A Randomized Controlled Trial on the Efficacy and Safety of a Modified Ready to Use Therapeutic Food among Malnourished Children

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ABSTRACT

Rationale. In the Philippines, 25% of children <10 years old are underweight. The use of energy-dense ready-to-use therapeutic food (RUTF) augments caloric intake. No local studies have evaluated RUTF.

Objective. To determine the efficacy, safety and acceptability of a modified RUTF (mRUTF) to supplement caloric intake

Method. One hundred (100) children 18 months to 10 years old with mild to moderate malnutrition were randomized to either mRUTF or control group. The treatment arm received mRUTF during weekdays for 5 weeks while controls had no supplementation. Anthropometric measurements were taken at baseline, weekly for 5 weeks and 2 weeks post-supplementation

Results. The two groups were comparable at baseline. At five weekly intervals, there was no significant difference in weight, height and mid upper arm circumference between groups, although the mean percentage weight gain of the mRUTF group was higher compared with controls (8% vs 2.6%, p=0.15). Cessation of supplementation resulted in weight loss in the mRUTF group. [mRUTF: -0.40 (0.33) vs -0.03 (0.35), p=0.00]. The taste of mRUTF was acceptable.

Conclusion. Ready-to-use-therapeutic food is an effective, safe and acceptable alternative supplement for children, 18 months to 10 years old, with mild to moderate malnutrition.

Key Words: energy-dense food, food supplementation, weight gain

Introduction

It is estimated that nearly 20 million children under 5 years of age suffer from severe acute malnutrition most of them in South Asia and Sub-Saharan Africa.[1] The latest statistics for the global prevalence of underweight shows that of the 556 million children under 5 years in low income countries, 20% (112 M) were underweight, 32% (178 M) were stunted, while 10% (55 M) were wasted, including the 3.5% (19 M) severely wasted.[2] About 36 million children are suffering from moderate wasting. Being underweight, stunting and wasting are significant contributors to child mortality and disease. Current estimates suggest that, globally, about 1 million children die of malnutrition each year.[1]

The World Health Organization,[3] previously recommended that severely malnourished patients be admitted to hospitals for a month or until the primary problems have resolved. While very effective, this resulted in disruption of the family cycle, especially if other children in the family needed attention and care or the parents needed to perform manual labor for the survival of the entire family.

In 2007, the community-based management of severe uncomplicated malnutrition was recommended by the UNICEF and WHO.[1] The effectiveness of community-based therapeutic centers in the rehabilitation of uncomplicated severe malnutrition has consistently been shown in places like Ethiopia, Malawi, Sudan and Niger[4] since 2001. This shift in treatment approach from hospital to community-based management was brought about largely by the development of high energy food.

Community-based therapeutic centers make use of high energy-dense foods called ready-to-use therapeutic food (RUTF). RUTF is an energy-dense paste consisting of different types of foods made into a spread or compressed products. It has a similar nutritional value as the F-100.[1] RUTF is made up of 5 ingredients : peanut butter, vegetable oil, powdered sugar, dry skim milk, and a mineral and vitamin mixture. RUTF does not need any cooking and resists bacterial contamination because of its low water content.[5] It is commercially available as Plumpynut® (Nutriset, Malaunay, France) but can also be prepared locally by communities.[5]

In the Philippines where 40% of families live below the poverty line, malnutrition continues to be a problem. The 2008 National Nutrition Survey[6] showed an increase in proportion of underweight children 0-10 years old with 26 in every 100 children being underweight. Currently, there are

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no local studies that have evaluated the use of RUTF in children with mild to moderate malnutrition.

This study aimed to determine the efficacy of the addition of a modified RUTF (mRUTF) to the regular diet in promoting weight gain among mild to moderately malnourished children aged 18 months to 10 years old. The acceptability and safety of the mRUTF was also determined.

Methods

Subjects

One hundred (100) children aged 18 months to 10 years old with mild to moderate malnutrition based on z scores were recruited from a feeding center in a poor urban community in Metro Manila. Children with neurologic problems, severe infections, history of lactose intolerance, cow's milk allergy and peanut allergy were excluded from the study. The children were also examined for signs of edema. An informed consent was obtained from the parents or caretakers. This study was approved by the Ethics Review Board of the Philippine General Hospital-University of the Philippines.

Experimental Design

This was a randomized controlled trial that assigned subjects into two groups, an mRUTF and a control group, using a computer-generated random sampling table. The treatment group received the mRUTF while the controls had no supplementation.

Preparation of the RUTF

The modified RUTF (mRUTF) was made from commercially available ingredients. It was composed of 22% milk, 8% sugar, 14% coconut oil and 56% peanut butter. The proportions were computed based on weight. Vitamin-mineral mix was not available for inclusion in the mRUTF. Moisture content was not determined but published data shows that the maximum moisture content of a preparation of RUTF is 2.5%.[1] The final product had a spread-like consistency.

The mRUTF was prepared by the Dietary Department of the Philippine General Hospital following accepted standards for food preparation. Containers and mixing bowls were air-dried to ensure that no water was present that might promote bacterial contamination. Batches of 50 mRUTF were produced with each preparation. Fresh batches of mRUTF were prepared weekly. We were able to keep the mRUTF at room temperature without spoilage or development of rancidity for up to 2 weeks. Commercial preparations of RUTF have a shelf life of 2 years[7] while locally developed RUTFs have a shelf life of 3-4 months in tropical conditions.[5]

A standard preparation of mRUTF containing 107 g, equivalent to 600 calories was placed in plastic containers with cover lids. The nutritional content of each container or serving is shown in Table 1.

Table 1. Nutritional Content of the Locally Prepared mRUTF

Nutritional Components	mRUTF
Serving size	107 g
Calories	600 cal (5.6 cal/g)
Protein	22.3 g
Carbohydrate	41.4 g
Fats	38.2 g

Conduct of the study

Baseline anthropometric measurements were performed at day 0 and repeated every week for five consecutive weeks (intervention period) and two weeks after the end of the intervention (follow-up period). Trained personnel blinded to the group allocation performed the measurements. Three consecutive measurements were taken and the average was recorded. Weight was measured using a standard weighing scale calibrated to the nearest 0.1 kg. Height was measured for children more than two years old and length for those below two years old using a measuring tape. Mid-upper arm circumference (MUAC) was measured with the non-dominant arm hanging naturally at the side at the midpoint between the acromial process and the olecranon. Only those children with mild or moderate malnutrition based on their z scores[8] were included. Repeat anthropometric measurements were performed 2 weeks after the cessation of the feeding.

At the feeding center, all the children were provided the same kind and amount of afternoon meal 5 days a week. In addition, the treatment group was given the mRUTF The mRUTF was weighed before distribution. To avoid sharing, the children were given one mRUTF container each in the morning and asked to eat ad libitum. The remaining mRUTF for each child was offered to them again upon their return in the afternoon. Any unconsumed mRUTF was weighed to compute the daily consumed calories.

During the intervention period, the caloric intake was monitored three times per week. The caretakers were instructed to complete a food diary three times a week that included two weekdays (Tuesday and Thursday) and one weekend (Saturday). The diaries were collected the next day for computation of the caloric intake. In order to have a better approximation of the food intake, a dietitian went around the community to observe commonly eaten foods being sold in the different eateries and checked the usual measuring devices used by the families.

The acceptability and safety of the mRUTF and the presence of co-morbidities were monitored on a weekly basis. The acceptability of the mRUTF was evaluated using the 5-point facial Hedonic Scale.[9,10] For children below two years of age, their behavior following intake was interpreted by their caretaker and the caretaker was the one who filled

the Hedonic scale. Those who did not give an answer despite encouragement were tallied under the no answer category. Any concomitant illness that occurred during the study were actively sought, monitored and recorded.

Statistical Analysis

This study made use of summary measures such as means, percentages, and standard deviation on the attributes of the subjects. Repeated measure ANOVA was used to test for between-group comparisons between weight and other variables over time. The T-test for independent samples was used to analyze continuous variables. Intention to treat analysis was used to compare the groups in weeks 5 and 7 to determine if there was a difference in the weight of the two groups after the cessation of the intervention. The last observation carried forward was utilized to cover for missing data. The 95% confidence interval was applied to all the statistical analyses. A p-value less than 0.05 was considered significant.

Sample size

Sample size computation was based on the study by Ciliberto M, et al.[11] A sample size of 50 subjects per group was calculated to detect a difference between the two groups of at least 3 g/kg/day, with a power of 80%, and a level of significance at 5%.

Results

A total of 100 children were screened and included in the study with an equal number of mild to moderately malnourished children assigned to the treatment and control groups. The control group had more males and included older subjects but these differences were not statistically significant. (Table 2)

Table 2. Comparison of the Demographic Data of the mRUTF Group vs. the Control Group

	mRUTF group (N=50)	Control (N= 50)	P value
Sex: Male; n (%)	20 (41)	29 (59)	0.07
Age (years); mean (SD)	4.81 (1.86)	5.48 (2.11)	0.09
Range	(1.75-8)	(1.5-9)	
Weight (kg)			
Mean (SD)	13.65 (3.09)	14.11 (3.2)	0.47
Range	(9-20)	(7.5-21)	
Height (cm)			
Mean (SD)	101.69 (11.66)	103.11 (12.67)	0.56
Range	(82-122)	(74-127)	
Mid upper arm circumference			
Mean (SD)	14.71 (1.02)	14.67 (1.14)	0.85
Range	(13-17)	(11.5-17)	
Nutritional Status			
Mild wasting; n (%)	30 (52)	28 (48)	0.69
Moderate wasting;n (%)	20 (48)	22 (52)	

The baseline caloric intake of the mRUTF group (46.26 cal/kg) was lower compared with the controls (51.10 cal/kg). The mRUTF accounted for 42% of the total caloric intake of the treatment group providing a significant amount of fats (62%), protein (45%) and carbohydrates (23%) in their diet. This resulted in a higher caloric intake of the mRUTF group during the intervention period than the controls. (Table 3)

Effect on Growth

At weekly intervals during the intervention period, there was no significant difference in the weight, height and mid upper arm circumference between the two groups. However, the mean percentage weight gain of the mRUTF group was higher as compared with the control group (8% vs 2.6%, p=0.15).

Forty eight children in the mRUTF group could be evaluated two weeks post supplementation as two were lost to follow-up. Weight loss was exhibited by children in both groups with a more significant decrease in the weight of the children who received mRUTF as compared with the children in control group. [RUTF: -0.40 (0.33) vs -0.03 (0.35), p=0.00]

Acceptability and safety of mRUTF

Using the Hedonic scale for acceptability, all patients during the start of the treatment period either liked a little (12%) or liked very much (80%) the mRUTF. By the end of the study period, 98% of subjects liked the product very much. Only one child developed diarrhea during the first week of the intervention period which resolved spontaneously after 2 days and did not require discontinuation of the mRUTF. Eighty percent (80%) of children in the mRUTF group developed soft stools during the first week of intervention but returned to normal by the second week. Co-morbidities that developed during the study period include cough and colds, impetigo, otitis media intestinal parasitism and chicken pox with no difference in the frequency between the two groups.

Discussion

According to the WHO and UNICEF, "preparing low cost fortified supplementary food from available ingredients, using suitable small to medium scale production technologies in community settings, can help meet the nutritional needs of young children."[12]

Our study is the first Philippine study to evaluate the use of RUTF in mild to moderately malnourished children in a community setting. Our population's diet was low in calories and the mRUTF provided significant augmentation of caloric intake, particularly fat and protein calories in their diet. The increased caloric intake while still below the recommended values was able to promote weight increases. The weight gain seen in our study was higher than that observed in the study by Nackers et. al. in the Niger.[13] Our inability to show significant differences in weight at the end of the study may be due to the overall inadequacy of the diet

Table 3. Comparison of the Energy and Nutrient Intake of the Treatment and Control Group

Study period	Calories (cal/kg body wt) N= 50		Carbohydrate (g/kg body wt) N = 50		Protein (g/kg body wt) N = 50		Fats (g/kg body wt) N = 50	
	Treatment	Control	Treatment	Control	Treatment	Control	Treatment	Control
W eek 1								
Mean +/-	75.22	51.10	9.73	8.62	2.53	1.55	2.90	1.26
(SD)	(24.60)	(15.06)	(3.28)	(2.80)	(1.07)	(0.60)	(1.03)	(0.57)
Week 2								
Mean +/-	87.88	54.71	10.36	8.49	3.09	1.93	3.73	1.89
(SD)	(21.47)	(14.51)	(2.91)	(3.91)	(0.91)	(0.82)	(0.89)	(0.99)
Week 3								
Mean +/-	83.10	54.70	9.93	8.75	2.89	1.68	3.68	1.42
(SD)	(24.81)	(14.01)	(3.86)	(2.46)	(0.90)	(0.53)	(1.17)	(0.58)
Week 4								
Mean +/-	83.25	56.69	9.95	9.34	3.00	1.79	3.62	1.72
(SD)	(24.01)	(13.95)	(3.11)	(3.01)	(1.38)	(0.55)	(1.27)	(1.42)
Week 5								
Mean +/-	82.84	53.54	9.76	8.37	2.87	1.77	3.68	1.52
(SD)	(22.83)	(14.64)	(2.66)	(2.36)	(1.47)	(0.71)	(1.27)	(0.66)

and the limited provision of the mRUTF. In other studies,[14-17] where RUTF was used as the main food source in the rehabilitation of severe acute malnourished children, a sufficient amount and duration of RUTF supplementation was provided for catch-up calories.

In 2005, Patel et al[18] were able to show that supplementary feeding with RUTF for 8 weeks promotes better growth in children at risk of malnutrition than the standard fortified cereal/legume-blended food. A similar study[19] of preventive supplementation with RUTF in Niger showed that short-term supplementation for 8 months in non-malnourished children was able to reduce the decline in weight for height and the incidence of wasting and stunting.

The baseline diet provided to our patients was very deficient in terms of calories and probably even lacking in micronutrients, given the quality of food they were receiving. Our mRUTF was not fortified with micronutrients unlike the RUTF used in the studies[5,6,13] performed in other countries. Neither was supplementation with micronutrients provided. While the commercial peanut butter and milk used to make the mRUTF may contain some amounts of vitamins and minerals, these are not enough to address the needs of malnourished children. Thus, the micronutrient deficiency that was probably present was not addressed by the mRUTF. As such, the growth rate may not have been optimized.

No deworming was done prior to the start of the study. Two of the subjects were treated for intestinal parasitism during the course of the study. Considering that hygiene was a problem among the subjects, intestinal parasitism may have posed an added strain on their nutritional state. Increased intestinal load of parasites has been shown to have a negative impact on growth particularly if the diet is low in protein.[20]

The mRUTF was found to be acceptable and liked by this population. Initially, the children needed bread and used the mRUTF as a spread but in time, the children preferred to take the mRUTF as is. This is similar to the experience of others.[21,22]

A major concern during the first week was that the children's stools became soft. One child developed diarrhea during the study period. This might become a barrier to acceptability as this may be interpreted by mothers as intolerance of the child to the product. This change in consistency however, was no longer observed by the second week. Since the mRUTF was high in fat, the detected change in consistency was probably due to the increased fat in diet of the study group. In a population where the diet is insufficient in fat, a sudden increase in the fat content may result in temporary fat malabsorption.[23]

This study utilized premium commercial sources for ingredients. A 600-calorie mRUTF in a plastic cup costs P35.82; without the cup, P34.22. Since peanuts are indigenous to our country and readily available, the approximate cost using raw peanuts instead of the commercially prepared peanut butter would be P 25.90. Large-scale production of the mRUTF using raw materials would lower the cost of the product making it more accessible to the less privileged population as shown by the experience in Malawi.[6]

The preparation of the RUTF is simple. It can be done in a community setting without need for expensive technology and can easily be accomplished by any adult member of the community. As such, this may be a better alternative to feeding programs that use food that needs cooking and intricate preparation. However, care must be taken to avoid aflatoxin contamination.[5]

Conclusion

RUTF is a practical alternative to milk-based formulas used in clinics and hospitals for nutritional rehabilitation. Its "spreadable format" offers a variety and texture that makes it well-accepted by children. While our results may not have achieved statistical significance, the study has shown that the mRUTF taken together with the usual diet can augment caloric intake and increase weight. Studies on a locally made RUTF using other indigenous ingredients with micronutrients given for a sufficient period are needed.

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