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ORIGINAL ARTICLE

Comparison of Home-Based Therapy with Ready to Use Therapeutic Food with Standard Therapy (F-100) in Treatment of Malnourished Children

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ABSTRCT

Background: Malnutrition in children is a major health issue in Egypt, and weak recovery rates result from standard treatment, which meets international guidelines. In pilot trials of home-based therapy with ready-to-use therapeutic Comparison of recovery rates among children with moderate and serious malnutrition who receive either RUTF home therapy or standard therapy.

Methods: An interventional study (single blinded randomized clinical trial study) was conducted in Zagazig University Hospitals with 56 malnourished children during the period of April 2019 to October 2019. Children were systematically allocated to either standard therapy (28 children) or home-based therapy with RUTF (28 children). The primary outcomes was recovery, identified as achieving a weight-for height z score > -2. The weight gain rate was the secondary consequence.

Results: Children who received home-based therapy with RUTF were more likely to achieve a weight-for-height z score > -2 than were those who received standard therapy (85.7% compared with 57.2%; P = 0.037) and no adverse events attributed to the use of RUTF. Children who received home-based therapy with RUTF had greater rates of weight gain at 8 weeks of therapy (5.08 compared with 3.37 g/kg/day).

Conclusion: Home-based RUTF therapy has greater childhood weight gain than regular therapy.

Keywords: Malnutrition, ready-to-use therapeutic food, RUTF, home-based therapy

INTRODUCTION

More than 50% of child mortality under the age of 5 is caused by malnutrition; approximately 3.5 million undernourished children die annually in developing countries **[1]**. Lack of food supplemented with micronutrients, poor breastfeeding are the major causes of malnutrition **[2]**. Infections such as diarrhea, measles and pneumonia affect malnourished children more often **[3]**.

In order to treat waste among malnourished children, a therapeutic food (RUTF) was implemented. Ready to use therapeutic food (RUTF) is a home-based product because its dehydrated and sealed packaging poses a very low risk of bacterial contamination**[1]**. Ready to use therapeutic food (RUTF) does not need cooling to extend its storage life, as it contains low humidity and does not need any planning **[4]**. Ready to use therapeutic food (RUTF) contains nutrients such as peanut, butter, sugar and powdered milk **[5]**. There are various types of RUTF, most widely used are F-75 and F-100 **[6]**. Formula F-75 is used to stabilize and formula F-100 is used to rehabilitate **[7]**. F-75 and F-100 are made of powdered milk and are used to treat malnutrition **[8]**. Ready to use therapeutic food (RUTF) is associated with a rapid increase in the weight of undernourished children **[5-7]**.

The aim of this study was to determine the operational efficacy of RUTF home-based therapy for moderate and severe malnutrition in children. The hypothesis tested was that in practice, RUTF-based home therapy should produce reasonable clinical outcomes compared to international norms, and better outcomes than traditional therapy is recorded.

METHODS

All children aged 12–48 months presenting to Nutrition Department and pediatric OPC of Zagazig university hospitals at Al Sharkia governorate, during the period of April 2019 to October 2019 with either moderate or severe malnutrition and with a good appetite were eligible to participate in this study. Severe malnutrition was defined as weight-for Z-score <-3; moderate malnutrition was defined as weight-for Z-score < -2 [1]. When the caretaker said the child ate food at home, an appetite was expected to be good. The study was approved by the Faculty of Medicine's Research Ethics Committee, University of Zagazig. The work was carried out for studies involving humans in accordance with the World Medical Association's Code of Ethics (Helsinki Declaration).

Inclusion Criteria: Underweight children (weight for age Z score <- 2) aged between 1-5 years. **Exclusion Criteria:** Patients with: Systemic diseases. Chronic infection. TORCH. Cerebral palsy. 5. Congenital heart and chest diseases. 6. Immunodeficiency.

Methods: This study was a single blinded randomized clinical trial study of 2 different management strategies for treatment of childhood malnutrition. Randomized assignment with RUTF to either standard or home therapy. Test dose (30g) of peanut was given to cases initially to exclude food allergy. Caretakers and kids returned every 2 wks to the clinic for re-evaluation. At this time, the weight, length and MAC of the children were measured. WHO Anthro 2005 (http:/www.who.int/childgrowth/en) used the 2005 WHO growth standards to calculate weight-for-age z-score, height-for age z-score (HAZ) and WHZ. MUAC-for age z-score was calculated using the method of **De Onis et al. [9]**. Using the WHO definition, children are classified as having either moderate or severe malnutrition. Participation in the study lasted eight weeks, after which all kids were released.

Diets: The RUTF was given as a cooperative effort by the study team. RUTF was given in glass jars containing 300 g with an airtight seal consisting of 15 g (23%) fat, 2.5g (13%) saturated fat, sodium 140 mg, total carbohydrates 8g (3%), dietary fibers 2g, sugars 3g and protein 7g. Serving size is 32 g and serving per container is 9. Amount per serving is 190 calories. Each child took 175 Kcal/kg/day. The micronutrient content of the RUTF was identical to that of F-100 before dilution and was consistent with the WHO's catch-up growth recommendations **[10].** Children usually eat the RUTF directly from the bottle, without mixing or diluting it with other foods. F-100 were administered to children who sought regular hospital therapy.

STATISTICAL ANALYSIS

Data was analyzed using version 20 of the Social Sciences Statistical Package (SPSS). Data showing normal distribution as the means and standard deviation are given. For comparison between the means of two groups, the t-test was used. The non-parametric

values were tested using the Mann Whitney-U test. The value information are defined by frequency and relative percentage, and the chi-square method was used to evaluate the qualitative data association. P values < 0.05 have been considered statistically significant in all analyzes.

RESULTS

There was no statistically significant difference between the studied groups regarding age and gender (table 1).

On comparing rate of daily weight gain at different points of time compared to baseline, there was statistically significant difference between both groups with rate of weight gain was higher among patients within RUTF group. Only 3.6% with F100 group versus 57.1% of those received RUTF had rate of weight gain ≥5g/kg/day (table 2).

There was no statistically significant difference between both groups regarding baseline Z score of body weight while there was statistically significant difference at 8 weeks. Only 42.9% of patients received F100 had been on ≥-2 SD while 89.3% of those within RUTF group attained that level. Within each group, there was significant improvement in Z score (table 3).

There was no statistically significant difference between both groups regarding baseline Z score of MUAC while there was statistically significant difference at 8 weeks. Only 71.4% of patients received F100 had been on ≥-2 SD while all those within RUTF group attained that level (table 4).

There was statistically significant difference between both groups regarding baseline and at 2 months Z score of height. There was also significant improvement in Z score of height in each group after intervention (table 5).

There was no statistically significant difference between both groups regarding baseline Z score of weight for height while there was statistically significant difference between them after intervention where the difference was significant between percentage of mild in both groups. There was also significant improvement in Z score of weight for height in each group after intervention (table 6).

Table (1): Comparison between the studied groups regarding demographic characteristics

Demographic characteristics	Groups		Test	
	Standard formula	RUTF	Z/χ^2	p
	N=28 (%)	N=28 (%)		
Age (months):				
Mean ± SD	18.75 ± 8.02	22.54 ± 10.77	-1.951	0.051
Range	15.5 (12 – 48)	17 (14 – 48)		
Gender:				
Male	6 (21.4)	11 (39.3)	2.112	0.146
Female	22 (78.6)	17 (60.7)		

Table (2): Comparison between the studied groups regarding rate of weight gain in body weight

Rate of weight gain (g/day)	Groups				Test	
	Standard formula 100		RUTF		Z	p
	Mean ± SD	Median	Mean ±SD	Median		
At 2 weeks	4.01 ± 4.31	2.85	5.64 ± 5.31	5.24	-3.647	<0.001**
At 4 weeks	3.78 ± 2.19	3.25	5.09 ± 2.94	5.15	-3.467	<0.001**
At 6 weeks	3.54 ± 1.49	3.23	5.02 ± 2.18	5.08	-3.589	<0.001**
At 8 weeks	3.37 ± 1.24	3.17	5.08 ± 0.83	5.21	-5.015	<0.001**
	N=28	%	N=28	%	χ^2	p
Rate ≥5g/day	1	3.6	16	57.1	Fisher	<0.001**

Table (3): Comparison between the studied groups regarding Z score of weight baseline and 2 months after intervention

Z score of weight	Groups		Test	
	F100	RUTF	χ^2	p
	N=28 (%)	N=28 (%)		
Baseline:				
Mild	0 (0)	0 (0)	1.122	0.289
Moderate malnutrition	16 (57.1)	12 (42.9)		
Severe malnutrition	12 (42.9)	16 (57.1)		
After 2 months:				
Mild	12 (42.9)	25 (89.3)	14.446	<0.001**
Moderate	8 (28.6)	3 (10.7)		
Severe	8 (28.6)	0 (0)		
p	**<0.001****	**<0.001****		

Table (4): Comparison between the studied groups regarding Z score of MUAC baseline and 2 months after intervention:

Z score of MUAC	Groups		Test	
	F100	RUTF	χ^2	p
	N=28 (%)	N=28 (%)		
Baseline:			0	>0.999
MUAC ≥ -2	6 (21.4)	4 (14.3)		
-2 > MUAC > -3	13 (46.4)	17 (60.7)		
MUAC < -3	9 (32.1)	7 (25)		
After 2 months:			8.115	0.004*
MUAC ≥ -2	20 (71.4)	28 (100)		
-2 > MUAC > -3	4 (14.3)	0 (0)		
MUAC < -3	4 (14.3)	0 (0)		
p	**<0.001****	**<0.001****		

Table (5): Comparison between the studied groups regarding Z score of height baseline and 2 months after intervention:

Z score of height	Groups		Test	
	F100	RUTF	χ^2	p
	N=28 (%)	N=28 (%)		
Baseline:				
height ≥ -2	9 (32.1)	17 (60.7)	9.81	0.007*
-2 > height > -3	9 (32.1)	9 (32.1)		
height < -3	10 (35.7)	1 (3.6)		
After 2 months:				
height ≥ -2	14 (50)	27 (96.4)	Fisher	<0.001**
-2 > height > -3	5 (17.9)	1 (3.6)	Fisher	0.197
height < -3	9 (32.1)	0 (0)	Fisher	<0.001**
p	**0.016***	**0.002***		

Table (6): Comparison between the studied groups regarding Z score of weight for height baseline and 2 months after intervention:

Z score of weight for height	Groups		Test	
	F100	RUTF	χ^2	p
	N=28 (%)	N=28 (%)		
Baseline:				
-2 > WHZ > -3	17 (60.7)	10 (35.7)	3.054	0.061
WHZ < -3	11 (39.3)	18 (64.3)		
After 2 months:				
WHZ ≥ -2	16 (57.2)	24 (85.7)	Fisher	0.037*
-2 > WHZ > -3	10 (35.7)	4 (14.3)	Fisher	0.121
WHZ < -3	2 (7.1)	0 (0)	Fisher	0.491
p	**0.001****	**<0.001****		

DISCUSSION

These results suggest that RTUF given in moderate and extreme malnutrition management is superior to F100 in promoting weight gain. This analysis was not blind, and factors other than the biological effectiveness of each food may have affected these tests.

There was a statistically significant difference in weight gain (higher in RUTF (57.1 percent) than in Formula 100 category (3.6 percent) between the two groups in the present study). In agreement with our study, Ashraf et al. [11] and Thakur et al. [7] during the rehabilitation phase of acute malnutrition management, the rate of weight gain was found to be significantly higher with RUTF than F100. A systematic review has indicated that the use of therapeutic food products such as RUTF to treat uncomplicated acute malnutrition at home appears safe and effective [12].

In addition, Jadhav et al.[13] stated that, compared to the standard therapy model, the increase in mean weight at each follow-up during treatment was

more normal in all RUTF models. A total of 129 children have completed two weeks of treatment on RUTF and 113 on regular therapy. The average mean weight gain rate in the RUTF group was 4.5 g / kg / d and during treatment in the regular therapy group was 2.9 g / kg / day. The mean weight gain rate was significantly higher in the RUTF group over the first 8 weeks compared to the standard therapy group ($P<0.05$) and was the highest in the initial 14 days (RUTF 5.63 g / kg / day and standard therapy 3.43 g / kg / day).

The current study showed significant changes in the weight score of Z, the height of Z within the RUTF unit.This was accepted with Bashir and Zaman[14] who tested p-values to determine the significant difference between pre-and post-effect on age weight and children's height after treatment was 0.000 and 0.000 but before and after treatment there was no effect on age Z scores. (P= a value of 0.14). This may be due to differences in their time of analysis.

In the present study, there was a significant difference between the two groups in weight score Z, height Z. In line with our research, Isanaka, et al.[5] found in her analysis on Malawian children ($p=0.001$) a significant difference in Z scores in weight for height and height for age between intervention and non-intervention classes. Nevertheless, the height-for age influence of RUTFs was small. Similarly, Ciliberto et al.[8] found that the RUTFs community was more likely than those undergoing standard normal therapy ($p<0.001$) to reach a height Z score > -2 weight.

The recovery rate (defined as achieving a weight-for height z score > -2) in the present study was higher in the RUTF group (85.7%) than in the F100 group (57.2%). This was in accordance with Manary et al.[15] who estimated that 66% of RUTF patients had achieved their graduation weight. Jadhav et al.[13] have found that 60.4% of malnourished children in the RUTF group met the target weight compared with 47.8% in the regular therapy group. Bhandari et al. [16] approximately half of the children benefited from RUTF therapy. In another North India study, the rate of recovery (defined as recovering 115% of baseline weight) was 46% and the weight gain in the RTUF community was 3 g / kg / day [17].

CONCLUSION

Our study shows that home-based management of children with uncomplicated malnutrition is safe, effective and feasible option and that use of a RUTF results in higher recovery and body weight gain rates than feeding F-100 in the short-term. RUTF products are very useful for rapid change in weight within a very limited time period. Malnourished children consumed it easily and its acceptability was good among them. Many approaches to enhancing long-term results need to be addressed, including the sustained use of RUTFs.

Declaration of interest : no conflicts of interest.

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