

Comparison of the efficacy of a solid ready-to-use food and a liquid, milk-based diet for the rehabilitation of severely malnourished children: a randomized trial¹⁻³

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ABSTRACT

Background: The World Health Organization recommends a liquid, milk-based diet (F100) during the rehabilitation phase of the treatment of severe malnutrition. A dry, solid, ready-to-use food (RTUF) that can be eaten without adding water has been proposed to eliminate the risk of bacterial contamination from added water. The efficacies of RTUF and F100 have not been compared.

Objective: The objective was to compare the efficacy of RTUF and F100 in promoting weight gain in malnourished children.

Design: In an open-labeled, randomized trial, 70 severely malnourished Senegalese children aged 6–36 mo were randomly allocated to receive 3 meals containing either F100 ($n = 35$) or RTUF ($n = 35$) in addition to the local diet. The data from 30 children in each group were analyzed.

Results: The mean (\pm SD) daily energy intake in the RTUF group was 808 ± 280 (95% CI: 703.8, 912.9) kJ \cdot kg body $\text{wt}^{-1} \cdot \text{d}^{-1}$, and that in the F100 group was 573 ± 201 (95% CI: 497.9, 648.7) kJ \cdot kg body $\text{wt}^{-1} \cdot \text{d}^{-1}$ ($P < 0.001$). The average weight gains in the RTUF and F100 groups were 15.6 (95% CI: 13.4, 17.8) and 10.1 (95% CI: 8.7, 11.4) g \cdot kg body $\text{wt}^{-1} \cdot \text{d}^{-1}$, respectively ($P < 0.001$). The difference in weight gain was greater in the most wasted children ($P < 0.05$). The average duration of rehabilitation was 17.3 (95% CI: 15.6, 19.0) d in the F100 group and was 13.4 (95% CI: 12.1, 14.7) d in the RTUF group ($P < 0.001$).

Conclusions: This study indicated that RTUF can be used efficiently for the rehabilitation of severely malnourished children. *Am J Clin Nutr* 2003;78:302–7.

KEY WORDS Child malnutrition, ready-to-use food, nutritional rehabilitation, energy density, catch-up growth, Sénégal

INTRODUCTION

The management of severe malnutrition is described in detail by the World Health Organization (WHO) (1). The WHO recommends that malnourished children be fed for a few days a low-protein diet (F75) containing 313 kJ and 0.9 g protein/100 mL and fortified with vitamins and minerals until life-threatening complications are under control. When children begin the nutritional rehabilitation phase, they should receive an energy- and protein-dense, milk-based diet fortified with the same vitamin and mineral mix (F100) to promote rapid weight gain. This rehabilitation

usually takes 3–4 wk and is carried out in the hospital or in a residential therapeutic feeding center. During this phase, the mother is usually required to stay with her child, which is often difficult to achieve and is potentially disadvantageous for other members of the family (2). Also, residential care predisposes to cross infections (2). To avoid these problems, community-based rehabilitation has been proposed that also has the advantage of decreasing the cost of treatment (3, 4). This has been impossible to implement with the use of F100 and was not recommended by the WHO for the following reasons: 1) F100 is an excellent growth medium for pathogenic bacteria, and home use under unhygienic conditions cannot be recommended; and 2) F100 resembles infant formula and its distribution by nutrition health workers might undermine efforts to discourage formula feeding and promote breastfeeding. Nonmilk-based diets could be used to avoid these problems, but these diets are less effective in the rehabilitation of severely malnourished children (5) and can also become contaminated when used at home.

A solid ready-to-use food (RTUF) designed to be a possible substitute for F100 has been developed. This food has an energy density that is > 5 times that of F100, but it has a similar ratio of nutrients to energy. This food is obtained by replacing part of the dried skim milk used in the F100 formula with peanut butter. RTUF is at least as well accepted by children as is F100 (6) and can be eaten directly by the child without the addition of water, which eliminates the risk of bacterial contamination from the added water. Yet, the efficacy of RTUF has never been tested in a controlled trial; therefore, its recommendation for extensive use in the community might be premature. We therefore carried out a randomized trial to compare the efficacy of RTUF with that of F100, which is considered to be the reference diet during the rehabilitation phase.

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SUBJECTS AND METHODS

Subjects

This study took place in a therapeutic feeding center attached to a clinic (Dispensaire Saint Martin, Rebeuss, Dakar, Sénégal) that is attended by poor families. Recruitment and follow-up were conducted between March and September 2001, the peak season for malnutrition. During the study period, eligible children were identified by the study physician on the basis of anthropometric status. Seventy severely malnourished children defined on admission, or after edema resolved, by a weight-for-height (WFH) z score < -2 in relation to the National Center for Health Statistics reference (7) were eligible for inclusion in the study. Randomization took place just after admission to the feeding center, before the rehabilitation phase began. Before randomization, the purpose of the study was explained in the local language to the mothers of all eligible children, and the mothers' consent was obtained after clarifying that their refusal would have no bearing on their children's care. The protocol was approved by the Ethical Committee of the University Cheikh Anta Diop (Faculté des Sciences et Techniques, Dakar, Sénégal).

Methods

Group allocation was made from a computer-generated random number list (EPI INFO 6.0; Centers for Disease Control and Prevention, Atlanta) at the Nutrition Department of the University Cheikh Anta Diop. Several random lists were produced until a list with an equal number of odds and even numbers (35 for each) was obtained. Children aged ≥ 6 mo with an inclusion number corresponding to an odd number on the final random number list were allocated to the F100 group ($n = 35$) and those with an even number were allocated to the RTUF group ($n = 35$).

On admission, all patients received vitamin A orally (100 000 IU for children aged 6–12 mo and 200 000 IU for children aged > 12 mo), 5 mg folic acid, antibiotics, and measles vaccine according to WHO guidelines (1). The children were examined daily by a physician. During the initial phase of the treatment, and after rehydration with ReSoMal (WHO Rehydration Solution for Malnutrition; Nutriset, Malaunay, France), all children received the same F75 formula 6 times/d according to WHO recommendations (1) for an average of 1.6 d (range: 1–4 d). During the recovery phase, the children received either 3 meals of F100 or 3 meals of RTUF daily ad libitum according to the group allocation. At this stage, the children received an iron supplement: 60 mg Fe as iron sulfate in the F100 group and 2 mg Fe as iron sulfate/418 kJ in the RTUF group. There was no transition between the 2 phases. In addition, during the rehabilitation phase, children in both groups received 3 meals/d that were prepared with locally available foods; these meals were the same in both groups.

F100 and RTUF looked different; therefore, the trial was not blind. F100 looked and tasted like any infant formula, and RTUF looked and tasted like peanut butter.

RTUF, F75, and F100 were industrially prepared (Nutriset). Although the energy, macronutrient, and micronutrient contents of F100 and RTUF (per 100 g) were different, their nutritional composition per MJ was similar (Table 1). The main difference between these 2 foods is that part of the dried skim milk in the F100 formulation was replaced with peanut butter (25% total weight) in the RTUF. Both foods complied with specifications of the United Nations Development Programme for the preparation of F100 (8).

The meals given to children in addition to F100 and RTUF during the rehabilitation phase were prepared according to 6 different

TABLE 1

Comparison of the nutritional composition of the 2 diets¹

	Per 100 g		Per MJ	
	F100	RTUF	F100	RTUF
Macronutrients				
Energy (kJ)	414	2281	—	—
Protein (g)	2.5	13.6	6.0	6.0
Lipid (g)	5	35.7	12.2	15.8
Minerals				
Potassium (mg)	212	1111	513.6	487.3
Calcium (mg)	58	320	140.9	140.9
Phosphorus (mg)	58	349	140.9	152.9
Magnesium (mg)	15	92	38.2	40.6
Zinc (mg)	2.1	14	5.0	6.2
Copper (mg)	0.3	1.8	0.7	0.7
Iodine (μ g)	14	110	33.4	47.8
Selenium (μ g)	4	30	9.6	14.3
Iron (mg)	0.4	11.5	1.0	5.0
Vitamins				
Thiamine (mg)	0.1	0.6	0.2	0.2
Riboflavin (mg)	0.3	1.8	0.7	0.7
Vitamin B-6 (mg)	0.1	0.6	0.2	0.2
Vitamin B-12 (μ g)	0.3	1.8	0.7	0.7
Vitamin C (mg)	9.7	53	23.4	23.2
Folic acid (μ g)	39	210	93.2	93.2
Niacin (mg)	1	5.3	2.4	2.4
Biotin (μ g)	12	65	28.7	28.7
Pantothenic acid (mg)	0.6	3.1	1.4	1.4
Retinol (μ g)	154	910	372.7	398.9
Vitamin D (μ g)	2.9	16	6.9	6.9
Vitamin K (μ g)	2.9	21	6.9	9.3
Vitamin E (mg)	3.9	20	9.3	8.8

¹F100, liquid, milk-based diet; RTUF, solid ready-to-use food.

local recipes prepared in a standardized way by the mothers at the center.

The macronutrient contents of these 6 standard recipes were determined by using *Official Methods of Analysis of AOAC International* (9). Humidity was determined by weighing the meals before and after drying at 105 °C for 4 h. Total protein was determined by the Kjeldahl method, and total ash was measured after incineration of samples for 4 h at 600 °C. Total lipids were analyzed by *n*-hexane extraction, and the Weende method was used to measure total fiber. The carbohydrates content was estimated as the difference between 100 and the sum of percentages of humidity, total ash, total lipids, total protein, and total fiber. The energy content was estimated assuming that 1 g protein and 1 g carbohydrate had an energy content of 16.7 kJ and that 1 g lipid had an energy content of 37.6 kJ. The nutritional composition of each of these samples was determined in triplicate, ie, a total of 9 measures for each recipe. Three samples of each of the 6 recipes were taken during 3 different weeks for analysis. The average value of these measures (Table 2) was used to calculate the energy and macronutrient intakes of children from these recipes during the study. The energy and nutrient contents of F100 and RTUF were not determined; the manufacturer's values were used for the analysis.

Most of the children were fed by their mothers: 27 in the F100 group and 29 in the RTUF group (NS); the other children were fed by another member of the family. All efforts were made to have children fed ad libitum. Breastfed children were offered their meals

TABLE 2

Energy and macronutrient contents of the local meals prepared with locally available foods and given in addition to the liquid, milk-based (F100) and solid ready-to-use food (RTUF) diets during the rehabilitation phase

	Protein	Lipid	Carbohydrate	Energy
	<i>g/100 g</i>	<i>g/100 g</i>	<i>g/100 g</i>	<i>kJ/100 g</i>
Millet porridge with powdered milk, sugar, and oil	4.11	2.63	16.6	444
Rice and fish	4.33	1.10	8.7	259
Rice and meat	5.71	0.22	8.2	238
Rice and smoked fish prepared with peanut butter	5.12	2.45	8.6	327
Rice and smoked fish	5.33	1.31	7.2	253
Millet flour, peanut flour, and smoked fish	4.54	2.44	10.5	342

after being breastfed. Each child was offered a large amount of the assigned food and, if the quantity provided was finished, a new cup or packet was given and its weight recorded. Children in the F100 group were fed directly from the cup or with a spoon if it was more convenient for the mother. Children in the RTUF group were usually fed directly from the packet and more rarely with a spoon. In both groups, local meals were served from a cup with a spoon.

The total amount of food consumed with each meal (F100, RTUF according to group allocation, and local recipes) was determined by subtracting the weight of the cup or packet (92 g) and any leftovers from the meal from the initial weight of the cup or packet. Breast-milk intake was not measured.

The children's body weight was measured daily to the nearest 10 g with an automatic scale (Téraillon, Paris), and weight gain—the main outcome measure—was compared between the groups during the rehabilitation phase. The precision of the scale was checked regularly with standard weights. Children were discharged from the unit once their WFH *z* score was ≥ -1.5 . Children who left the unit before reaching this target weight were excluded from the analysis.

Weight gain was measured by calculating the weight gain expressed in $\text{g} \cdot \text{kg body wt}^{-1} \cdot \text{d}^{-1}$ as follows:

$$(W_2 - W_1) \times 1000 / (W_1 \times \text{Nb days}) \quad (I)$$

where W_2 is the weight measured when the WFH *z* score reached -1.5 , W_1 is the weight at the beginning of the rehabilitation phase, and Nb days is the number of days between the measurement of W_2 and W_1 .

Statistical analysis

Statistical analysis was carried out with standard statistical software (SYSTAT 8.0; SPSS Inc, Chicago). Means were compared with the Mann-Whitney *U* nonparametric test. Chi-square tests were performed to compare categorical variables. Statistical significance was set at $P < 0.05$.

RESULTS

All of the 70 eligible children were enrolled in the study. Of the 35 children allocated to the F100 group, 2 children died from HIV-associated infection at the hospital where they were referred. In the RTUF group, 1 child was referred to another hospital because of severe dehydration and 2 because of tuberculosis and 1 child was above the target weight after their edema resolved. Of the children who did not meet the discharge criterion before their mother decided to leave the center and who were excluded from the analysis, 3 were in the F100 group and 1 was in the RTUF group (Figure 1). The data from 30 children in each of the F100 and the RTUF groups were available for the analysis.

The mean age of the children (range: 6–36 mo) was not significantly different between the 2 groups: 17.8 (95% CI: 15.0, 19.9)

and 15.8 (95% CI: 13.7, 18.0) mo for the F100 and RTUF groups, respectively. At the beginning of the rehabilitation phase, the mean WFH *z* scores were -2.77 (95% CI: -2.61 , -2.93) and -2.96 (95% CI: -2.74 , -3.19) in the F100 and RTUF groups, respectively (NS). Sixteen children in the F100 group and 14 in the RTUF group were breastfed (NS). Four of 30 children in the F100 group and 5 of 30 children in the RTUF group had edema (kwashiorkor and marasmic kwashiorkor). The average duration of phase 1 was not significantly different between the 2 groups: 1.5 (95% CI: 1.2, 1.7) d and 1.6 (95% CI: 1.2, 1.9) d in the F100 and RTUF groups, respectively.

Total energy intakes during the rehabilitation phase were significantly different between the 2 groups (Table 3). In addition, total energy intakes were significantly different between the breastfed and non-breastfed children: 785.7 (95% CI: 694.5, 876.8) and 598.2 (95% CI: 511.9, 684.3) $\text{kJ} \cdot \text{kg}^{-1} \cdot \text{d}^{-1}$ for the non-breastfed and breastfed children, respectively ($P < 0.01$). Energy intakes in the RTUF group were significantly greater than in the F100 group, whereas energy intakes from local recipes were not significantly different.

Weight gain in the children who initially had edema was not significantly different from that in the children who did not have edema: 12.5 (95% CI: 8.6, 16.3) compared with 12.9 (95% CI: 11.2, 14.6) $\text{g} \cdot \text{kg body wt}^{-1} \cdot \text{d}^{-1}$, respectively. Therefore, the weight gains of children with and without edema on admission were pooled for the rest of the analysis. On average, weight gain during the rehabilitation phase was 10.1 (95% CI: 8.7, 11.4) $\text{g} \cdot \text{kg body wt}^{-1} \cdot \text{d}^{-1}$ in the F100 group and 15.6 (95% CI: 13.4, 17.8) $\text{g} \cdot \text{kg body wt}^{-1} \cdot \text{d}^{-1}$ in the RTUF group ($P < 0.001$) (Figure 2).

There was no significant correlation between the age of the children and their weight gain. In the RTUF group, there was an inverse significant correlation between WFH *z* score at the start of rehabilitation and observed weight gain ($r = -0.425$, $P < 0.05$). This relation between WFH *z* score at the start of rehabilitation and weight gain was not significant in the F100 group (Figure 3). In a linear regression analysis with weight gain as the dependent variable and WFH *z* score at the start of rehabilitation and food type as the independent variables, only the interaction term was significant ($P < 0.05$). This finding indicated that RTUF was significantly more effective than was F100 in the most wasted children. The average duration of rehabilitation was 17.3 (95% CI: 15.6, 19.0) d in the F100 group and 13.4 (95% CI: 12.1, 14.7) d in the RTUF group ($P < 0.001$).

DISCUSSION

These results suggest that RTUF given in a supervised setting is superior to F100 in promoting weight gain during the rehabilitation phase of the management of severe malnutrition. This study

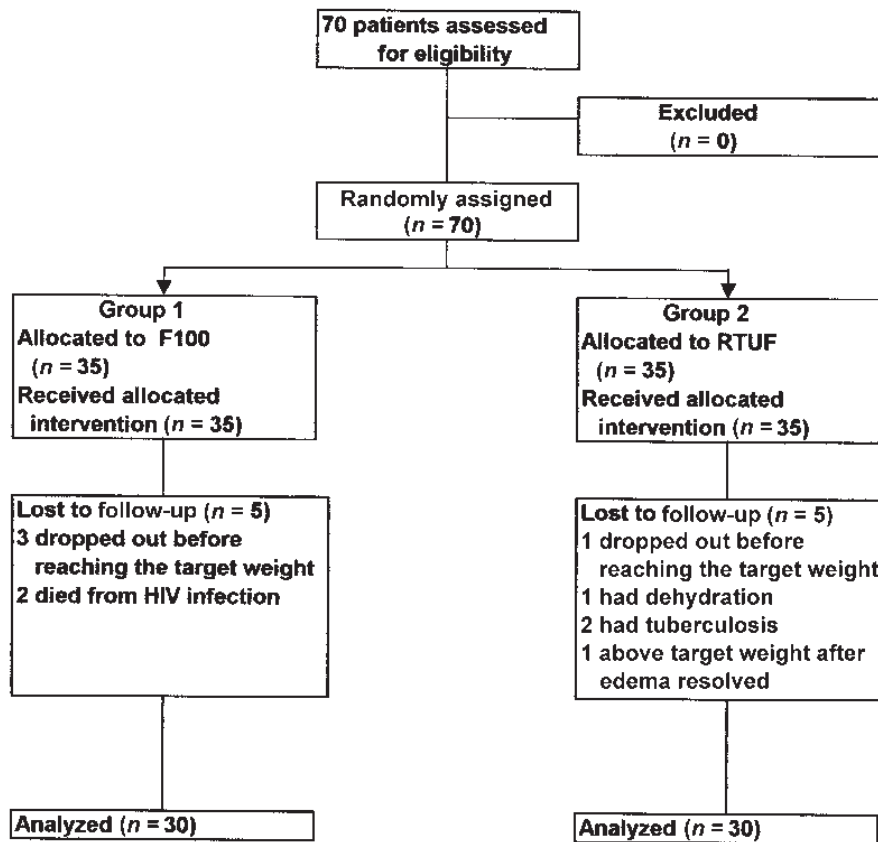


FIGURE 1. Study design.

was not blind, and these results may have been influenced by factors other than the biological efficacy of each food. On the other hand, the greater number of children who left the center before reaching the target weight in the F100 group than in the RTUF group may have led to an underestimation of the difference in efficacy between the 2 foods.

Our results also suggest that energy intake was greater from RTUF than from F100, with no significant reduction in the energy from local food in the RTUF group. This finding, however, does not take into account possible differences in breast-milk intake between the 2 groups. Also, estimates of energy and nutrient intakes were obtained from a small sample of meals, which may have limited the validity of our results; energy intakes, however, were measured in the same way in both experimental groups.

The higher energy intake observed in the RTUF group is consistent with the finding of a first acceptability trial in which children consumed alternative RTUF or F100 foods (6).

This high energy intake in the RTUF group is likely related to the high energy density of RTUF, which is a major determinant of energy intake (10, 11). This relation between energy density and energy intake seems more important when small numbers of meals are consumed (11), which may have influenced our results because only 3 meals of F100 or RTUF were given daily in our study. The consumption of meals with a high energy density by malnourished children is known to result in higher weight gains than is the consumption of meals with a low energy density (11, 12).

The energy density of RTUF is considerably higher than that of F100 and of any other food used thus far for the treatment of

TABLE 3

Comparison of daily energy and macronutrient intakes from the liquid, milk-based (F100) and solid ready-to-use food (RTUF) diets and from local recipes in the 2 experimental groups¹

	F100 group			RTUF group		
	F100	Local recipes	Total	RTUF	Local recipes	Total
Energy (kJ/kg body wt)	275 ± 111	298 ± 128	573 ± 201	557 ± 219 ²	251 ± 106	808 ± 280 ²
Protein (g/kg body wt)	2.0 ± 0.6	3.9 ± 2.0	5.9 ± 3.2	3.3 ± 1.3	3.1 ± 1.4	6.5 ± 2.3
Carbohydrate (g/kg body wt)	7.2 ± 2.9	10.0 ± 4.2	17.2 ± 6.0	10.3 ± 4.0	8.8 ± 3.7	19.1 ± 6.5
Lipid (g/kg body wt)	3.3 ± 1.3	1.6 ± 0.6	4.9 ± 1.7	8.8 ± 3.5	1.4 ± 0.6	10.2 ± 3.7 ²

¹ $\bar{x} \pm SD$.

²Significantly different from respective mean in the F100 group, $P < 0.001$ (Mann-Whitney U test).

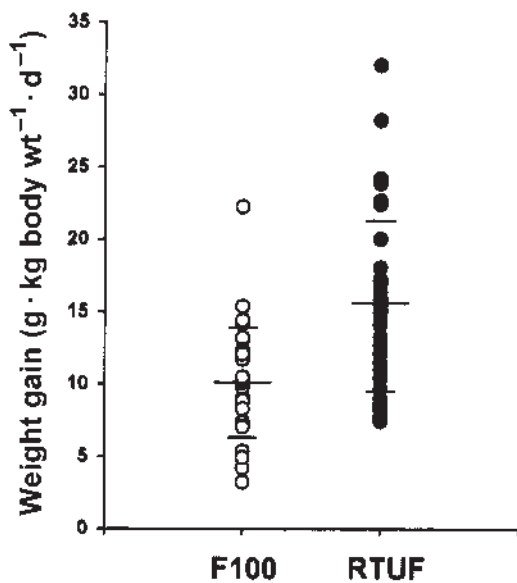


FIGURE 2. Weight gains in the liquid, milk-based diet (F100) and solid ready-to-use food (RTUF) groups during the rehabilitation phase. Weight gain was significantly greater in the RTUF group, $P < 0.001$. The central horizontal line for each group represents the mean, and the upper and lower horizontal lines represent the 95% CI. $n = 30$ per group.

severe malnutrition. The energy density of liquid feeds, such as F100, is limited by their osmolarity. F100 is designed to be diluted with water before consumption and, therefore, must be water soluble. As a result, all of the water-soluble components of F100 are in solution and osmotically active, and its energy density cannot be increased beyond its present value without turning it into a hyperosmolar food. In practice, liquid feeds cannot have an energy density > 420 kJ/100 mL without being hyperosmolar (13). RTUF, on the other hand, does not need to be, and is not, water soluble: its water-soluble components are surrounded by fat, preventing them from being osmotically active. This phase inversion allows an energy density of RTUF that is 5.4 times that of F100, a similar

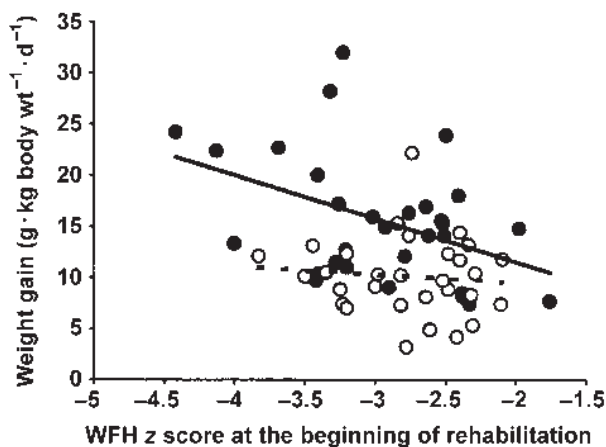


FIGURE 3. Weight gain in the liquid, milk-based diet (F100; ○) and solid ready-to-use food (RTUF; ●) groups relative to weight-for-height (WFH) z scores at the beginning of the rehabilitation phase. The slopes of the regression lines were significantly different between the F100 (-0.8) and RTUF (-4.2) groups, $P < 0.01$. $n = 30$ per group.


proportion of macronutrients in the 2 foods, and no difference in osmolarity between the 2 foods.

Initially, RTUF was not designed to achieve very high weight gains but to be safely used at home and to reduce the duration and cost of hospital treatment. Consuming liquid feeds in an unhygienic environment exposes one to the risk of diarrhea because of the proliferation of pathogenic bacteria (14, 15). This risk is avoided if the RTUF contains no water and can be consumed without added water because experimentally introduced bacteria do not grow in it (16).

Further studies are needed to measure the effectiveness (in terms of weight gain) of RTUFs consumed at home. Weight gain at home is likely to be lower than that in a controlled setting because the RTUF might be shared with siblings and because of being consumed with less supervision. Yet, achieving a rapid weight gain is not as important at home as it is in a residential treatment unit for economic, social, and familial reasons. Also, the lower risk of cross infection from other children in a family setting makes a rapid recovery less important. The weight gain observed in the current study was > 10 times the weight gain of well-nourished children of the same age, and a lower weight gain seems acceptable during home-based treatment.

Peanut butter used in RTUF preparations contains potent allergens, which may be enhanced further during cooking (17). Clinical allergy is rare in developing countries, especially in severely malnourished children with suppressed immune reaction (18). The potential risk of allergic reaction should be put in perspective with the potential advantages of home treatment of severe malnutrition, especially in areas where peanuts are part of the traditional diet. In other areas, the development and field testing of a peanut-free spread might be warranted.

The technology for producing RTUF is not sophisticated and, presumably, can be reproduced at a small scale level in any developing country. Actually, the preparation of RTUF is not more difficult than that of F100, which involves mixing dried skim milk, oil, sugar, minerals, and vitamins and then adding water as now recommended in the WHO guidelines. The main difference between RTUF and F100 recipes is that part of the dried skim milk in F100 is replaced by peanut butter in the RTUF recipe. The resultant RTUF spread is likely to be more stable than is the F100 powder because of its lower surface contact area with oxygen (16). Hence, RTUF can be prepared in larger quantities in a more central setting, which facilitates supervision and quality control.

In conclusion, our results suggest that the solid RTUF obtained after peanut butter was added to the WHO recipe is convenient and safe and has nutritional properties that promote weight gain. Further research to evaluate the effectiveness of this food and that of its locally produced equivalents in a community setting is warranted. If these evaluations yield positive results, we suggest that the widespread use of these foods could change the way we treat severe malnutrition (2). 

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EID participated in the fieldwork, data collection and analysis, study design, and writing of the manuscript. NID participated in the fieldwork. MMN was responsible for the treatment and medical follow-up of the children. AB helped with the study design, analysis of the results, and writing of the manuscript. SW supervised the entire study, participated in the study design, submitted the protocol to the Ethical Committee of the University Cheikh Anta Diop de Dakar

for review, checked the quality of the data collection, and reviewed the manuscript. AB received a consultancy from Nutriset during the study. All authors declared that they participated in the study as mentioned above and that they reviewed and approved the manuscript in its final version. The authors also declare that they had no conflict of interest in connection with this paper, other than any noted above.

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