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Original research article a randomized controlled study on use of locally prepared therapeutic food for treatment of sam children

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Abstract
Background: Severe acute malnutrition (SAM) remains as one of the major killers of children under five years of age. As per WHO's guidelines for the inpatient management of SAM, after initial stabilization phase, dietary management plays a big role in the longer rehabilitation phase of management of SAM. Milk used for making F-100 diets used for the same has disadvantages like short self-life, liable to get adulterated and can act as a medium for pathogenic bacteria. RUTFs are now being used as a substitute to F-100 diet in the management of SAM around the globe.
Aims and Objectives: To compare the efficacy of locally-prepared ready-to-use therapeutic food (LRUTF) and F-100 diet in promoting weight-gain in children with severe acute malnutrition during rehabilitation phase in hospital. To assess the effectiveness of LRUTF diet in the recovery of children with severe acute malnutrition. To compare the duration of hospital stay among children receiving LRUTF diet with that of F-100 diet.
Materials and Methods: It was a hospital based randomized controlled trial conducted over a period of 2 years (Oct 2015 to Sept. 2017) at paediatrics ward of SCB Medical College, Cuttack, India. A total of 120 children were included in the study. Children aged 6 to 60 months, diagnosed as severe acute malnutrition as per WHO criteria and hospitalized during study period and in rehabilitation phase. Random group allocation was followed for selection of study (LRUTF) and control (F-100) cohorts. The control cohort enrolled received F-100 while the study cohort received LRUTF diet. Both the groups received a total of 6 feeds per day which included 3 feeds of either LRUTF or F100 as per the allocation and 3 feeds from family pot amounting to an intake of approximately 150kcal/kg/day and 1.5-2gm/kg of protein to both groups. Children were examined daily for clinical status and anthropometry. Children were discharged once they gain at least 15% of admission weight and were followed up every 15 days till they reach weight of 1 S.D. below mean for height.
Results: There were 60 subjects in each group. Both groups were comparable in terms of initial Social, demographic and anthropometric profiles at the time of admission. Rate of weight gain was found to be (9.15 ± 3.39 gm/kg/day) in LRUTF group and (6.72 ± 1.05 gm/kg/day) in F-100 group. Significant difference in rate of weight gain was observed in LRUTF group ($P<0.0001$; 95%). No serious adverse effect was observed with use of LRUFT. Duration of hospital stay was lesser in LRUTF group (17.07 days) than F-100 group (23 days). Recovery rates in LRUTF group was better (93.3%) than F-100 (86.7%) group.
Conclusion: LRUTF promotes more rapid weight-gain when compared with F100 in patients with severe acute malnutrition during rehabilitation phase. Duration of hospital stay is lesser in LRUTF group than that of F-100 group.

Keywords: SAM, management, locally prepared ready-to-use therapeutic food

Introduction: Background

The world health organization defines malnutrition as the cellular imbalance between the supply of nutrients and energy and the body's demand to ensure growth, maintenance and specific functions [1].

The term severe acute malnutrition (protein energy malnutrition) includes a group of disorders that include marasmus, kwashiorkor and intermediate states of marasmic – kwashiorkor [2].

Severe acute malnutrition or severe wasting as defined by WHO criteria includes

a) Very low weight for height (< 70 % of expected or below -3 SD scores for the median WHO standards) and /or
b) Visible wasting and / or
c) By the presence of nutritional edema and / or
d) Mid upper arm circumference less than 11 5mm [3].

Severe acute malnutrition remains as one of the major killers of children under five years of age. It contributes to approximately one million child deaths every year. Globally, it is estimated that 13 million children under five years of age are severely acutely malnourished. Most of them live in south Asia and sub Saharan Africa. India alone is home to approximately 8,105,000 children with severe acute malnutrition (31.2% of the world's severely wasted children).

Case fatality rates in hospitals treating severe acute malnutrition in developing countries average 20-30% and have remained unchanged since the 1950 's despite the fact that clinical management protocols currently available are capable of reducing the case fatality rates to 1- 5%. This is attributed to the greater discrepancy between actual practice in most of the institutions treating severe acute malnutrition and our knowledge of what works.

Many factors including food inadequacy, poverty, religion,

education, superstitions, infections, cultural practices, socioeconomic factors, availability of health services and its utilization play a causal role in severe acute malnutrition.

As per the WHO's guidelines for the inpatient management of Severe acute malnutrition children, after initial stabilization phase where the acute medical conditions Like hypoglycemia, hypothermia, dehydration, electrolyte imbalance, infections are managed, there after Dietary management plays a big role in the longer rehabilitation phase of management of severe acute malnutrition.

Dietary management involves correcting micronutrient deficiencies like vitamins and minerals, followed by starting cautious feeding with formulas like F75 and then a prolonged catch up growth dietary therapy with F-100 or RIJTFs (Ready to Use Therapeutic Feeds).

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

F-100 diet needs to be prepared just before consumption, cow milk used sometimes can act as growth medium for pathogenic bacteria if proper hygienic conditions are not maintained during diet preparation. Milk is also liable to get adulterated easily. Self-life of F-100 depends on its constituents like milk which has a very short self-life of few hours in tropical climates.

To deal with these problems there was a need to develop a therapeutic feed which had prolonged self-life, was a poor growth media for pathogens, could be prepared locally with available resources, was cheap and locally acceptable. In the present study a local ready to use therapeutic food (LRUTF) was prepared from groundnut, milk powder, sugar and vegetable oil. In this study, efficacy of this LRUTF in promoting weight gain during rehabilitation phase was compared with that of F-100 diet.

Aims and objectives

To compare the efficacy of locally prepared ready to use therapeutic food with that of F-100 diet in promoting weight gain among children with severe acute malnutrition during rehabilitation phase. To assess the effectiveness of LRUTF diet in the recovery of children with severe acute malnutrition. To compare the duration of hospital stay among children receiving LRUTF diet with that of F-100 diet.

Materials and methods

The study was a hospital based randomized controlled trial conducted over a period of 2 years (Oct. 2015 to Sept. 2017) at pediatrics ward of SCB Medical College, Cuttack, India. Institutional ethics committee approved the study. Children aged 6 months to 5 year diagnosed to have SAM as per WHO criteria and those passed the appetite test were included in the study. The sample size was 120.

A total of 120 children were included in the study. Children aged 6 to 60 months, diagnosed as severe acute malnutrition as per WHO criteria and hospitalized during study period and in rehabilitation phase.

Random group allocation was followed for selection of study (LRUTF) and control (F-100) cohorts. The control cohort enrolled received F-100 while the study cohort received LRUTF diet. Both the groups received a total of 6 feeds per day which included 3 feeds of either LRUTF or F100 as per the allocation and 3 feeds from family pot amounting to an intake of approximately 150kcal/kg/day and 1.5-2gm/kg of protein to both groups. Children were examined daily for clinical status and anthropometry. Children were discharged once they gain at least 15% of admission weight and were followed up every 15 days till they reach weight of 1 S.D. below mean for height.

Statistical analysis was carried out with graph pad prism version 5 software. Continuous date was computed as mean plus or minus standard deviation. Student Unpaired t-test was applied for comparison of means. Data was analyzed by ANOVA followed by Bonferroni's multiple comparison tests. Chi-square tests were performed to compare categorical variables. Statistical significance was set at $P<0.05$. Microsoft excel sheet was used for data storage and for tables & graphs.

Results

The mean weight, Height and MUAC in both groups at the admission were comparable and difference in both groups was not significant.

In LRUTF group, 6.6% children failed appetite test, 5% had oedema, 36.6% children had wasting and 9.1% children had pallor at discharge. In F-100 group, 13.3% children failed appetite test, 10% children had oedema, 25% children had wasting and 9.1% children had pallor at discharge.

LRUTF group had a weight gain of 9.15gm/kg/day and F-100 group had a weight gain of 6.72gm/kg/day at the time of discharge. Secondary failures in LRUTF and F-100 groups were 6.67% and 13.3% respectively.

In LRUTF group weight gain was highest (9.15gm/kg/day) in the age of 13 to 24 months. In F-100 group weight gain was highest (7.19gm/kg/day) in the age of 25 to 48 months. However there was no significant intra group variation in weight gain among different ages in both groups (p value >0.05).

L-RUTF group had a height and MUAC gain of 0.56mm and 0.42mm respectively. F-100 group had a height and weight gain of 0.42mm and 0.35mm respectively.

Duration of hospital stay in LRUTF group was 17.07 days. In F-100 group average hospital stay was for 23 days.

Weight gain in LRUTF group was 9.01gm/kg/day and in F-100 group it was 6.47gm/kg/day. No deaths and secondary failures were noted in both groups at first follow up. Height and MUAC gain in LRUTF group were 0.6mm and 0.4mm per day respectively. Height and MUAC gain in F-100 group were 0.46mm and 0.35mm respectively.

Weight gain in LRUTF group was 8.41gm/kg/day and in F-100 group it was 6.47gm/kg/day. No deaths and secondary failures were noted in both groups at second follow up. Height and MUAC gain in LRUTF group were 0.52mm and 0.42mm per day respectively. Height and MUAC gain in F-100 group were 0.45mm and 0.35mm respectively.

Weight gain in LRUTF group was 8.05gm/kg/day and in F-100 group it was 6.04 gm/kg/day. No deaths and secondary failures were noted in both groups at third follow up. Height and MUAC gain in LRUTF group were 0.43mm and 0.37mm per day respectively. Height and MUAC gain in F-100 group were 0.44mm and 0.34mm respectively.

Average duration for recovery in LRUTF was 41.96 days. In F-100 group average duration of hospital stay was 48.66 days. LRUTF group had better recovery rate (93.3%) when compared to F-100 groups (86.7%).

Table 1: Baseline anthropometrics at the time of admission

Criteria	LRUTF, mean (SD)	F-100, mean (SD)	CI (95%)
Weight in kg, mean (SD)	7.15 (1.66)	7.39 (1.42)	-2.5 to 3*
Height in cm, mean (SD)	77.8 (9.77)	78.34(8.81)	-2.14 to 3.37*
MUAC in mm, mean (SD)	109.92 (5.48)	111.8(5.34)	-0.87 to 4.6*

* P Value > 0.05, SD – Standard deviation, CI – Class interval

Table 2: Clinical and anthropometric determinants at the time of discharge

Determinant	LRUTF N=60		F-100 N = 60	
	At admission	At discharge	At admission	At discharge
Failed appetite test	26 (43.3%)	4 (6.67%)	33 (55%)	8 (13.3%)
Presence of oedema	20 (33.3%)	3 (5%)	22 (36.7%)	6 (10%)
Presence of wasting	60 (100%)	22 (36.6%)	60 (100%)	15 (25%)
Presence of pallor	15 (25%)	5 (9.1%)	12 (20%)	5 (9.1%)
Weight (kg)*, Mean ± SD	7.15±1.66	8.21±1.91	7.39±1.42	8.47±1.65
Height (cm)*, Mean ± SD	77.8±9.77	78.75±9.74	78.34±8.81	79.34±8.8
MUAC (mm)*, Mean ± SD	109.92±5.48	117.17±5.85	111.8±5.34	117.83±15.19

* P – value > 0.05

Table 3: Outcomes in both groups at the time of discharge

Outcome	LRUTF N = 60	F-100 N = 60
Average weight gain gm/kg/day, mean (SD)*	8.85 (1.90)	6.43 (1.04)
Average weight gain gm/kg/day, among failures mean (SD)	4.58 (0.89)	4.53 (0.63)
Average weight gain gm/kg/day, among improved* mean (SD)	9.15 (1.56)	6.72 (0.77)
Secondary failures	4 (6.67%)	8 (13.3%)
Deaths	4	5
LAMA	5	5

* P-value < 0.0001

Table 4: Age wise average weight gain in both groups

Age in months	LRUTF N = 60 gm/kg/day, mean (SD)	F-100 N = 60 gm/kg/day, mean (SD)
6 – 12	8.46 (1.91)	6.01 (1.03)
13 – 24	9.15 (1.98)	6.30 (1.10)
25 – 48	8.29 (2.23)	7.19 (0.51)
49 – 60	8.81 (0.43)	7.11 (0.15)

P – Value > 0.05 for all

Table 5: Average gain in height and MUAC in both groups

Study group	Height gain mm/day, mean (SD)	MUAC gain mm/day, mean (SD)
LRUTF	0.56 (0.008)	0.46 (0.06)
F-100	0.42 (0.10)	0.35 (0.04)

Table 6: Average duration of hospital stay in LRUTF and F-100 groups

Study group	Duration in day Mean, (SD)*
LRUTF	17.07 (2.64
F-100	23 (2.87)

* P-value < 0.0001

Table 7: Clinical well-being and outcomes at first follow up

Determinant	LRUTF, N=60	F-100, N=60
Wasting	0	1
Oedema	0	0
Failed Appetite test	0	0
Average weight gain gm/kg/day, mean (SD)	9.01 (1.58)*	6.47 (0.74)
Average height gain in mm/day, mean (SD)	0.6 (0.007)	0.4(0.006)
Average MUAC gain in mm/day, mean (SD)	0.46(0.06)	0.35(0.03)
Secondary failures	0	0
Deaths	0	0

* P – value < 0.001

Table 8: Clinical well-being and outcomes at second follow up

Determinant	LRUTF, N=60	F-100, N=60
Wasting	0	0
Oedema	0	0
Failed Appetite test	0	0
Average weight gain gm/kg/day, mean (SD)	8.41 (1.11)*	6.47 (0.71)
Average height gain in mm/day, mean (SD)	0.52 (0.006)	0.42(0.005)

Average MUAC gain in mm/day, mean (SD)	0.45(0.05)	0.35(0.03)
Secondary failures	0	0
Deaths	0	0

* P – value < 0.001

Table 9: Clinical well-being and outcomes at third follow up

Determinant	LRUTF, N=60	F-100, N=60
Wasting	0	0
Oedema	0	0
Failed Appetite test	0	0
Average weight gain gm/kg/day, mean (SD)	7.15 (0.34)	6.04(0.45)
Average height gain in mm/day, mean (SD)	0.43(0.008)	0.37(0.001)
Average MUAC gain in mm/day, mean (SD)	0.44(0.003)	0.34(0.008)
Secondary failures	0	0
Deaths	0	0

Table 10: Final outcome of both groups

Study group	Recovered (%)	Failure (%)
LRUTF, N = 60	54 (90)	6 (10)
F-100, N = 60	52 (86.7	8 (13.3)

Discussion

In the present study 100% children had weight for height less than 3 SD and 71.6% had MUAC less than 115mm including both groups. This was comparable to the study of Singh, *et al*. [4].

Weight, height and MUAC of all children were recorded at the time of admission and then every day till discharge. Mean weight, height and MUAC in LRUTF group were 7.18 kg, 78.13cm and 109.9mm respectively. In F-100 group, Mean weight, height and MUAC were 7.43kg, 78.7cm and 111.8mm respectively. The data in both groups were comparable and the difference in both groups was not significant (p value > 0.05). This was in unison with the study of Ciliberto, *et al*. which had a mean weight of 7.7 kg in RUTF group and 7.6kg in F100 group respectively [5].

In LRUTF 4 children (6.67%) failed appetite test at discharge while it was 13.3% in F-100 group. 5% children in LRUTF group had oedema and 10% children had oedema in F-100 group at discharge. All children who failed appetite test and had oedema in both groups were considered as secondary failures and were treated again in the hospital. 36.6% children in LRUTF group and 25% children in F-100 group still had wasting at discharge time. The higher number of wasting in LRUTF group was due to a lower baseline admission weight in LRUTF group i.e. 7.15kg when compared to F-100 group which was 7.39 kg at the time of admission.

In the present study weight gain in LRUTF group was significantly better than F-100 group (p value < 0.0001). a similar study in hospitalized patients done by Diop, *et al*. reported average weight – gains of 15.6 and 10.1 g/kg/d in the RTUF and F-100 groups respectively [6].

A total of 120 children were enrolled in the present study. Majority were in the age group of 13 to 24 months. Males predominated over females in number in both study and control groups at admission. More than half of children in both groups were from rural areas. Majority of them belonged to lower socioeconomic status in both groups. Most of the mothers in both LRUTF and F-100 groups were illiterates. All children had wasting at the time of admission in both groups. Around one third of children had oedema at admission in both groups at admission. Fever was the common medical indication for admission followed by cough and diarrhea in both groups. Similar distribution of children who failed appetite test at admission was seen in both study and control groups. LRUTF group had significantly better weight gain (9.15gm/kg/day) than F-100 (6.72gm/kg/day) at the time of discharge. Number of secondary failures was less in LRUTF group than F-100 group at the time of discharge. Duration of hospital stay among children in LRUTF (17 days) group was significantly lesser than F-100 group (23 days). Weight gain was better in children without oedema and with good appetite in both groups. Children in LRUTF group had better weight gain in both with or without oedema and with either good or poor appetite than F-100 group. LRUTF had better weight gain in all age groups when compared to children in F-100 group. However, there was no significant intra group variation in weight gain in both LRUTF and F-100 groups. Both males and females in LRUTF group had better weight gain than males and females of F-100 group. There was no significant difference in weight gain between males and females within F-100 group. However, females did better than males in LRUTF group. Average gain in height and MUAC were significantly better in LRUTF group than F-100 group at discharge. Weight gain during follow up was significantly better in LRUTF group (8.75gm/kg/day) than F-100 group (6.47gm/kg/day). Average gain in height and MUAC were better in LRUTF group than F-100 group during follow up period. Recovery rate was better in LRUTF group than F-100 group secondary failures were less in LRUTF group when compared to F-100 group.

Conclusion

LRUTF diet is found to be superior to F-100 in the promotion of weight gain during the rehabilitation phase of the management of severe acute malnutrition. Acceptability of LRUTF is good in both urban and rural population. With no adverse reactions and better weight gain, LRUTF is of great help in the management of SAM.LRUTF also has lesser duration of hospital stay which has a great relevance in treatment of SAM at national level as it can decrease the cost of treatment to a greater extent and can give psychosocial satisfaction to caregivers.

Hence LRUTF diet can be recommended as a substitute for F-100 to be used by National health Mission in Nutritional Rehabilitation programmes to promote the weight gain of

SAM children both at Nutrition Rehabilitation Centers and as well as at community level. However further studies with large sample size should be conducted at grass root level in community level among the socioeconomically disabled groups to assess the feasibility, acceptance and efficacy of LRUTF diets.

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