

# Clinical and Anthropometric Profile of Severe Acute Malnourished Children on Therapeutic Intervention with WHO/UNICEF Recommended Therapeutic Food and Home Based Therapeutic Food

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**Abstract:** *Objective:* To compare the WHO/ UNICEF recommended therapeutic food to the home based therapeutic food in management of SAM children. *Methodology:* Prospective randomized control trial over two groups of patients comprising 70 patients in each group in time duration of one year. One group was receiving WHO/UNICEF recommended therapeutic food and other group receiving home based therapeutic food. Both kind of therapeutic food was having almost equal amount of energy density, proteins, vitamins and minerals. Fisher's exact test was applied to compare the proportions of two groups. Subjects were enrolled after the approval of ethical committee. *Results:* Out of 137 patients 22 (32.3%) were belonging to less than -4 z score in group A while 27(39.1%) in group B, 31(22.6%) had associated oedema. Rate of weight gain was significantly high in group receiving home based therapeutic food. Rate of height/length gain is statistically significant in group received home based therapeutic food. Change in MUAC is also high among the children received home based therapeutic food. *Conclusion:* After comparing both groups we found that both kinds of therapeutic food are effective for management of SAM, but home based therapeutic food found to be more effective.

**Keywords:** Severe Acute Malnutrition, Management, Efficacy, Therapeutic food, India

## 1. Introduction

Malnutrition in children is the consequence of food insecurity, which stems from poor food quality and quantity, severe repeated infections or combinations of all three. They are related to the standard of living and basic needs. Severe acute malnutrition (SAM), though the least prevalent form of malnutrition is associated with high mortality risk. These children are undernourished and susceptible to disease. Infants and young children are the most vulnerable as they require extra nutrition for growth and development. So, we are in need of finding and treating cases of acute malnutrition early in the progression of condition, before the metabolic and immunological aspects of the condition and treating them adequately to prevent the occurrence of diseases and mortality in them. If the condition is caught in the early stages, the technical aspects of treatment are simple: all that is required is a balanced diet of sufficient quantity and quality.

SAM contributes to 1 million child deaths every year<sup>1</sup>. According to NFHS-III during 2005-2006 in India, Indian data for under-nutrition, wasting and stunting is that there are about 132 million under-five children and amongst them 8.1 million are suffering from severe malnutrition.

The composition of diets used for SAM are relatively cheap to produce and are easy to administer, making success rates high and costs of treatment low. In practice this means that the actual clinical treatment of severe malnutrition is not the only crucial aspect of a successful program.

WHO recommended Ready to use therapeutic food (RUTF), high energy foods to be provided to the caregiver of malnourished child. Evidence is largely restricted to severe malnutrition, where home-based and community-based therapy with nutrient-dense foods has been found to be more cost-effective than in-patient care of severe acute malnutrition (SAM). Home-based treatment are recommended during rehabilitation phase for malnutrition in areas where follow up is possible<sup>2</sup>. The cost of therapeutic food is very high, which is not affordable by the poor families. Whereas home-made food are cheap, locally available, socially acceptable, easily prepared at home and sustainable.

The idea behind our study is to introduce a locally available energy dense food for the management of SAM which is having qualities similar to therapeutic food in terms of energy, minerals and multivitamins which is also culturally acceptable, palatable, safe and affordable.

## 2. Review of Literature

Malnutrition can be classified as over- and under-nutrition. SAM<sup>3</sup> is defined by a very low weight for height (below -3 z scores of the median WHO growth standards), by visible severe wasting, or by the presence of nutritional edema. In children aged 6-59 months, mid upper arm circumference less than 115 mm is also indicative of severe acute malnutrition.

Vinod R wasniketal<sup>4</sup> studied the effect of locally made Ready-to-Use Therapeutic Food for Treatment of Malnutrition in Children aged 6 to 72 Months in Amravati District of Maharashtra, India: showed significant weight gain and height

gain in Experimental group. This study showed that immediate therapeutic treatment for short duration of period is a feasible, effective and well-accepted intervention to combat moderate and severe malnutrition in tribal areas.

Thakur GS et al<sup>5</sup> conducted a non-randomized controlled trial among children aged 6 to 60 months, 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 Locally made RUTF. He concluded that Locally made RUTF promotes more rapid weight-gain when compared with F100 in patients with severe acute malnutrition during rehabilitation phase.

Ciliberto et al<sup>6</sup> conducted a comparative, clinical effectiveness trial was conducted in southern Malawi with 1178 malnourished children. He concluded that home-based therapy with RUTF is associated with better outcomes for childhood malnutrition than is standard therapy.

Manary et al<sup>7</sup> concluded that Home-based therapy with ready-to-use therapeutic food administered by village health aides is an effective approach to treating malnutrition during food crises in areas lacking health services.

Sandigeet et al<sup>8</sup> found that home-based therapy with RUTF was successful. Locally produced and imported RUTF have similar efficacy.

Amthor RE, et al<sup>9</sup> found that Home-based therapy with ready-to-use therapeutic food administered by village health aides is an effective approach to treating malnutrition during food crises in areas lacking health services.

Ciliberto MA et al<sup>10</sup> conducted a study in found that children with oedematous malnutrition and good appetite may be successfully treated with home-based therapy.

Age of weaning, birth weight, antenatal visits of mother, breast feeding, immunization, diarrhoeal episodes in past 2 weeks, frequency of food intake per day, height of mother, practise of exclusive breast feeding practices, use of unhygienic latrines etc, are the factors that affects the prevalence of malnutrition and leads to the mortality, morbidity in under five children.<sup>11</sup>

So the prevention of malnutrition is must. SAM occurs mainly in families that have limited access to nutritious food and are living in unhygienic conditions, which increase the risk of repeated infections. It include improving access to high-quality foods and to health care; improving nutrition and health knowledge and practices; effectively promoting exclusive breastfeeding for the first six months of a child's life where appropriate; promoting improved complementary feeding practices for all children aged 6–24 months with a focus on ensuring access to age-appropriate complementary foods; and improving water and sanitation systems and hygiene practices to protect children against communicable diseases. Thus, preventive programmes have an immense job to do in the context of poverty, and in the meantime children who already are suffering from SAM need treatment.

### 3. Material & Method

A randomized control trial was done in Nutrition rehabilitation centre (NRC) at BRD Medical College, Gorakhpur, UP. in which two groups of severely malnourished children over a time period of 1 year. One group received WHO/UNICEF recommended therapeutic food and other group received home based therapeutic food for 10 weeks to each child.

#### Inclusion Criteria

All SAM children (6 month to 5 years) presented in pediatric OPD or admitted in pediatric ward of Nehru hospital.

#### Exclusion Criteria

- Infants <6 months
- Cerebral palsy
- CHD
- Hemolytic anemia
- Malignancy
- Metabolic disorder
- Malabsorption syndrome
- Chromosomal disorder
- CRF
- Hepatic disorder.
- HIV

### 4. Study Procedure

SAM children fulfilling the inclusion criteria were enrolled in group I & group II by computer generated random number table, whether they were taken from pediatric ward or OPD . SAM children with associated complications and failed appetite test were admitted till they get stabilized &/or their appetite returns. If SAM child is having good appetite & no complications, he was directly admitted in NRC. Here Group I received F-100 & locally made therapeutic food (TF) & Group II received F-100 & homemade TF. Both Groups were given multivitamins and minerals as recommended by WHO. Breastfeeding, it was continued in both the Groups . Calories & protein content of food of two groups was same as it was calculated by nutritionist. Lactose free was given to children with lactose intolerance.

#### WHO/UNICEF recommended food

- F- 75
- F-100
- Locally made therapeutic food (TF)
- Lactose free F-75
- Lactose free F-100

#### HOME BASED THERAPEUTIC FOOD-

- Milk dalia with oil
- Vegetable dalia
- Suji-halwa and kheer
- Besanhalwa
- Atta halwa
- Sago kheer
- Banana shake with oil
- Rice+dal+vegetable+coconut oil
- Sattuparatha ,aloo paratha
- Aloopuri, plain puri

- Green veg+aloo
- Boiled egg, omelets
- Khichdi+oil
- Milk with roti
- Rice+sugar+milk
- Roasted peanut
- laddu
- Roasted channa
- Sprouts pulse

During hospitalization monitoring was done in terms of daily weight gain (edematous SAM children will initially loose weight), appearance of social smile, disappearance of edema, anthropometry and improvement in associated complications. Complications during hospital stay was recorded and managed accordingly. If any child of any group refused to take food of that group, he was given food of his/her choice, but was excluded from the study.

A detailed history was taken from each SAM child including breastfeeding, dietary history, recent changes in feeding habits & history regarding associated complications on predefined performa. A detailed general and physical examination & anthropometry (Weight, Length, HC, CC, MUAC) was taken.

All the SAM children were underwent routine investigations (Hb,TLC, DLC, Chest-Xray/Abdomen-Xray, Urine-routine and microscopy, Urine culture & sensitivity, Montoux test, Stool examination, RBS,RDT-MP,LFT, RFT)

**Sample Size**

Sample size was calculated by using the given formula-

$$N = \frac{P_1(1-P_2) + P_2(1-P_1) \times f(\alpha, \beta)}{(P_2 - P_1)^2}$$

N=size per group;

P<sub>1</sub> = effect of treatment in study group (home based)= 78

P<sub>2</sub>= effect of treatment in control group(TF)=95

f at(α=0.05 & β=0.2) =7.9

i.e. assuming power of study =80% and type I error 5%

By above given formula sample size was calculated 60 for each group.

Adding 20% to minimum sample size for adjusting presumed dropouts,the sample size for each group is calculated as 70. The total sample for study will be 140.

**Assessment of Outcome**

This study was helpful for the assessment of outcome of SAM Children by two types of therapeutic food.

**Primary Outcome**

complete recovery: It was defined by > 15% weight gain from the weight on admission or weight on the day free of oedema.

**Secondary Outcome**

Rate of weight gain : 5-10 g/kg/day

Defaulter

Non-responders :has not reached the discharge criteria after 40 days of intervention Mortality

**Follow-Up**

Every child was followed for a period of 10 weeks. Interval of follow up was of 7 days. During each follow up anthropometry was taken & each child was ensured to be taking assigned food.

**Statistical Test of Significance**

Fisher’s exact test was applied to compare the proportions of two groups. Unpaired t-test was used to compare the means of two groups. P value <0.05 was taken as significant, p<0.01 denotes the test is highly significant, and p<0.0001 denotes test is most significant

**Ethical Issues: Approval and Consent**

The study was approved by Institutional Ethical Committee, B.R.D. Medical college, Gorakhpur. Written Consent was taken from patient’s parent by explaining them nature and purpose of study in their language.

**5. Results**

**Table 1: Age Wise Distribution**

Age in months	Group A	Group B	Total
6-12	06 (8.82%)	12(17.39%)	18(13.13%)
13-24	23 (33.82%)	25 (36.23%)	48(35.03%)
25-36	30(44.11%)	18 (26.086%)	48(35.03%)
37-48	07 (10.29%)	11(15.94%)	18(13.13%)
49-60	02 (2.94%)	3(4.34%)	5(3.64%)
Total	68	69	137

Maximum number of children in group A and B were between 13 to 36 months of age (77.93% and 62.31% respectively). (P=0.18)

**Table 2: Weight Wise Distribution**

Weight of children (kg)	Group A	Group B
<5	2(2.9%)	1(1.4%)
5 – 8	46(67.64%)	50(72.4%)
>8 – 12	20(18%)	18(26%)
>12 *	0	0

\* - excluded from statistical analysis.

Maximum number of children in group A and B were between 5 - 8 kg body weight (67.64% and 72.4% respectively). No significant difference was found.(P=0.74)

**Table 3: Sex wise Distribution of study participants**

	Group A	Group B	Total
Male	40(58.8%)	45(65.2%)	85(62%)
Female	28(41.1%)	24(34.7%)	52(37.9%)
Total	68	69	137

A total of 137 children were enrolled in the study, of which 85(62%) were male and 52(37.9%) were females. Group-A had 58.8% boys and 41.1% girls and Group-B had 65.2% boys while 34.7% girls. There was no statistically significant difference between both groups (P=0.44).

**Table 4:** Socioeconomic status wise distribution (kuppuswamy classification 2012)

	Group A	Group B	Total
Upper (I)*	0	0	0
Upper middle (II) *	0	0	0
Lower middle (III)*	4(5.8%)	5(7.2%)	9(6.5%)
Upper lower (IV)	27(39.7%)	20(28.9%)	47(34.3%)
Lower (V)	37(54.4%)	44(63.7%)	81(59.1%)
Total	68	69	137

\* - for statistical evaluation, these groups have been merged together

Maximum number of SAM children in both groups were from lower class(V) of society. No significant difference was present between two groups. (P=0.41)

**Table 6:** Initial Nutritional status (WHO Standard)

'Z' score	Group A	Group B	Total
-3 to -4	46(67.6%)	42(60.8%)	88(64.2%)

**Table 8:** IYCF Practices in Mother of SAM Children

	Gp A	Gp B	TOTAL	P value
initiation of breast feeding at birth	45/68 (66.1%)	52/69(75.3%)	97/137(70.8%)	0.477
Exclusive breast feeding upto 6 month	35/68(51.4%)	42/69(60.8%)	77/137(56.2%)	0.468
Continuation of breast feeding upto 1 year	57/68(83.8%)	52/69(75.3%)	109/137(79.5%)	0.632
Continuation of breast feeding upto 2 yr	32/68(47%)	40/69(57.9%)	72/137(52.5%)	0.345

Out of 137 patients 97 started breast feeding at the time of birth. In group A 66.1% and in group B 75.3% patients started breast feeding at the time of birth. In group A 51.4% and in group B 60.8% patients were on exclusive breast feeding upto 6 month. In group A 83.3% and in group B 75.3% patients continued breast feeding upto 1 year. There was no significant difference.

**Table10:** Comorbid Condition Associated With SAM

	Gp A	Gp B	Total
G. I. infection	36(52.9%)	33(47%)	69(50.3%)
R.T.I.	4(5.8%)	5(7.2%)	9(6.5%)
U.T.I.	3(4.4%)	4(5.7%)	7(5.1%)
Skin infection	5(7.3%)	2(2.8%)	7(5.1%)

50.3% SAM children presented with acute diarrheal disease. 6.5% SAM children had respiratory tract infections, 5.1% had urinary tract infections and skin infections.

Mean rate of weight gain in group A was 7.20 gram/kg/day, while mean rate of weight gain in group B was 8.2gram/kg/day. Rate of weight gain was significantly high in group receiving home based therapeutic food.(P<0.0001).

**Table 11:** Assessment of Outcome

Parameters	GroupA (WHO recommended Therapeutic food)	GroupB (HOME based therapeutic food)	'p' value
Mean rate of weight gain (gm/kg/day)	7.2±0.8	8.9 ± 2.4	<0.0001
Mean rate of weight gain(gm/day)	58.6 ±22	68.6 ±16	0.0028
Mean duration of treatment (days)	20 ± 2.1	14.7± 1.67	<0.0001
Rate of height/length gain (cms/week)	0.15±0.01	0.17±0.02	<0.0001
Rate of increase in MUAC	0.1±0.014	0.1±0.015	<0.0016

≤ -4	22(32.3%)	27(39.1%)	49(35.7%)
Total	68	69	137

Among 137 children 64.2% are between z score -3 to -4 and 35.7% are below -4. Out of these 35.7% (≤ -4), 22(32.3%) are in group A while 27(39.1%) in group B. There was no statistical difference (P=0.40).

**Table 7:** SAM children presented with bilateral pedal oedema

Oedema	Group A	Group B	Total
Present	18(26.4%)	13(18.8%)	31(22.6%)
Absent	50(73.5%)	56(81.1%)	106(77.3%)
Total	68	69	137

Out of 137 subjects, 31(22.6%) had oedema. Group A had 26.4% and group B had 18.8% children with oedema. No statistically significant difference (P=0.28).

(cms/week)			
Non-responders	2	1	0.619
Mortality	0	0	

Mean rate of weight gain in gram per day in group A was 58.6 gram/day, while mean rate of weight gain in group B was 68.6gram/day. Rate of weight gain was significantly high in group receiving home based therapeutic food.(P<0.0028). Mean rate of height gain in group A was 0.15 cm/week, while mean rate of height gain in group B was 0.17cm/week. Rate of height gain was significantly high in group receiving home based therapeutic food(P<0.0001). Mean rate of MUAC gain in group A was 0.12cm/week, while in group B was 0.13cm/wk . Rate of MUAC was significantly high in group receiving home based therapeutic food(P<0.0016).

## 6. Discussion

Maximum number of children in group A and B were between 13 to 36 months of age (77.93% and 62.31% respectively). NFHS 06 shows that the proportion of children who are stunted or underweight increases rapidly with the child's age from birth to age 20-23 months; peaking at age 20 months.<sup>12</sup>

Maximum number of children in group A and B were between 5 - 8 kg body weight (67.64% and 72.4% respectively). Mean weight is 7.6 and 7.9 in group A and group B respectively.

A total of 137 children were enrolled in the study, of which 85(62%) were male and 52(37.9%) females. The percentage of population of undernourished boys is higher than the girls. While according to NFHS 05-06 overall, girls and boys are about equally to be undernourished.<sup>41</sup>

Out of 137 subjects, 31(22.6%) had oedema. Group A had 26.4% and group B had 18.8% children with oedema. Kumar et al<sup>13</sup> shown 27% children are edematous in his study.

Out of 137 patients 70% patients started breast feeding at the time of birth which is higher than then NFHS 06 data<sup>40</sup> A study by Khan M. E. in Gujarat revealed that 31.6% infants were breast fed within first 12 hours of life.<sup>43</sup> Increased number of children started breast feeding at the time of birth in this study is because of awareness about the breast feeding. In group A, 51.4% and in B, 60.8% SAM children received exclusive breast-feeding upto 6 months.

Gopujkar et al<sup>14</sup> showed that the practice of not putting the infant to breast within first 24 hours widely prevalent in cities like Kolkata (47.6%) & Chennai (23.8%) but less in Mumbai (3.4%)

Out of 137 patients 56% patients were on exclusive breast feeding upto 6 month which is slightly higher than the NFHS-06 data.<sup>12</sup>

The comorbid conditions amongst study patients are diarrhoea (50.3%), respiratory tract infections (6.5%), UTI (5.1%) and skin infections (5.1%) patients. Kumar et al<sup>13</sup> studied diarrhoea to be the most common.

Outcome of the study population is given in terms of weight gain. It was found that mean weight gain at 10 weeks was higher in the group b (n=69): 8.9 gm/kg/day as compare to control group (n=68) 7.2 gm/kg/day (p < 0.001) which is highly significant.

Increase in height/length is also greater among the children receiving home based TF. It again shows that home based TF has better outcome than WHO-TF. MUAC increases more rapidly among children receiving home based TF. Home based TF has better outcome in every grade of malnutrition. Cliberto et al<sup>10</sup> shows children who received home based therapy with RUTF were more likely to achieve weight gain than those who received standard therapy. It supports our study.

Manary et al<sup>7</sup> studied home based therapy for severe malnutrition with ready-to-use food shows the average weight gain was 5.2 gm/kg/d in RUTF group compared to 3.1 gm/kg/d for the maize soy & RUTF supplement groups. Sandiege H et al<sup>24</sup> shows the rate of weight gain was greater among children receiving locally produced RUTF.

Amphor et al<sup>9</sup> studied mean weight gain 2.7 gm/kg/day, mean height gain 0.3 mm/d, MUAC gain is 0.2 mm/day with use of RUTF which is lower than the weight gain found in our study.

Vinod R wasnik et al<sup>4</sup> studied effect of locally made RUTF for treatment of malnutrition on children aged 6 to 72 months. In this study the mean weight gain was higher in intervention group 1.7 gm/kg/d as compared to 0.9 gm/kg/d. It supports the finding of our study that locally made food is superior than RUTF.

Thakur et al<sup>5</sup> compared the efficacy of locally made RUTF and locally made F-100 diet in promoting weight gain in hospitalised children showing weight gain of 9.59 gm/kg/d and 5.41 gm/kg/d respectively. This also support that locally made food is superior in terms of weight gain.

## 7. Conclusion

After comparing both groups we found that both kinds of therapeutic food are effective for management of SAM, but home based therapeutic food found to be more effective. As it has shown higher weight gain and lesser duration to achieve target weight. It is liked by carers, teach mothers about child feeding. Family foods for rehabilitation also form the basis for good complementary foods. It has potential to prevent malnutrition in the long term by learning to make good food mixtures, feed frequently and responsively. But families must have food resources, carer must be at home full-time. Need clinic nearby or community health worker to monitor progress and provide timely treatment when ill. We also studied the contributory factors for SAM children. It shows illiteracy among mothers, low socioeconomic status, poor hygiene, sanitation, faulty feeding habits and lack of knowledge about complimentary feeding are most important contributory factors. To combat all these factors is the only way to prevent malnutrition. Besides treatment prevention is must.

## 8. Research Needs

- Comparative trials are needed of the cost-effectiveness of home foods vs. RUTF.
- Operational research is needed to determine the effectiveness of scaling-up community-based rehabilitation in routine health services in non-emergency settings and barriers.

In home-based rehabilitation, the optimum frequency of visits to achieve low mortality and rapid recovery needs to be determined. Some children fail to achieve rapid weight gain with home-based rehabilitation. Research is needed to determine if these children or their families share certain characteristics that could be used to identify them as high risk and in need of additional care.

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