J HEALTH POPUL NUTR 2005 Dec;23(4):351-357 © 2005 ICDDR,B: Centre for Health and Population Research
ISSN 1606-0997 $ 5.00+0.20

Supplemental Feeding with Ready-to-Use Therapeutic Food in Malawian Children at Risk of Malnutrition

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ABSTRACT

The study was a controlled, comparative clinical effectiveness trial of two supplementary feeding regimens in children at risk of malnutrition from seven centres in rural Malawi. Being at risk of malnutrition was defined as weight-for-height <85%, but >80% of the international standard. A stepped-wedge design with systematic allocation was used for assigning children to receive either ready-to-use therapeutic food (RUTF) (n=331) or micronutrient-fortified corn/soy-blend (n=41) for up to eight weeks. The primary outcomes were recovery, defined as weight-for-height >90%, and the rate of weight gain. Children receiving RUTF were more likely to recover (58% vs 22%; difference 36%; 95% confidence interval [CI] 20-52) and had greater rates of weight gain (3.1 g/kg.d vs 1.4 g/kg.d; difference 1.7; 95% CI 0.8-2.6) than children receiving corn/soy-blend. The results of this preliminary work suggest that supplementary feeding with RUTF promotes better growth in children at risk of malnutrition than the standard fortified cereal/legume-blended food.

***Key words*:** Food supplementation; Infant food; Food, Fortified; Infant nutrition; Infant nutrition disorders; Child nutrition; Child nutrition disorders; Infant growth; Child growth; Risk factors; Comparative studies; Malawi

INTRODUCTION

Malawi is a poor, agrarian, food insecure nation in sub-Saharan Africa where half of children aged less than five years are stunted. Over half of deaths of these children are attributed to malnutrition (1). When a crisis compromises food production in nations, such as Malawi, non-governmental organizations and international agencies often respond with supplementary feeding targeted to vulnerable children, hoping to prevent severe malnutrition and excess mortality. Supplementary feeding is defined as the distribution of food to supplement energy and other nutrients missing from the diet of those who have special nutritional requirements (2). Most supplementary foods are micronutrient-fortified combinations of cereals and legumes, the one used most commonly is corn/soy-blend. Children at risk of malnutrition are identified by low weight-for-height. However, the results of such programmes have been disappointing, with over 50% of the programmes in sub-Saharan Africa reporting no significant weight gain with take-home supplementary feeding (3). An analysis of supplementary feeding programmes in Lesotho found no improvement in weight gain with their intervention, but there was improvement in clinic attendance (4). A comprehensive review of supplementary feeding published in 1999 did not identify any efficacy studies assessing the effect of fortified corn/

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soy-blended foods (5), and a Medline search of the subsequent time period did not reveal any such studies either.

Ready-to-use therapeutic food (RUTF) has recently been introduced in Malawi in conjunction with home-based therapy for severe childhood malnutrition (6-8). RUTF is an energy-dense paste that does not require cooking, resists bacterial growth because of its low water content, and can be stored without spoiling for several months (9). Recovery rates among severely-malnourished Malawian children using RUTF were 78% compared to 46% using the standard protocol advocated by the World Health Organization (WHO) (10).

This study tested the hypothesis that supplemental feeding with RUTF would result in better growth in Malawian children at risk of malnutrition (80% <weight-for-height <85%) than feeding with corn/soy-blend.

MATERIALS AND METHODS

Patients

Children, aged 10-60 months at risk of malnutrition, weight-for-height >80%, but <85% of the standard reference values of WHO (11) without oedema, were eligible for the study. These anthropometric criteria defining children at risk of malnutrition are those specified by the Malawian national guidelines. This group is targeted for supplementary feeding. Children presenting to any of seven nutritional rehabilitation units (NRUs) from December 2002 to May 2003 were screened for eligibility for the supplementary feeding programme. This study was done in conjunction with a study of home-based therapeutic feeding of severely-malnourished children (10). The children screened included all inpatients in the NRUs and children brought by caretakers from the surrounding community. The participating NRUs were three mission hospitals and four public-health centres in small towns and rural areas of southern Malawi. Children aged less than 10 months were excluded from the study because of the concern that supplementary feeding might interfere with breastfeeding.

Informed consent was obtained from all participating caretakers. The Research and Ethics Committee of the College of Medicine, University of Malawi, and the Human Studies Committee of Washington University in St. Louis approved the study.

Experiment design

This was a controlled, comparative clinical effectiveness trial of two different management strategies for supplementary feeding of children at risk for development of malnutrition.

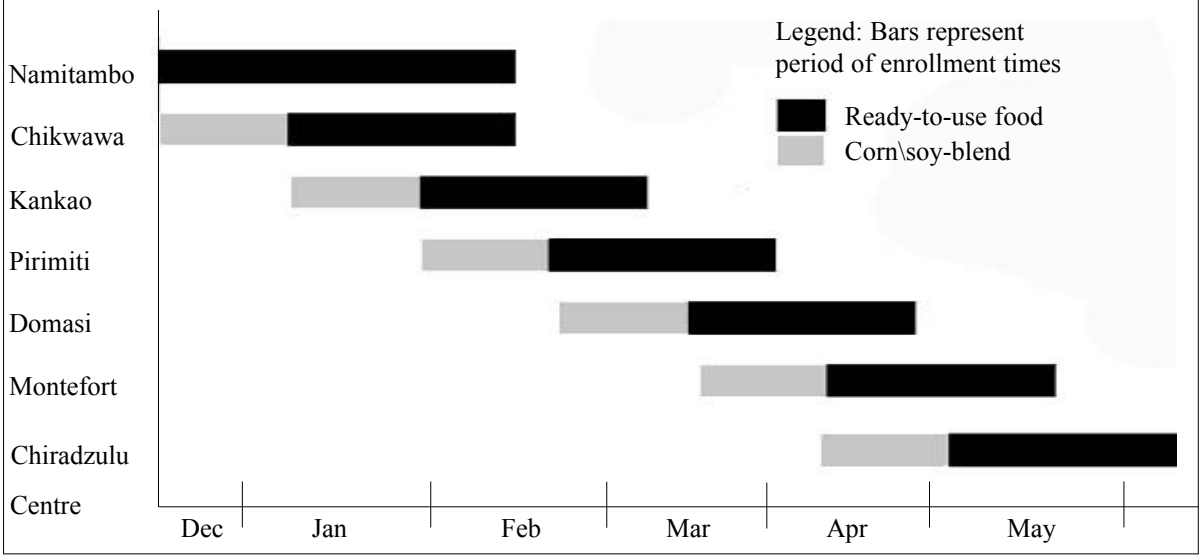
Since randomized assignment to supplementary feeding with RUTF or corn/soy-blend was not possible in this setting due to resource constraints and cultural beliefs, prospective systematic allocation using a stepped-wedge design was employed (12). Children were recruited at six of the seven NRUs during the first three weeks of centre's participation to receive corn/soy-blend, during which supplementary feeding with RUTF was not offered. After these first three weeks, supplementary feeding with RUTF was offered for the next eight weeks at that centre. Feeding with RUTF was not offered during the first three weeks of centre's participation and feeding with corn/soy-blend was not offered during the next eight weeks of centre's participation. The seventh participating NRU offered supplementary feeding with RUTF at the onset of the study. The first two centres began to participate in December 2002, and an additional NRU began participation every three weeks thereafter. Thus, children receiving corn/soy-blend were enrolled throughout the duration of the study, but in much lesser numbers (Fig.). Supplementary food was provided to each child for eight weeks.

Malawi is an agrarian country with a single annual harvest in April, and most cases of childhood malnutrition occur in the pre-harvest season (December-April), when the study was conducted. The stepped-wedge design was used for controlling bias that might be introduced by seasonal variations in severity of childhood malnutrition.

Caretakers and children returned to the clinic for re-assessment every two weeks. The caretakers were questioned whether the children had developed any new rashes or manifestations of food allergy, and if they had consumed the supplement well. Their weight, length, and mid-upper arm circumference were measured at this time. If children were receiving RUTF, an additional two-week supply of RUTF was distributed. Children having corn/soy-blend received additional food every four weeks. Study participation lasted for eight weeks, after which all children were discharged. Children were discharged from the study before eight weeks if they reached weight-for-height >90% based on their admission height, clinically relapsed (occurrence of oedema or systemic infection) requiring inpatient treatment at the NRUs or died. All follow-up data were collected in the same manner for all children.

All children were asked to return for follow-up anthropometric measurements six months after recovery to assess the rate of relapse after the intervention was complete. During this six-month interval, these children received no food or other interventions from the study team.

Fig. Timeline illustrating subject dietary assignment in the stepped-wedge design



The time for enrollment for supplementary feeding with corn/soy-blend was much shorter than that for RUTF. Thus, we anticipated that about 80% of the participants would receive RUTF, and 20% would receive corn/soy-blend. A sample size of 250 children was calculated to provide 95% confidence and 80% power to detect a minimum of 25% absolute increase in recovery rate assuming 1:4 allocation of participants into corn/soy-blend and RUTF groups with 50% recovery in the corn/soy-blend group.

The primary outcomes of the study were successful recovery, defined as the attainment of weight-for-height >90% while remaining free of oedema, relapse/death, and the rate of weight gain. The secondary outcomes were the rates of growth in length and mid-upper arm circumference.

Those children who failed to attend follow-up visits were sought out through local village health workers. This active case finding began three weeks after the child's last follow-up visit, and its purpose was to determine if the child had died or relapsed.

Supplemental foods

RUTF was a locally-produced energy-dense, lipid paste consisting of peanut-butter, sugar, milk-powder, vegetable oil, and a vitamin/mineral supplement (CMV, Nutriset, Malaunay, France) (10). Its micronutrient content was in accordance with the recommendations of WHO for catch-up growth (13). Typically, children ate RUTF directly from the jar, without diluting it or mixing it with other foods. Mothers were given seven kg of RUTF per month.

The corn/soy-blend was a blended cereal/legume flour fortified with vitamins and minerals as specified by the World Food Programme (14). The Malawian staple food is corn-flour consumed as a soft, solid, cooked dough, and mothers were asked to prepare the corn/soy-blend in a similar manner. Mothers were given 50 kg of corn/soy-blend per month.

All mothers were asked to feed their children seven times a day. As with most supplementary feeding programmes, it was assumed that there would be significant sharing of food within the home and, thus, the amounts of food dispensed were much larger than what the children themselves would require as a food supplement, especially for the corn/soy-blend, which looked and tasted similar to the local staple food. The distributed RUTF provided 5,700 kJ per day and the corn/soy-blend 28,300 kJ per day. The energy density of RUTF was five times greater than the typical preparation of corn/soy-blend after cooking. Compliance with usage instructions and consumption of supplementary food was not measured.

Statistics

Weight-for-height expressed as a percentage of the National Center for Health Statistics (USA) standard was used as the anthropometric index for determining eligibility in the study and as the primary outcome because this index was used in the national nutrition guidelines in Malawi. Weight gain and growth in mid-upper arm circumference were determined by calculating the change per day during the first four weeks of the study, the period when weight gain from catch-up growth is expected to be greatest. Statural growth rate was calculated as change

in height per day over eight weeks, to include a period of time after which most weight was regained. Intention to treat analyses was used. Comparisons of outcome measures were made by calculating the differences and 95% confidence intervals of the differences between those children receiving corn/soy-blend and RUTF. Linear regression modelling was used for accounting for the effect of the covariates, such as age, sex, initial anthropometric indices, and the status of parents, on the comparisons (enter mode, SPSS version 10.0.0, Chicago, 1999). A probability of <0.05 was considered to be statistically significant.

RESULTS

Of 372 children enrolled in the study, 331 received supplementary feeding with RUTF and 41 received corn/soy-blend. Seven children—five receiving RUTF and two receiving corn/soy-blend—did not complete eight weeks of supplemental feeding. There were no differences between the two groups in demographic or nutritional characteristics (Table 1). No allergic or other serious adverse reactions were observed among the participants.

One hundred ninety-two (58%) children receiving supplementary feeds with RUTF recovered, while only nine (22%) children receiving fortified corn/soy-blend recovered (difference 36%; 95% CI 20-52) (Table 2). Forty-seven children receiving RUTF (14%) and 11 children receiving fortified corn/soy-blend (27%) did not reach a weight-for-height of 85% (difference 13%; 95% CI 1-24), thus remaining at risk for development of more severe malnutrition. The children receiving RUTF also had greater growth rates of weight, height, and mid-upper arm circumference than the children receiving fortified corn/soy-blend (Table 2).

Linear regression modelling was conducted to predict weight-for-height at eight weeks (Table 3). The model found that the food used in supplementary feeding was a significant predictor of outcome.

Two hundred one (61%) children who received supplementary feeding with RUTF were followed up at least six months after receiving their last food supplement. As a group, they were 28 months old, and 131 (65%) maintained a weight-for-height >90%, 50 (25%) had weight-for-height between 85% and 90%, and 20 (10%) had a weight-for-height <85%. None of these children had enrolled in other supplementary feeding programmes after discharge from the study. Twenty-five children who received corn/soy-blend were followed up six months after receiving their last supplementary food from the study, and 20 children had subsequently been enrolled in other supplementary feeding programmes because their weight-for-height had fallen to <85%.

DISCUSSION

The comparative effectiveness trial of two different modalities of supplemental feeding (RUTF and corn/soy-blend) documented that supplementary feeding with RUTF resulted in better growth in Malawian children at risk of malnutrition.

The two supplementary feeding regimens compared in this study both supplied quantities of food that were

Table 1. Demographic and nutritional characteristics of children upon enrollment to supplementary feeding programme

Characteristics	Standard fortified corn/soy-blend feeding (n=41) (male=8, female=33)	Supplementary feeding with ready-to-use food (n=331) (male=92, female=239)
Age (months)	19±8	21±10
Weight (kg)	7.2±1.7	7.3±1.3
Length (cm)	71.5±8.3	71.6±6.2
Weight-for-height (% of international standard)	82±1	82±2
Weight-for age (% of international standard)	66±9	66±8
Height-for-age (% of international standard)	84±7	83±8
Mid-upper arm circumference (cm)	11.8±1.4	11.7±1.0
Children still breastfeeding	30 (73%)	242 (73%)
Age (months) when breastfeeding was stopped	25±8	22±7
Mother alive	40 (98%)	326 (98%)
Father alive	39 (95%)	312 (94%)
Source of clean water	35 (85%)	285 (86%)
Grass used as roofing material	39 (95%)	301 (91%)

Data expressed as no. (%) for dichotomous characteristics and mean±SD for continuous characteristics

Table 2 Outcome data for supplementary feeding of moderating wasted children

Outcome	Standard fortified corn/ soy-blend feeding (n=41)	Supplementary feeding with ready-to-use food (n=331)	Difference 95% CI	p value
Outcomes after 8 weeks				
Weight-for-height >90%	9 (22%)	192 (58%)	36% (20-52%)	
85% <weight-for-height <90%	21 (51%)	92 (28%)	-23% (8-38%)	0.0002
Weight-for-height <85%	8 (20%)	36 (11%)	9% (-2-19%)	
Relapsed or died	1 (2%)	6 (2%)	0%	
Dropped out	2 (5%)	5 (2%)	-3%	
Rate of weight gain during first 4 weeks (g/kg.d)	1.4±2.5	3.1±2.7	1.7 (0.8-2.6)	0.0002
Rate of height gain during first 8 weeks (mm/d)	0.17±0.21	0.28±0.27	0.11 (0.02-0.2)	0.003
Rate of mid-upper arm circumference gain during first 4 weeks (mm/d)	0.18±0.29	0.30±0.31	0.12 (0.02-0.2)	0.02

Data expressed as no. (%) for dichotomous characteristics and mean±SD for continuous characteristics
Chi-square test was used for comparing the outcomes of the two groups, and Student's *t*-test was used for comparing the growth rates
CI=Confidence interval

much larger than would actually need to be consumed by the children to achieve accelerated growth, and both the foods were simply distributed to mothers as dry rations, who then incorporated these foods into daily feeding of their children. This supplementary feeding strategy—distributing food to families with children deemed to be at risk of malnutrition—is common in sub-Saharan Africa because it is less expensive and more practical than establishing feeding centres and preparing supplemental meals for poor communities. RUTF had the advantages of requiring no further preparation before consumption and having a high energy density, thus allowing for the consumption of small portions of the supplemental food to result in a substantial increase in energy intake. Poorer outcomes with fortified corn/soy supplementary feedings may be the result of the lower energy density of the food and the inconvenient, time-consuming process needed to cook the food. Finding the fuel and time to feed a child several times a day may well be impossible for many mothers in sub-Saharan Africa. The use of RUTF circumvents these challenges.

A major concern of any targeted supplementary feeding programme, such as the one described in this study, is the consumption of food by individuals other than the intended recipients; this has been called leakage. Various targeted supplementary feeding programmes in the developing world have found that 50-75% of the ration does not reach the intended recipients, which is understandable in the context of food-insecure families, such as those in Malawi (18). In response to the anticipated leakage, the ration in most supplementary feeding programmes is usually much larger than that needed to make up the energy-deficit of targeted individuals, just as was done in this study. RUTF may not be subject to as much leakage as cereal/legume-blends because

Table 3 Association of anthropometric, demographic and dietary characteristics with weight-for-height after 8 weeks of supplementary feeding

Characteristics	Standardized coefficient ß	p value
Age	0.11	0.11
Weight-for-height at admission	0.19	0.001
Height-for-age at admission	-0.02	0.74
Mid-upper arm circumference	0.05	0.44
Mother alive	-0.05	0.39
Father alive	-0.05	0.33
Type of supplementary food (RUTF or corn/soy-blend)	0.18	0.001

*These are the results of linear regression modelling of weight-for-height after 8 weeks, using demographic, anthropometric and dietary characteristics
The overall model had r=0.29, with a F statistic=4.3, predictive significance of the model was p<0.0001
RUTF=Ready-to-use therapeutic food

ready-to-eat spreads are not usually part of the habitual diet. Therefore, other family members do not see it as food, but more as 'medicine'. This may allow smaller rations of supplementary RUTF to be given to underweight children to have a beneficial effect, as was the case in this study.

RUTF was previously found to be an acceptable food to Malawian children in this age-group (6,7,8,10), and it was assumed that RUTF was acceptable in this supplementary feeding study. Compliance with either supplementary feeding regimen was not monitored with home-visits or further questionnaire because this was an effectiveness trial rather than an efficacy trial. Either of the foods given in a supervised setting will increase the rate of weight gain. The primary outcomes of this study themselves indirectly measure the compliance and suggest that compliance was better with the RUTF regimen.

Our outcomes from the 41 children given corn/soy supplemental feeding were similar to best reported results from sub-Saharan Africa. Chadian children gained 1.7 g/kg.d in a 60-day programme that distributed corn/soy-flour and milk-powder, while children from this study receiving corn/soy gained 1.4 g/kg.d (15). In Guinea-Bissau, a successful programme distributed a flour mixture containing millet, milk, and eggs and reported that 67% reached a weight-for-height >85% and had a weight gain of 4 g per day (16). Seventy-three percent of the children in this study receiving corn/soy reached a weight-for-height >85% and, on average, they gained 10 g per day. Unfortunately, several reports from supplementary feeding programmes in sub-Saharan Africa showed no improvement in child growth (3,4,17).

The main limitation of this study was that its participants were not randomly assigned to receive either corn/soy-blend or RUTF. The children were instead systematically allocated to each group based on when and where they were enrolled. Randomization was not possible for two reasons. First, the local belief of communitarianism (6), which states that justice is achieved when each member of the community receives a similar treatment, cannot accept blatant differences in the type of food given upon enrollment. This has been a challenge to us previously and led us to abandon randomization schemes in other studies. Second, the limited resources of the Malawian health services made the creation of two parallel feeding options impractical. In addition, blinding of the staff and participants was impossible because of the obvious difference in appearance of the two types of supplemental foods. There is no evidence that use of systematic allocation has introduced bias into our results, as the characteristics of the two dietary groups were similar upon enrollment (Table 1), and we are not aware of any confounding variables that were distributed disproportionately between the two groups.

Another limitation of the study was the large disparity between the numbers of children receiving RUTF and those receiving fortified corn/soy-blend. Recruitment for the study took place during the pre-harvest season when the prevalence of malnutrition was at its highest level; so, as the season progressed and food became more scarce, the number and severity of under-weight children increased. Thus, a stepped-wedge design was necessary to control for this seasonal variation, but its implementation resulted in a seven-fold greater number of children receiving RUTF. However, regression analyses performed to control for the effect of covariates indicated that type of supplementary food was an independent, significant determinant of the outcome.

The data from this study suggest that supplementary feeding with RUTF might be a more effective alternative. However, results of larger-scale programmes often do not achieve the success seen in research studies (18), and data from the use of RUTF as a supplemental food on a larger-scale are needed to evaluate its utility. Thus, further research with RUTF as a targeted supplementary food in sub-Saharan Africa is warranted.

ACKNOWLEDGEMENTS

This work was supported by a gift from the St. Louis Children's Hospital Foundation and donations of supplementary foodstuff from the World Food Programme.

REFERENCES

1. Pelletier DL, Frongillo EA, Jr., Schroeder DG, Habicht JP. A methodology for estimating the contribution of malnutrition to child mortality in developing countries. *J Nutr* 1994;124(Suppl 10):2106S-22S.

2. Gillespie S. Supplementary feeding for women and young children. Washington, DC: World Bank, 1999. 105 p. (Nutrition toolkit module no. 5).

3. Beaton GH, Ghassemi H. Supplementary feeding programs for young children in developing countries. *Am J Clin Nutr* 1982;35(Suppl 4):863-916.

4. Tjon a Ten WE, Kusin JA, de With C. The effects on weight and attendance of a supplementary feeding programme operating in two under-5 clinics in Lesotho. *Ann Trop Paediatr* 1990;10:411-9.

5. Caulfield LE, Huffman SL, Piwoz EG. Interventions to improve intake of complementary foods by infants 6 to 12 months of age in developing countries:

impact on growth and on the prevalence of malnutrition and potential contribution to child survival. *Food Nutr Bull* 1999;21:183-200.

6. Manary MJ, Ndkeha MJ, Ashorn P, Maleta K, Briend A. Home based therapy for severe malnutrition with ready-to-use food. *Arch Dis Child* 2004;89: 557-61.

7. Sandige H, Ndekha MJ, Briend A, Ashorn P, Manary MJ. Locally produced or imported ready-to-use-food. *J Pediatr Gastroenterol Nutr* 2004;39:141-6.

8. Ndekha MJ, Manary MJ, Ashorn P, Briend A. Home-based therapy with ready-to-use therapeutic food is of benefit to malnourished, HIV-infected Malawian children. *Acta Paediatr* 2005;94:222-5.

9. Briend A. Highly nutrient-dense spreads: a new approach to delivering multiple micronutrients to high-risk groups. *Br J Nutr* 2001;85(Suppl 2):S175-9.

10. Ciliberto MA, Sandige H, Ndekha MJ, Ashorn P, Briend A, Ciliberto HM, Manary MJ. Comparison of home-based therapy with ready-to-use therapeutic food with standard therapy in the treatment of malnourished Malawian children: a controlled, clinical effectiveness trial. *Am J Clin Nutr* 2005;81:864-70.

11. World Health Organization. Physical status: the use and interpretation of anthropometry; report of a WHO Expert Committee. Geneva: World Health Organization, 1995. 452 p. (WHO technical report series no. 854).

12. The Gambia Hepatitis Study Group. The Gambia hepatitis intervention study. *Cancer Res* 1987;47: 5782-7.

13. World Health Organization. Management of severe malnutrition: a manual for physicians and other senior health workers. Geneva: World Health Organization, 1999. 60 p.

14. Food and Nutrition Technical Agency. Enhancing the nutritional quality of relief diets: workshop proceedings, April 28-30, 1999:35. (http://www.fantaproject.org/downloads/pdfs/reldiets.pdf, accessed on 30 September 2004).

15. Stefanak MA, Jarjoura D. Weight gain in supervised and take-home feeding programmes in Chad. *J Trop Pediatr* 1989;35:214-7.

16. Nielsen J, Valentiner-Branth P, Martins C, Cabral F, Aaby P. Malnourished children and supplementary feeding during the war emergency in Guinea-Bissau in 1998-1999. *Am J Clin Nutr* 2004;80: 1036-42.

17. Jacob F, Gordon G. An evaluation study of a preschool health program in Ghana. Nairobi: Catholic Relief Services, 1975. (Field bulletin no. 24).

18. Kennedy ET, Alderman HH. Comparative analyses of nutritional effectiveness of food subsidies and other food-related interventions. Washington, DC: International Food Policy Research Institute, 1987:54-56. (Occasional paper no. 7).