



An Optimized Dose of Therapeutic Feeding Results in Noninferior Growth in Midupper Arm Circumference Compared with a Standard Dose in Children in Sierra Leone Recovering from Acute Malnutrition

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ABSTRACT

Background: Ready-to-use therapeutic food (RUTF) given at 175 kcal/kg per day throughout severe acute malnutrition (SAM) treatment is recommended. Some treatment programs have diverged from this paradigm in 2 ways: reducing the supplemental food dose to 75 kcal/kg per day when midupper arm circumference (MUAC) is >11.4 cm or simplifying to a fixed-dose regimen.

Objective: The objective was to determine if transitioning to an optimized, fixed-dose supplementary feeding regimen during SAM treatment when MUAC is >11.4 cm would result in noninferior gain in MUAC compared with standard treatment.

Methods: Using data from 2 clinical trials conducted in Sierra Leone, a retrospective dual-cohort study was performed. The 2 cohorts included children with SAM who had improved to meet criteria for moderate acute malnutrition (MAM). The standard dose cohort continued to receive weight-based RUTF at 175 kcal/kg per day, while the optimized dose cohort received fixed-dose, 500 kcal/d of supplementary feeding. The primary outcome was a noninferiority margin of 1 mm of MUAC after 4 wk of treatment, while secondary outcomes included rate of anthropometric changes as well as time-to-relapse to SAM or death.

Results: MUAC after 4 wk was noninferior (Δ : -0.1 mm; 95% CI: -0.05 , 0.03 ; inferiority rejected $P = 0.008$). Rates of weight gain and MUAC gain were the same in the optimized-dose and standard-dose groups, whereas the rate of length gain was slower in the optimized-dose cohort. Time-to-relapse to SAM or death was not different (HR: 1.05 ; $P = 0.71$).

Conclusions: This study supports the practice of treating children with SAM who have recovered to meet criteria for MAM with a reduced and fixed-dose regimen of RUTF. The results also raise the question of whether this strategy might adversely impact linear growth during SAM treatment. *Curr Dev Nutr* 2021;5:nzab007.

Keywords: community-based management of acute malnutrition, moderate acute malnutrition, severe acute malnutrition, ready-to-use therapeutic food, supplementary feeding, midupper arm circumference, wasting, stunting, child

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Supplemental Table 1 is available from the "Supplementary data" link in the online posting of the article and from the same link in the online table of contents at <https://academic.oup.com/cdn/>.

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

Introduction

Acute malnutrition, or wasting, is common and deadly, affecting >50 million children at any one time and causing ~15% of child deaths worldwide each year (1, 2). Severe acute malnutrition (SAM) is treated with ready-to-use therapeutic food (RUTF) at a dosage of ~175 kcal/kg per day until the child reaches anthropometric measurements such that he/she no longer qualifies as wasted (3). This RUTF dose provides all of the SAM child's nutrient needs for maintenance and catch-up growth, and increases as they recover. Supplemental foods are often given for moderate acute malnutrition (MAM) and provide ~75 kcal/kg per day

(4). The physiology of catch-up growth is such that the greatest increases in lean tissue accretion are seen in the most wasted children, and as children improve from SAM to MAM restoration of body tissue decelerates (5). Thus, the rationale for continued provision of high doses of RUTF in children recovering from SAM as they improve to meet criteria for MAM is dubious. There is evidence that SAM treatment can be simplified with the use of a fixed-dose treatment regimen and that the dose of supplementary food can be decreased when children treated for SAM improve to meet anthropometric criteria for MAM (6–10). In this retrospective cohort study, we hypothesized that providing an optimized, fixed-dose regimen of supplementary food of 500 kcal/d to

children with SAM who have reached criteria for MAM would yield noninferior midupper arm circumference (MUAC) gain compared with standard weight-based dosing.

Methods

Setting

Children were enrolled from clinics in rural, unelectrified Pujehun District, Sierra Leone. Over 4 m of rain falls annually, creating conditions of continuous malaria transmission. Most families practice subsistence farming, with rice, cassava, yams, and fish being the most common foods.

Study design

This was a retrospective cohort study assessing the noninferiority of optimized-dose supplementary feeding compared with standard weight-based dosing of RUTF among children aged 6–59 mo with SAM who improve to meet criteria for MAM. The optimized-dose cohort data were extracted from clinical trial NCT03146897, which investigated the cost-effectiveness of 4 different therapeutic feeding regimens for MAM (11), while the standard-dose data were extracted from clinical trial NCT03407326, which compared standard RUTF with an oat-based RUTF in the treatment of SAM (12). Study foods were similar in energy and micronutrient content (Supplemental Table 1).

The primary outcome was noninferiority of MUAC after 4 wk of treatment, adjusted for baseline MUAC. Week 4 was chosen to allow for meaningful growth while recognizing that most children achieve an outcome by this time. Secondary outcomes included rates of gain in MUAC, weight, and length, programmatic outcome rates, and time-to-relapse to SAM or death. Week 8 was chosen to compare programmatic outcomes because the standard-dose cohort did not have consistent follow-up beyond this time.

Recovery was defined by the criteria used for admission: MUAC ≥ 12.5 cm for those enrolled by MUAC alone, weight-for-height z score (WHZ) ≥ -2 for those enrolled by WHZ alone, or either criterion when both were used for admission. Relapse to SAM was similarly defined based on admission criteria: MUAC < 11.5 cm and/or WHZ < 3 or development of edema. Children designated as “remained MAM” were those who neither relapsed nor met criteria for recovery by week 8. Defaulting was missing 3 consecutive visits. When death was reported by the caretaker, it was recorded as such.

The noninferiority margin of 1-mm MUAC at 4 wk was selected as the primary outcome after review of the literature and consideration of clinical judgment. Average MUAC gains of 1–3 mm/wk have been reported when baseline MUAC was 11.5–12 cm, corresponding to 4–12-mm gain over 4 wk (5, 13). Our chosen noninferiority margin of 1 mm is within 8–25% of these values. Using a 5% significance level for a 1-sided test, our sample size at 4 wk ($n = 673$) yields $> 85\%$ power to detect noninferiority at this margin.

Participants

All children aged 6–59 mo treated for SAM at 42 government health clinics in Pujehun and Western Rural Districts between April 2017 and December 2019 were assessed for inclusion in the 2 clinical trials from which these data were drawn. Children were included in this analysis

if they reached anthropometric criteria for MAM, which were defined in each child by the criterion that had been used to diagnose SAM—for example, if the child was diagnosed with SAM by MUAC < 11.5 cm, MAM criteria was MUAC ≥ 11.5 cm and < 12.5 cm. If both MUAC and WHZ criteria were used to diagnose SAM, MAM was determined by whichever criterion was met first. Exclusion criteria were nutritional edema at any time prior to inclusion or presence of a chronic, debilitating health condition such as cerebral palsy, congenital heart disease, and cleft lip. The visit at which these children first met criteria for MAM became the initial visit for this comparison.

Ethical approval was obtained from the Washington University Human Studies Committee and the Sierra Leone Ethics and Scientific Review Committee. Informed consent was obtained from the primary caregiver and documented by a signature or thumbprint if the caregiver was unable to write.

Cohorts

The optimized-dose cohort included children treated for SAM with 175 kcal RUTF/kg per day between April 2017 and September 2018 before being transitioned to a supplemental food once they had improved sufficiently to meet criteria for MAM. All children had been diagnosed with SAM by MUAC < 11.5 cm. All children were followed for 12 wk after MUAC > 11.4 cm or until they recovered, relapsed to SAM, defaulted, or died, whichever occurred first. The optimized-dose supplementary food was 1 of 3 fortified-blended flours or a single sachet of ready-to-use supplemental food; all provided ~ 500 kcal/d with 1 RDA of most micronutrients (Supplemental Table 1). Blended flours were provided by the US Agency for International Development (USAID) and RUSF was produced by Project Peanut Butter Sierra Leone. The standard-dose cohort included children treated for SAM between October 2018 and December 2019 who received 175 kcal RUTF/kg per day until discharge. Children were diagnosed with SAM by either MUAC < 11.5 or WHZ < 3 . All children were followed for 8 wk after meeting criteria for MAM or until a programmatic outcome, whichever occurred first. RUTF was produced by MANA International.

Study visits and procedures

Anthropometry were measured fortnightly. MUAC was measured on the left arm with a standard insertion tape to the nearest 0.1 cm, nude weight was measured to the nearest 5 g, and recumbent length was measured in triplicate to the nearest 0.1 cm using a rigid length board. Caregivers were interviewed about recent symptoms of acute illness and the child's food consumption.

Data analysis

Data were double-entered in Microsoft Access (Microsoft Corporation). Anthropometric indices were calculated based on 2006 WHO guidelines (Anthro version 3.2.2; WHO). Analyses were performed using SPSS (version 27; IBM Corporation) and GraphPad Prism (version 9.0.0; GraphPad Software, Inc.).

Averages were calculated for anthropometric assessments that were measured repeatedly at a visit. Both categorical characteristics and programmatic outcome rates were compared using Fisher's exact test. Continuous characteristics and outcomes were assessed for conformance to the normal distribution and, if confirmed, compared using Student's t test. Continuous variables that were not normally distributed were

TABLE 1 Baseline characteristics of standard- and optimized-dose cohorts¹

	Standard dose (n = 398)	Optimized dose (n = 657)	P
Female, n (%)	227 (57)	382 (58)	0.748
Age, ² mo	11.5 (6.4, 43.7)	11.2 (6, 58)	0.513 ³
Length, cm	67.4 ± 5.3	67.1 ± 6.4	0.445
Weight, kg	6.6 ± 0.9	6.5 ± 1.0	0.579
MUAC, cm	11.8 ± 0.3	11.9 ± 0.3	0.002
WHZ	−1.8 ± 0.8	−1.8 ± 0.8	0.565
HAZ	−3.2 ± 1.2	−3.3 ± 1.4	0.243
WAZ	−3.1 ± 0.7	−3.1 ± 0.8	0.263
Fever, n (%)	102 (26)	146 (22)	0.231
Diarrhea, n (%)	17 (4)	28 (4)	1.000
Vomiting, n (%)	8 (2)	13 (2)	1.000
Cough, n (%)	67 (17)	113 (17)	0.866
Admission strategy, n (%)			<0.001
MUAC	364 (91)	657 (100)	
WHZ	34 (9)	0	

¹Values are means ± SDs unless otherwise indicated. Fisher's exact test was used for comparison of categorical variables, whereas independent-samples t test was used for comparison of continuous variables unless otherwise indicated. HAZ, height-for-age z score; MUAC, midupper arm circumference; WAZ, weight-for-age z score; WHZ, weight-for-height z score.

²Values are medians (minimum–maximum).

³Mann-Whitney *U* test.

compared using Mann-Whitney *U* test. Statistical significance was set at <0.05. Results were reported as differences between the optimized dose and standard dose.

ANCOVA was used to adjust for the baseline difference in MUAC between the 2 cohorts, and these adjusted means and SDs were used to test for noninferiority. Time-to-event for relapse to SAM or death was analyzed using both the Kaplan-Meier method with Mantel-Haenszel test and Cox proportional hazards regression, with the latter adjusted for age, sex, enrollment strategy, and baseline anthropometry. The potential impact of age on the efficacy of the optimized dosing strategy was assessed by adding an interaction term (age × group) into the regression.

Results

Baseline characteristics of the 1055 children were similar between the 2 groups, with the exception of MUAC which was 1 mm greater in the optimized-dose group (Table 1; $P = 0.002$). All participants in the optimized-dose group were enrolled by MUAC criteria, while 91% of the standard-dose group were enrolled by MUAC and 9% by WHZ. At time of enrollment, participants in the standard-dose cohort received an average of 184 ± 8 kcal/kg per day, while those in the optimized-dose group received an average of 78 ± 11 kcal/kg per day ($P < 0.001$). Missing data were rare, with 1 child each having no documented date of birth and no sex.

ANCOVA-adjusted MUAC at week 4 was noninferior in the optimized-dose group compared with the standard-dose group (Δ : -0.01 ; 95% CI: $-0.05, 0.03$; inferiority rejected $P = 0.008$; Figure 1). The 2 cohorts had similar average rates of MUAC gain and weight gain (Table 2). Average rate of length gain was lower in the optimized-dose group by 0.4 mm/wk (Table 2). Six children in the standard-dose cohort defaulted prior to their second visit and were not included in anthropometric analyses.

There was no significant difference in programmatic outcomes between the 2 cohorts (Table 2). Average time to recovery in the 2 groups was 4 wk ($P = 0.645$). There was no difference in time-to-relapse to SAM or death between the 2 groups in either unadjusted (Figure 2) or adjusted analyses (HR: 1.2; 95% CI: 0.9, 1.6). In addition, age did not influence the effect of dosing strategy on time-to-relapse to SAM or death (interaction term HR: 0.99; 95% CI: 0.95, 1.03).

Discussion

This cohort study investigated the effectiveness of using an optimized dose of therapeutic food in children during recovery from SAM. MUAC at week 4 was noninferior with an optimized dose and no differences in rates of MUAC gain, weight gain, or recovery were seen. These

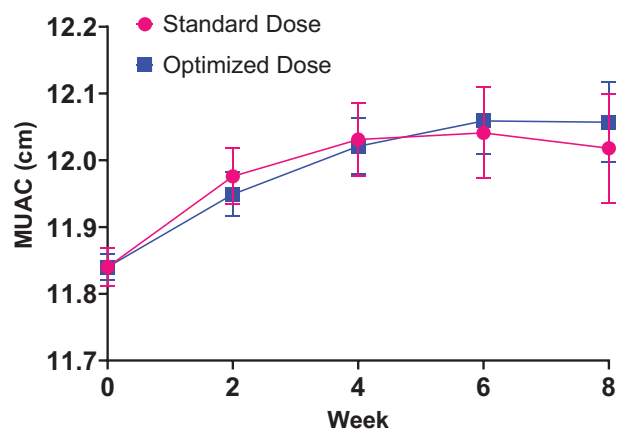


FIGURE 1 Mean MUAC by week of treatment and treatment group with 95% CIs, adjusted for baseline MUAC using ANCOVA. MUAC, midupper arm circumference.

TABLE 2 Changes in anthropometric measurements and programmatic outcomes of standard- and optimized-dose cohorts¹

	Standard dose (n = 398)	Optimized dose (n = 657)	Difference (95% CI)	P
MUAC gain velocity, mm/wk	0.5 ± 1.9 ²	0.5 ± 2.1	0 (−0.2, 0.2)	0.977
Weight gain velocity, g/kg/d	1.4 ± 2.4 ²	1.4 ± 2.8	0 (−0.3, 0.3)	0.87
Length gain velocity, mm/wk	2.8 ± 2.7 ²	2.4 ± 2.3	−0.4 (−0.7, 0)	0.031
Recovery, n (%)	170 (42.7)	273 (41.5)	−1.2 (−7.3, 5.1)	0.748
Remained MAM, n (%)	91 (22.9)	153 (23.3)	0.4 (−4.9, 5.7)	0.94
Relapse to SAM, n (%)	114 (28.6)	200 (30.4)	−1.8 (−7.5, 3.9)	0.578
Death, n (%)	2 (0.5)	7 (1.1)	−0.7 (−1.8, 0.4)	0.496
Default, n (%)	21 (5.3)	24 (3.7)	−1.6 (−4.2, 1)	0.212

¹Values are means ± SDs, n (%), or mean differences (95% CIs). Independent-samples t test was used for anthropometric comparisons, whereas Fisher's exact test was used to compare categorical outcomes. MAM, moderate acute malnutrition; MUAC, midupper arm circumference; SAM, severe acute malnutrition.

²n = 392.

results suggest similar efficacy of the optimized dosing strategy in this population.

This study adds to a growing body of literature that suggests that SAM can be treated effectively with transition to an optimized fixed dose of RUTF. In Myanmar, children treated for SAM were transitioned from standard dosing to a single sachet of RUTF when they met anthropometric criteria for MAM in the setting of an RUTF shortage and obtained a 90.2% rate of recovery (8). This dosing strategy enabled the treatment of a larger number of children than would have been possible using standard dosing. A randomized trial in Burkina Faso compared standard dosing with a strategy in which RUTF was decreased to 1–2 sachets/d based on weight after 2 wk of SAM treatment and demonstrated noninferiority of the novel regimen in rate of weight gain (9). A cluster-randomized controlled trial conducted in Kenya and South Sudan compared standard weight-based treatment of SAM and MAM with an integrated, fixed-dose regimen in which children with SAM were given 2 sachets of RUTF/d and children with MAM were given 1 sachet/d, demonstrating noninferiority of the novel regimen in rate of

recovery (7). This treatment strategy was associated with an estimated cost savings of US \$123 per child. In Sierra Leone, a cluster-randomized controlled trial showed similar rates of recovery when comparing integrated management of SAM and MAM with standard therapy (6). Integrated management provided 175 kcal/kg when MUAC <11.5 cm and 75 kcal/kg for MUAC of 11.5–12.4 cm and was associated with a higher rate of coverage and an ~50% decrease in cost per child compared with standard therapy. Together, these findings are consistent across a broad geography and point to several possible benefits of an optimized, fixed-dose strategy: simplified management and decreased costs. They also represent a fraction of the work investigating alternative dosing strategies and integrated management of malnutrition (14).

This study has multiple limitations. First, it is a retrospective cohort study, a design that limits control of confounding conditions and for which sample size is set irrespective of power considerations. Some characteristics differed between the cohorts, including enrollment MUAC, criteria used to diagnose SAM, and supplemental food used to complete the SAM treatment. However, only 9% of the standard-dose cohort qualified for SAM by WHZ and children have been shown to have very similar outcomes whether fed flour or ready-to-use food (13). The 2 cohorts were enrolled during consecutive years, so some undefined temporal vagaries may have been present. Second, due to follow-up limitations in the standard-dose group, we could only compare outcomes through 8 wk, which is shorter than the usual feeding program follow-up in the treatment of acute malnutrition. Eighty percent of participants did, however, reach a programmatic outcome by week 8.

There was 1 secondary finding from this study that raises concern: the optimized-dose group had a slower rate of length gain. This result is consistent with findings from trials of a reduced dosing strategy in Burkina Faso (9) and Sierra Leone (6). Thus, while the absolute difference was small and follow-up limited due to the design of this study, this was not the first time this result has been seen. We speculate that, upon initiation of therapeutic feeding, nutrients are directed to the most vital organs, including the brain, heart, lungs, and liver. Resumption of linear growth is seen after some restoration of these organs occurs (15). Perhaps the timing of the RUTF reduction in optimized dosing corresponds to the time when linear growth resumes, and the larger dose of RUTF is better meeting the needs to facilitate linear growth.

In addition to this concern, generalizability is limited: this study took place in a single country in a nonemergency setting and the majority of children were <2 y old and were enrolled by MUAC criteria. Whether

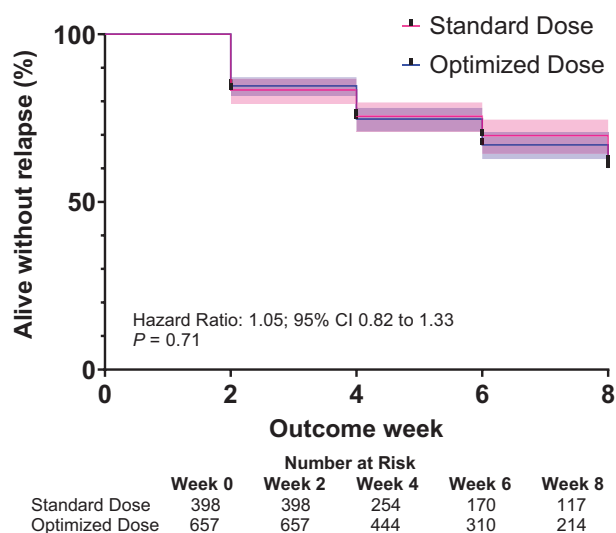


FIGURE 2 Kaplan-Meier method showing the proportion alive without relapse by week of treatment and treatment group, with shaded 95% CIs (Mantel-Haenszel HR). MUAC, midupper arm circumference.

the results apply to older children, or those enrolled by WHZ, is less certain. In addition, both cohorts had a high rate of relapse to SAM that might differ from other settings. Our definition of relapse contributed to the high rate seen in this study, with any child having 1 MUAC < 11.5 cm or WHZ < -2 (depending on criterion for initial diagnosis) being categorized as relapsed. While the lack of research data collected thereafter limits our analysis, we believe the key finding is that optimizing the dose did not lead to a significantly higher rate of relapse. The results also suggest that many children with SAM do not follow a linear trajectory, even during recovery. Thus, when considering adopting an optimized dosing strategy, it is essential to follow the children with MUAC \geq 11.5 cm and WHZ \geq -2 as closely as all others and have a coordinated response when decreases in MUAC or WHZ are seen. The validity of this cohort study is strengthened by the similarity in demographic and clinical characteristics at baseline, the paucity of missing data, and the large difference in the intervention, with the optimized-dose group receiving less than one-half of the energy per kilogram per day given to the standard-dose group.

Our findings are consonant with 4 known clinical trials and allow us to conclude that reduction in RUTF dose for children with SAM after they meet criteria for MAM produces equivalent outcomes with respect to MUAC, an excellent indicator of wasting. Length gain as a secondary outcome was not assessed in the studies from Myanmar or Kenya/South Sudan, but in the other trials linear growth was modestly reduced. This secondary finding may not allow for a streamlined management strategy using a single nutritional product, RUTF, at differing doses. Further research is needed with the explicit focus on linear growth seen during and after SAM treatment to allow for the most beneficial, evidence-based strategy to be adopted.

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