would result in an overall higher recovery rate and provide higher community coverage than the standard separate MAM and SAM treatment programs.

Methods

Participants

Children aged 6–59 mo with a midupper arm circumference (MUAC) <12.5 cm or bipedal edema and an adequate appetite who presented to 1 of 10 clinics in Port Loko District of Sierra Leone were eligible for this study. Adequate appetite was demonstrated on-site by the consumption of 30 g ready-to-use therapeutic food (RUTF) over 20 min. Children without an adequate appetite were admitted for inpatient treatment. Children with known chronic health conditions such as cerebral palsy or congenital deformities were excluded, along with children who had participated in a supplementary or therapeutic feeding program within the previous month. When more than one child from the same household was malnourished, only the youngest child was enrolled in the study. Any child with a history of peanut allergy was excluded.

Port Loko District is in rural western Sierra Leone, where almost all households engage in subsistence farming of rice and root crops, cassava and yam, as well as fishing along the local rivers and the ocean. A large iron mine exists in the district that provides employment to manual laborers. One-third of the households in the district rely on unprotected sources of drinking water.

Participation was fully explained to caretakers of eligible children in their local language, Temne. A consent document was signed with a thumbprint for those who agreed to participate. The study was approved by the Sierra Leone Ethics and Scientific Review Committee and the Human Research Protection Office at Washington University in St. Louis.

Study design

This was a cluster-randomized, unblinded, controlled clinical trial comparing the integrated management of GAM with standard management of MAM and SAM. Children were treated for up to 12 wk in either the integrated or standard programs. The primary outcomes were coverage and recovery rate. Coverage was defined as the fraction of children receiving treatment for malnutrition among all of those who were eligible. Primary outcomes were determined on an intention-to-treat basis. Secondary outcomes were duration of treatment, rates of weight and MUAC gain, clinical status 6 mo after recovery, and cost of foodstuffs used.

The planned sample size was 900 children in each study program. This was determined by estimating the number needed to detect a 5% difference in recovery, assuming a standard recovery rate of 85%, with 95% sensitivity and 80% power, and then increasing that number by 30% to account for the cluster-randomized design. Because the unit of randomization was the site of treatment and subjects were not randomly assigned, we anticipated controlling for differences between the clusters with linear regression modeling for continuous outcomes. The trial was registered with clinicaltrials.gov as NCT01785680.

The sites were randomly assigned to deliver either integrated or standard management of acute malnutrition with the use of a random-number generator by a study aid without knowledge of the characteristics of study sites. Table 1 summarizes the components of integrated and standard protocols for the management of GAM.

Participation

Integrated management. Upon enrollment, weight, length, and MUAC were measured; edema was assessed; and demographic characteristics were ascertained by trained nutrition research nurses. Children were designated as having MAM or SAM; SAM was determined by a MUAC <11.5 cm or the presence of bipedal edema and MAM was determined by a MUAC >11.4 and <12.5 cm. Children with SAM received a ration of RUTF plus amoxicillin at 175 kcal/(kg · d) and those with MAM received RUTF at 75 kcal/(kg · d).

All caretakers were referred to a care group at the clinic. The care group was a mother peer-counseling group that focused on a variety of child nutrition and health issues, including improving breastfeeding practices (6–8). The care groups were started and maintained by the International Medical Corps, a nongovernmental organization.

Children returned for follow-up every 14 d. When a child with SAM gained sufficient MUAC to be placed in the MAM category, the ration of RUTF was reduced. An RUTF ration sufficient for 2 wk was dispensed if the child had not recovered. After a child had received 6 rations of RUTF over 12 wk, he or she was deemed as having remained malnourished and no further RUTF was given. This definition of remaining malnourished was chosen because in previous work >95% of children reached their outcome by 12 wk, and no further improvement was seen between 12 and 16 wk of feeding.

Children who recovered received no more RUTF but instead were given 500 g of a lipid nutrient supplement that provided 100% of the RDA for all micronutrients and 200 kcal/d when taken as 40 g/d (Supplemental Table 1). Caretakers of recovered children were also given an insecticide-treated bed net and a package of oral rehydration salts, with instructions on when and how to use them.

Standard management. Standard management, as prescribed in the malnutrition treatment protocol of the government of Sierra Leone, was given at the 5 control sites (9). Standard management programs for MAM and SAM care were delivered separately on different days by different clinical teams. SAM management included RUTF (200 kcal/(kg · d)), high-dose vitamin A, folic acid, amoxicillin, a dose of an antimalarial drug, albendazole, and measles vaccination. Follow-up occurred weekly until the child had a weight-for-height z score (WHZ) of more than –3. MAM management included Super Cereal Plus, a fortified blended flour containing some oil and milk powder, given in a ration of 1250 kcal/d; vitamin A; albendazole; iron; and measles vaccination. MAM follow-up was every 14 d. No peer counseling was offered in standard management. Children were discharged from the standard management clinics when their WHZ was more than –2 on 2 consecutive visits; there was no limit to the duration of the treatment. Supplemental Table 2 compares the nutrient intakes of children with MAM who received integrated or standard management. The cost of the foods used in the 2 management schemes was \$4/kg for RUTF, which was the local producer's price in 2013, and \$1.30/kg for corn-soy blended flour.

A research nurse visited the standard management clinics each week and acted only as an observer and data recorder. She recorded the same information that was collected by the integrated management team. Outcomes of children receiving standard management were categorized in the same manner as those receiving integrated management.

Coverage survey

During May and June 2013 a community survey was implemented to assess coverage in each of the 10 clinic catchment areas. The community survey was conducted by using the Simplified LQAS Evaluation of Access and Coverage Sampling Design (10–12). The primary sampling units (PSUs) used in the survey were villages in the rural areas and portions of small towns.

A list of all potential PSUs was collected for each catchment area for the 10 clinics. To determine the number of PSUs to be surveyed, the following formula was used:

$$N_{\text{PSU}} = (\text{target sample size}) / (\text{average PSU population 6–59 mo} \times \text{GAM prevalence}) \quad (1)$$

Target sample size was determined by taking the total catchment area population multiplied by the percentage of children under 5 in the population multiplied by the GAM rate in Port Loko.

TABLE 1 Comparison of integrated and standard management of MAM and SAM¹

	Standard management		Integrated management	
	MAM	SAM	MAM	SAM
Program name	SFP	OTP	Integrated program	Integrated program
Admission criteria (children aged 6–59 mo)	MUAC ≥ 11.5 and <12.5 cm or WHZ ≥ –3 and < –2	Edema or MUAC <11.5 cm or WHZ < –3	MUAC ≥11.5 and <12.5 cm	Edema or MUAC <11.5 cm
Therapy/food given	Super cereal plus (CSB, oil, sugar), 1250 kcal/d	RUTF, 200 kcal/(kg · d)	RUTF, 75 kcal/(kg · d)	RUTF, 175 kcal/(kg · d)
Breastfeeding intervention	Messaging on-site	Messaging on-site	Care groups on-site and home visits	Care groups on-site and home visits
Cured discharge criteria	≥ –2 WHZ for 2 wk	MUAC ≥11.5 or WHZ ≥ –3, without edema	MUAC ≥12.5 cm	MUAC ≥12.5 cm without edema
Medical interventions	Vitamin A	Vitamin A, folic acid, oral amoxicillin, antimalarial (at admission)	Lipid nutrient supplement	Lipid nutrient supplement
	Albendazole	Albendazole (week 2), measles vaccination (week 4)	Oral rehydration solution	Oral rehydration solution
	Iron/folate	HIV-infected children receive co-trimoxizole	Malaria prophylaxis	Malaria prophylaxis
	Measles vaccination (at admission)		Program of immunizations that includes the entire complement recommended by WHO (at discharge)	Program of immunizations that includes the entire complement recommended by WHO (at discharge)

¹ CSB, corn-soy blended flour; MAM, moderate acute malnutrition; MUAC, midupper arm circumference; OTP, outpatient; RUTF, ready-to-use therapeutic food; SAM, severe acute malnutrition; SFP, supplementary feeding program; WHZ, weight-for-height z score.

Each rural health clinic was able to provide a complete list of the villages and town sections in their catchment areas. The district health office in Port Loko provided the recent population estimates for the villages and city sections. After determining the target sample size and the number of PSUs needed in each catchment area, a simple random sample of PSUs was selected from each catchment area.

A team of 12 local surveyors was hired with the assistance of the district health management team. Surveyors were trained on survey technique, MUAC measurement, and sampling design/method. Surveyors sampled each village using a house-to-house method. In the 2 of the more urban areas of Lunsar and Port Loko, a quarter method of sampling was used. Coverage was calculated as the fraction of children receiving treatment among the population identified as having GAM.

Study outcomes

Every child was assigned to 1 of 4 mutually exclusive categorical outcomes at their final visit for acute care: recovered, remained malnourished, died, or lost to follow-up. Because the integrated and standard management schemes used different anthropometric measurements to determine malnutrition, MUAC and WHZ, recovery was not equivalent in the 2 study arms. Recovery for children managed by using the integrated scheme was determined by a MUAC >12.4 cm and for children managed by using the standard scheme was determined by a WHZ of –2 or greater.

Coverage was expressed as a simple percentage of children in the community eligible for treatment who received it. Weight gain [in g/(kg · d)] and MUAC gain [in mm/d] were calculated for participants over the first 4 wk (or less if they graduated earlier) of treatment. Length (in mm/d) was calculated over the entire duration of study participation.

Data analyses

Data were double-entered in Microsoft Access. Anthropometric indexes were based on the WHO's 2006 Child Growth Standards, calculated by using Anthro version 3.22 (WHO) and AnthroPlus version 1.0.4 (WHO).

Comparisons of enrollment characteristics between study groups were made by using Fisher's exact test for categorical variables and Student's *t* test for continuous variables. *P* values <0.05 were considered to be significant.

A direct comparison of recovery rates was not possible because recovery was defined differently in the 2 study groups, so a CI was calculated by using a 1-sample *z* test to convey a sense of how often the schemes succeeded with the children they enrolled. Comparisons of weight gain, MUAC gain, the number of clinical visits, and final WHZ between the 2 management schemes were made by creating linear regression models that included the following controlling covariates: age, sex, mother as caretaker, number of siblings, treatment site, whether the child was a twin, MUAC on enrollment, WHZ on enrollment, height-for-age *z* score on enrollment, presence of edema, mother's report of fever, and mother's report of diarrhea. Coefficients with *P* values <0.05 were considered to be significant.

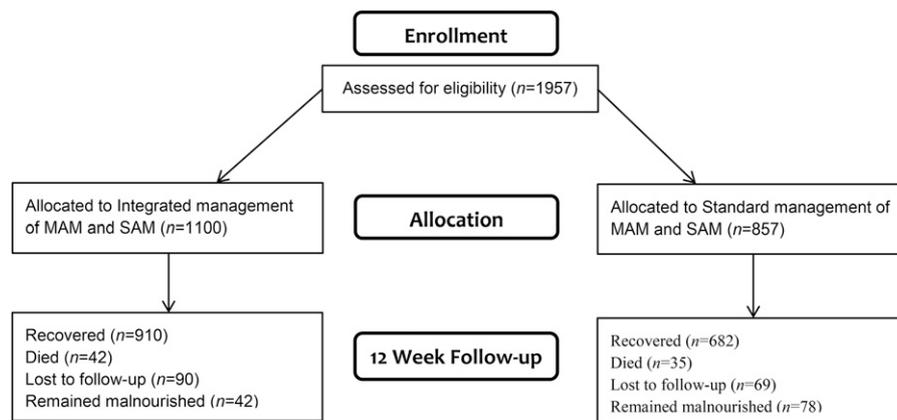
Results

Between January and November 2013, 1957 children were enrolled in the study (Figure 1, Table 2). The children who received integrated management were younger than those receiving the standard management, with a higher WHZ upon enrollment, and were less likely to be edematous and more likely to report fever (Table 2). Most of the children receiving integrated management had MAM and most receiving standard management had SAM (Table 2).

The coverage surveys identified 430 children with GAM in the community; 169 of 238 (71%) of the children in the catchment area of the integrated management received treatment and 107 of 192 (55%) of those in the area of the standard treatment received treatment (*P* = 0.0005). Of those 154 malnourished children who did not receive treatment, 107 (67%) of caretakers said that they were unaware that treatment was available, whereas 14 (9%) sought treatment but did not qualify and 11 (7%) of caretakers did not recognize that the child was malnourished. Approximately 81% of all children treated recovered from acute malnutrition (Table 3).

Children who received integrated management recovered more quickly, with greater MUAC gain and a higher WHZ upon

FIGURE 1 Study flow. MAM, moderate acute malnutrition; SAM, severe acute malnutrition.



completion (Table 4). Children who received standard management had greater rates of weight gain.

Among the children who received integrated management, 738 of 1100 were assigned to a care group. Among those with GAM, 623 of 738 (84%) assigned to peer counseling recovered, whereas 287 of 362 (79%) who did not receive peer counseling recovered ($P = 0.0001$).

The cost of RUTF used to treat a SAM case in integrated management was \$36, whereas for the standard management of SAM it was \$68. The cost of supplementary food used to treat a case of MAM in either the integrated or the standard management scheme was \$12.

The monthly enrollment of children with GAM indicates that more children presented for care from February through May than did from June through November ($P = 0.0001$) (Supplemental Figure 1). All children who recovered were asked to return to the clinic 6 mo after feeding was completed. Among children who received integrated management 6 mo previously, 604 of 1100 (55%) returned for their follow-up visit: 544 of these were well nourished and 60 were malnourished. Among children who received standard management, 6 mo after recovery 474 of 857 (55%) followed up: 459 were well nourished and 15 were malnourished. Although >90% who did return for follow-up remained well nourished, no comparisons between these children were made because of the large number lost to follow-up.

Discussion

This study documented that for SAM and MAM identified by using WHZ, standard treatment in an operational setting in Sierra Leone resulted in recovery among 79% of the children and provided 55% community coverage. A novel, integrated approach to the management of MAM and SAM with the use of a single food, RUTF, and MUAC as the single anthropometric indicator achieved 83% recovery and 71% coverage ($P = 0.0005$). Recovery rates in both of the management schemes met the Sphere standards for acceptability with >75% recovery, whereas the Sphere coverage standard of 70% was met only in the integrated management scheme (13).

This study was a cluster-randomized controlled trial, and those enrolled in the 2 arms had disparate baseline characteristics in part because different enrollment criteria were used for participation and there was as a different definition of recovery, so a direct comparison of outcomes is difficult (14, 15). Examination of the 95% CI of the proportions measured in each group separately for recovery and the use of linear regression modeling to control for clustering and different enrollment characteristics allow us to make some comparisons. Sierra Leone was then a postconflict country, one in which populations were still transient and communities lacked cohesion. Care should be exercised in extrapolating our findings to

TABLE 2 Characteristics of children receiving standard management or integrated management of GAM at enrollment¹

Characteristic	Integrated management of GAM <i>n</i> = 1100	Standard management of GAM <i>n</i> = 857	<i>P</i>
Males, <i>n</i> (%)	481 (44)	379 (44)	0.85
Age, mo	13.7 ± 8.6	14.5 ± 7.8	0.03
Mother is caretaker, <i>n</i> (%)	979 (89)	776 (91)	0.23
Father lives in home, <i>n</i> (%)	753 (68)	616 (72)	0.11
Siblings, <i>n</i> (%)	1.7 ± 1.8	2.1 ± 1.9	0.0001
Twins, <i>n</i> (%)	73 (7)	75 (9)	0.09
Currently breastfeeding, <i>n</i> (%)	805 (73)	618 (72)	0.61
Midupper arm circumference, cm	12.1 ± 0.3	11.4 ± 1.0	0.0001
Weight-for-height <i>z</i> score	-2.1 ± 1.0	-2.7 ± 1.6	0.0001
Height-for-age <i>z</i> score	-2.5 ± 1.4	-2.3 ± 1.0	0.0004
Weight-for-age <i>z</i> score	-2.9 ± 1.1	-3.2 ± 1.3	0.0001
Edema, <i>n</i> (%)	32 (3)	62 (7)	0.0001
Severe malnutrition, <i>n</i> (%)	326 (30)	537 (63)	0.0001
Mother reports fever, <i>n</i> (%)	947 (86)	645 (75)	0.0001
Mother reports diarrhea, <i>n</i> (%)	409 (37)	323 (38)	0.85

¹ Values are means ± SDs unless otherwise indicated. GAM, global acute malnutrition.

TABLE 3 Clinical and anthropometric outcomes of malnourished children treated with either integrated or standard management protocols

	Integrated management (<i>n</i> = 1100)	Standard management (<i>n</i> = 857)
Clinical outcome, <i>n</i> [% (95% CI)]		
Recovered	910 [83 (81, 85)]	682 [79 (77, 82)]
Remained malnourished	58 [5 (4, 7)]	78 [9 (7, 11)]
Died	42 [4 (3, 5)]	35 [4 (3, 5)]
Defaulted	90 [8 (7, 10)]	69 [8 (6, 10)]
Diarrhea during first 2 wk of feeding, <i>n</i> [% (95% CI)]	198 [18 (16, 20)]	216 [25 (22, 28)]
Fever during first 2 wk of feeding, <i>n</i> [% (95% CI)]	495 [45 (42, 48)]	456 [53 (50, 56)]
Weight gain during first 4 wk, g/(kg · d)	3.0 ± 0.2 ¹	3.8 ± 0.2
Length gain during entire feeding duration, mm/d	0.4 ± 0.02	0.5 ± 0.02
Mid-upper arm circumference gain during first 4 wk, mm/d	0.52 ± 0.04	0.25 ± 0.02
Clinic visits until recovery, <i>n</i> [% (95% CI)]	2.7 ± 0.06	3.5 ± 0.07
Children who qualify for treatment in both standard and integrated management schemes, <i>n</i> [% (95% CI)]	588 [53 (51, 56)]	811 [95 (93, 98)]
Weight-for-height <i>z</i> score upon completion of feeding	-1.3 ± 0.04	-1.9 ± 0.07

¹ Mean ± SEM (all such values).

other contexts, such as refugee camps or settings with stable, chronic poverty. Given that this was a comparison of 2 distinct management schemes, we were unable to determine the relative merits of the foods, anthropometric indexes, or other disparate aspects of the management schemes.

Children who received the integrated management of MAM and SAM were younger and a larger fraction had MAM than did those receiving standard management (Table 2). The duration of supplemental feeding was shorter in the integrated management scheme (Table 3), primarily because these children had less-severe malnutrition. We speculate that these differences were seen because mothers were actively seeking care earlier in the course of their children's malnutrition, perhaps because they believed care would be more available in the integrated delivery system. This is desirable because MAM treatment is associated with less cost and morbidity than SAM treatment.

Our observation of greater numbers of children presenting with malnutrition in February to May is not consonant with the pattern of food insecurity in Sierra Leone, in which July to October are the most food-insecure months; however, this observation does correspond to the driest time of year when travel to the clinic is easiest. July to October are also the months when a caregiver's tasks associated with food production are likely to be more time consuming, perhaps making health care visits less accessible.

Care group participation was associated with a greater recovery rate, suggesting that reinforcing good nutrition and hygiene practices may be a useful adjunct to feeding programs among children with GAM. This observation must be consid-

ered preliminary because we did not collect extensive data on care group attendance or the consistency of care group experiences that different participants experienced. Care groups in other settings have reduced child mortality; in a district in Mozambique, reductions of 40–50% in all child mortality were observed, with higher utilization rates of bed nets and oral rehydration solution (16, 17). A recent evidence-based review reinforces this observation by noting that community-based compliance activities that advocate for health service interventions improve the usage of such interventions (18). Community-based partnerships that emphasize the importance of malnutrition therapy and improve its access should be incorporated into MAM and SAM treatment efforts.

The differences in weight gain observed between the management schemes are attributable to the fact that children receiving standard management had more severe wasting and children with more severe wasting will have greater rates of weight gain upon therapeutic feeding. The ratio of coverage rates for the management schemes is similar to the ratio of children enrolled in the 2 management schemes, both 1.3. We speculate that greater coverage was achieved in the integrated management scheme because the clinical service was delivered in a more consistent manner, with adequate foods in stock at all times, and that mothers understood that their child would be assessed and treated for both MAM and SAM by attending the integrated clinic.

We were unable to determine whether the lipid nutrient supplement and simple infection control measures given in the integrated management scheme were of any benefit because of the large number of children without follow-up at 6 mo. Likewise,

TABLE 4 Linear regression modeling to compare secondary outcomes between children receiving integrated management and standard management of malnutrition¹

Outcome	Model <i>R</i> (<i>P</i>)	Significant covariates (<i>P</i> < 0.05)	Management scheme significant predictor (<i>P</i>)
Weight gain	0.25 (<0.001)	Male sex, age, edema, WHZ, HAZ	Yes (0.002)
Height gain	0.16 (<0.001)	Age, edema, WHZ	No
MUAC gain	0.14 (<0.001)	None	Yes (<0.0001)
Duration of feeding	0.42 (<0.001)	Female sex, age, MUAC, WHZ, HAZ	Yes (<0.0001)
WHZ upon completion of feeding	0.52 (<0.001)	MUAC, WHZ, HAZ	Yes (<0.0001)

¹ HAZ, height-for-age *z* score; MUAC, midupper arm circumference; WHZ, weight-for-height *z* score.

a comparison of the cost-effectiveness of the 2 management schemes cannot be made because many of the costs of care were not documented. Because of the reduced food costs and simpler logistical requirements, it seems likely that the integrated management would be less costly to implement per child treated, although greater coverage does increase the expenses of the treatment program. Future work should consider the cost-effectiveness of GAM management and whether the high dose of RUTF is needed in SAM children throughout the duration of treatment.

An integrated management scheme for GAM may be simpler for international agencies to implement in a humanitarian crisis where time is of the essence. Importing a single food product reduces logistical complexity; the exclusion of additional vitamin A, iron, and folate in the acute care of malnutrition makes delivery of care easier; and the exclusive use of MUAC as an anthropometric index may well be easier for local health aids to master. Our experience in postconflict Sierra Leone suggests that this integrated management scheme is an acceptable alternative to standard management, with greater coverage and similar recovery rates.

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