RESEARCH PAPER

Locally-Prepared Ready-to-Use Therapeutic Food for Children with Severe Acute Malnutrition: A Controlled Trial

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Objective: To compare the efficacy of locally-prepared ready-to-use therapeutic food **(**LRUTF) and locally-prepared F100 diet in promoting weight-gain in children with severe acute malnutrition during rehabilitation phase in hospital.

Study design: Non-randomized Controlled trial.

Setting: Pediatric ward of tertiary care public hospital in Central India.

Study period: 1 October, 2009 to 30th May, 2010.

Subjects: Children aged 6 to 60 months, diagnosed as severe acute malnutrition and hospitalized during study period.

Intervention: Random group allocation followed for selection of intervention and control cohorts. The control cohort enrolled during October 1, 2009 to January 31, 2010 received F100 while the intervention cohort enrolled during 1 February to 15 May 2010 received LRUTF. Subjects receiving either of the two therapeutic foods were temporally separated to minimize the spillover effect. The study subjects and the technician delegated for measuring weight was blinded for type of intervention.

Primary outcome variable: Rate of weight-gain/kg/day.

Results: There were 49 subjects in each group. Both groups were comparable. Rate of weight-gain was found to be (9.59±3.39 g/kg/d) in LRUTF group and (5.41 ± 1.05 g/kg/d) in locally prepared F100 group. Significant difference in rate of weight gain was observed in LRUTF group (*P*<0.0001; 95% CI 3.17-5.19). No serious adverse effect was observed with use of LRUTF.

Conclusion: LRUTF promotes more rapid weight-gain when compared with F100 in patients with severe acute malnutrition during rehabilitation phase.

Key words: Malnutrition, Management, Ready-to-use therapeutic food, India.

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Guidelines provided by World Health Organization (WHO) for management of children with severe malnutrition advise two formula diets, F75 and F100. F75 (75 kcal/100mL) diet is used during initial phase of treatment while F100 (100kcal/100mL) is used during rehabilitation phase after appetite has returned [1].These diets can be prepared locally using cow milk, sugar, vegetable oil, and water.

These diets need to be prepared just before consumption, as cow milk used can act as growth medium for pathogenic bacteria if proper hygienic conditions are not maintained. Milk can be easily adulterated. Shelf-life of locally produced F100 depends on its constituents like milk which has a very short shelf-life of few hours in tropical climates [2].

To deal with these problems there was a need to develop a therapeutic feed which had prolonged shelf-life, was a poor growth media for pathogens, could be prepared locally with available resources, was cheap and locally acceptable. A local ready to use therapeutic food (LRUTF) was prepared from groundnut (25%), milk powder (30%), sugar (30%), and vegetable oil (15%) by weight. In this study, efficacy of this LRUTF in promoting weight-gain during rehabilitation phase was compared with locally-prepared F100 diet.

METHODS

All patients aged 6 to 60 months, diagnosed as Severe acute malnutrition hospitalized in our institution during the study period (1 October 2009 to 30 May 2010) were included in study. The study was non-randomized controlled trial. Patients were divided into two groups depending on the dates of hospitalization. Study was conducted with permission from hospital authorities.

Severe acute malnutrition was defined as the presence of severe wasting (<70% weight-for-height or ≥3SD) (WHO standards) [3], bipedal pitting edema of nutritional origin or mid upper arm circumference (MUAC) of < 11.5 cm in children between 6-60 months of age [4]. Patient was labelled as uncomplicated if he was

alert, with preserved appetite *i.e.* appetite test passed, clinically assessed to be well (absence of general danger signs and severe anemia, cough and difficult/fast breathing, cold to touch and severe dehydration), and living in a conducive home environment. All uncomplicated patients were treated at home and others were hospitalized.

Appetite test: Poor appetite was one of the criteria for hospitalization and inpatient treatment. Appetite was tested with help of measured quantity of LRUTF (approximately 5g/kg). The idea of doing appetite test is that, any child who passes appetite test means that he is able to take ¼ of his maintenance calories at a time, and thus if four or five equal amounts of feeds are given at home child will not further lose weight. A child failing in appetite test was hospitalized [5].

Patients were excluded from study if they refused to get hospitalized, refused for consent, left against medical advice before discharge or died during stabilization phase. All children below age of 6 months with severe acute malnutrition were considered complicated and hospitalized, but they were excluded from study.

Sample size estimation: Primer of Biostatistics Ver. 5.0 was used for estimation of sample size based on expected means in two groups for hypothesis testing. With 5% alpha error, 80% power, expected difference of means as 2, and expected SD within two groups as 3.4, (calculated from the observations of Diop EHI, *et al.* [6]) the minimum sample size was estimated as 47 in each groups. A sample size of 49 was taken after adjusting for the effect of likely attrition.

Intervention: Upon patient enrolment, informed written consent was taken from the caregiver. Information about the history of illness, family demographics, and literacy status of caregiver was acquired. Appetite test was done using LRUTF. Initial stabilisation phase was begun after hospitalization, life-threatening problems were identified and treated, specific deficiencies were corrected, metabolic abnormalities were reversed and feeding was begun. During this initial stabilization phase, cautious feeding was begun with F75. This phase was similar in both cohorts. Once patient showed signs of improvement (disappearance of fever and other signs of infection, regaining of appetite, started losing edema) he was shifted into rehabilitation phase.

All those children who successfully completed stabilization phase were included in this study. On completing stabilization phase, children were given a test feeding of the LRTUF and locally prepared F100 to screen for food allergy and ensure acceptability. These children were assigned into one of the two groups by systematic allocation according to order of entry into the study, with initial participants receiving F 100 (all subjects admitted between October 1, 2009 to January 31, 2010), while children enrolled in later part of study (between 1 February to 15 May, 2010) received locally prepared LRUTF.

During rehabilitation phase, children received either 4 meals of F100 or 4 meals of LRUTF daily according to the group allocation, in addition to 4 meals of food from family pot. Children in LRUTF group received measured quantity of 12 g/kg/day of LRUTF daily. Children in F100 group received 60 mL/ kg/day of F100 in 4 quarters. This therapeutic food provided approximately 60 calories/kg/day. Patients also received approximately 60 kcal/kg/day by family food. Thus, a total of 8 feeds per day and around 120 kcal/kg/day with 1-1.5 g/kg of protein were given to every child. All children received vitamins and mineral supplements as per WHO recommendations [1].

F100 was prepared in lots, quantity of which was determined by number of children with severe acute malnutrition admitted at that particular time. It was prepared at 8.00 A.M., 2.00 P.M., 8.00 P.M. and 2 A.M. by one of the investigators. Food from family pot was consumed at 11.00 A.M., 5.00 P.M., 11.00 P.M. and 5.00A.M. under observation of an investigator. LRUTF was prepared every Sunday in hospital kitchen under all aseptic precautions and was stored in sterile airtight containers of 1kg each. Measured quantity of LRUTF was given just prior to consumption. Left over LRUTF at the end of day was discarded and new container was opened each day. Timings of feeding with LRUTF were similar to those of F100. If child felt hungry in between meals he was offered family food.

Children were considered ready for discharge when they were alert and active, eating at least 120-130 kcal/kg/day with consistent weight gain (of at least 5 g/kg/day for 3 consecutive days) on exclusive oral feeding, receiving adequate micronutrients, free from infection, had completed immunization appropriate for age and had gained at least 15% of admission weight; and the caretaker had been sensitized to weight gain [4].

Before discharge from hospital, caregiver of each child was taught to prepare LRUTF and locally prepared F100. They were advised to give LRUTF and locally prepared F100 at home in same quantity as in hospital and report every 15 days. Weight gain was calculated before discharge and on each follow-up. Patients were followed till they achieved weight <1 SD below mean for height. If a child had poor weight-gain during follow-up, he was readmitted and treated as secondary failure. Failure to

respond (secondary failure) was indicated by failure to gain at least 5 gm/kg/day for 3 consecutive days during rehabilitation phase [1].

Outcome: Primary outcome variable was rate of weight gain (g)/kg bodyweight/day. This was calculated as follows:

$$\frac{(W2 - W1) \times 1000}{(W1 \times N)}$$

Where, W2 – Weight at the time of discharge (kg); W1 – Minimum weight during study period (kg); and N – Number of days from minimum weight to discharge.

Recipe for F100 and LRUTF: Composition of LRUTF and F-100 is described in ***Table* I**. Production of LRUTF included grinding, mixing and packaging. Shelled peanuts were roasted in a roaster at a temperature of approximately 160º C for 40-60 minutes. This was followed by grinding them into smaller particle sizes in a grinder such as a hammer mill. Skimmed milk powder, the ground peanuts, vegetable oil, powdered sugar were then blended in a mixer. The paste was then homogenized to further reduce particle size (< 200 μm), and packed [7].

Data analysis: The collected data was entered into spread sheet programme and analyzed by statistical software Primer of Biostatistics (Ver. 5.0). The inter-group outcome variables were analysed by comparing mean and standard deviation in each group. Unpaired *t* test was used for hypothesis testing. $P<0.05$ was considered significant.

RESULTS

During the study period, 118 patients with severe acute malnutrition were identified, of which 9 patients died during initial stabilisation phase, 5 patients refused to get hospitalized and 6 patients left before treatment was completed, and were excluded from the study (***Fig.* 1**). 76 children were in age group of 6 months to 24 months and 22 children were in age group 25 months to 60 months. There were 49 boys (50%). Age and sex distribution in both cohorts was comparable. 31 (31.6%) patients had edematous malnutrition. 53 (54.1%) patients passed appetite test on admission.

***Table* II** compares the outcome variables between the two groups. None of the patient in LRUTF group had any complications related with LRUTF. No patient had peanut allergy.

TABLE I COMPOSITION OF F100 AND LOCALLY PREPARED F100 DIET AND LOCALLY-PREPARED READY-TO-USE THERRAPEUTIC FOOD USED IN THE STUDY

Ingredient	*LRUTF (1 kg)*	*F 100 (1 L)*
Fresh cow's milk	-	880 mL
Sugar	300 g	75 g
Vegetable oil	150 g	20 g
Peanut butter	250 g	-
Milk powder	300 g	-
Water	Nil	To make 1000 mL
Calories	5440 kcal/kg	1053.8 kcal/L
Proteins	136.3 g/kg	30 g/L

For a child weighing 10 kg received 120 g/day of LRUTF; i.e. 653 kcal of energy and 16.35 g of protein. For a child weighing 10 kg received 600 mL/day of F100; i.e. 632 kcal of energy and 18.4 g of protein.

DISCUSSION

The results indicate rate of weight-gain is significantly more with use of LRUTF than F100 during rehabilitation phase of SAM management. Further, the rate of weight-gain after discharge from hospital is more with use of

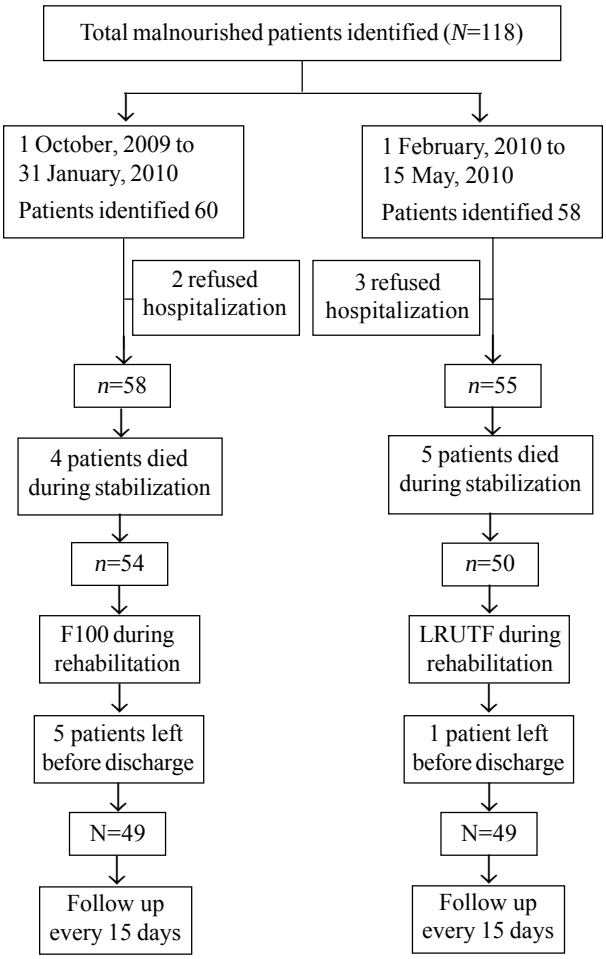

FIG. 1 *Study flow chart.*

TABLE II OUTCOME OF HOSPITALIZED MALNOURISHED CHILDREN MANAGED WITH LOCALLY-PREPARED F100 AND LOCALLY-PREPARED READY-TO-USE THERAPEUTIC FOOD*

	LRUTF Group (n=49)		*F100 group (n=49)*		*Mean difference (95 % CI)*
	Weight gain, Mean (SD)	*No.*	*Weight gain, Mean (SD)*	*No.*	
Rate of wt. Gain (g/kg/day) in study cohort	9.59 (±3.39)	49	5.41 (±1.05)	49	3.174-5.186
Rate of wt gain (g/kg/day) in edematous pt	7.94 (±2.19)	15	5.10 (±0.88)	16	1.629-4.051
Rate of wt gain (g/kg/day) in non edematous pt	10.32 (±3.59)	34	5.66 (±1.10)	33	3.356-5.964
Rate of wt gain (g/kg/day) in pt with good appetite	10.55 (±3.58)	28	6.06 (±0.85)	25	3.015-5.965
Rate of wt gain (g/kg/day) in pt with poor appetite	8.30 (±2.70)	21	4.73 (±0.78)	24	2.408-4.732
Rate of wt gain (g/kg/day) on follow up (g/kg/d)	9.43 (±2.90)	16	5.22 (±0.84)	18	2.756-5.664
Duration of hospital stay (days)	13.04 (±0.16)	49	16.20 (±4.73)	49	-4.502-1.818

**P<0.0001 for all measurements; LRUTF: Locally-prepared Ready-to-Use therapeutic food.*

LRUTF. Duration of hospitalization is also significantly less with use of LRUTF. This has great relevance in treatment of severe malnutrition at the national level as it can decrease the cost of treatment to a great extent. LRUTF was well tolerated in all age groups without showing any side-effects.

Major limitation of this study was that children were not randomly assigned thereby increasing chances of selection bias. Another limitation was that study was not blinded. There was a practical difficulty in blinding because of different appearance of the two therapeutic regimens; one being liquid and other being in powdered form. Observer bias in study was reduced by the fact that primary outcome measure of this study was determined by nude bodyweight determined on a calibrated electronic weighing scale rather than by a more subjective assessment. No observation was made to confirm whether mothers were actually feeding their children the recommended amount of LRUTF or F100 rigorously at home. Although no peanut allergy was found in study, this might not be the case in the general population. Sample size in this study was small as this study was done as a pilot project.

Ciliberto, *et al*. [8] conducted a study to test efficacy of LRUTF and standard WHO treatment (F100) in promoting weight-gain in children with severe acute malnutrition. Their study was done in uncomplicated SAM children and on outpatient basis [8]. The rate of weight-gain in the study was 3.5 g/kg/day in LRUTF group and 2 g/kg/day in other group.

Present study was conducted in complicated SAM patients who were hospitalized. A similar study in hospitalized patients by Diop, *et al*. [6] reported average weight-gains of 15.6 and 10.1 g/kg/d in the RTUF and F100 groups, respectively [6]. In our study, the average weight gain was 9.59g/kg/day and 5.41 g/kg/day. A systematic review also suggested that use of therapeutic nutrition products like RUTF for home-based management of uncomplicated SAM appears to be safe and efficacious [9].

Although rate of weight-gain in studies mentioned above was different, but in all these studies, rate of weight gain was better in LRUTF group *versus* F100. With good acceptability in the population, no adverse reactions, and better weight-gain, LRUTF is of great help in the management of rehabilitation phase of severe acute malnutrition. Further studies with large sample size and home-based follow-up should be conducted to assess the feasibility and efficacy of locally-prepared RUTF in management of SAM.

WHAT IS ALREADY KNOWN?

- F100 promotes weight gain in rehabilitation phase of malnutrition treatment.

WHAT THIS STUDY ADDS?

- Locally-prepared Ready-to-use Therapeutic Food is better than F100 in promoting weight-gain in hospitalized children with severe acute malnutrition during hospitalization and after discharge.

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