RESEARCH PAPER

Indigenously Prepared Ready-to-use Therapeutic Food (RUTF) in Children with Severe Acute Malnutrition

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Objective: To compare efficacy of indigenous Ready-to-use Therapeutic Food (Medical Nutrition Therapy) with Standard Nutrition Therapy in children with Severe acute malnutrition.

Design: Two facility-based and two community-based models: (*i*) Open prospective randomized controlled trial comparing Indigenous Ready-to-use Therapeutic Food (Medical Nutrition Therapy) with Standard Nutrition Therapy; (*ii*) Only Indigenous Ready-to-use Therapeutic Food (Medical Nutrition Therapy); (iii) Doorstep Child Care Centre; and (*iv*) Community-based Management of Acute Malnutrition.

Setting: (*i*) Urban Health Center, Dharavi, Mumbai; (*ii*) Two day care centers of Non-governmental Organization SNEHA – Mumbai; (*iii*) Urban slums, M East and L Ward, Mumbai

Participants: 1105 children aged 6-60 months in community or hospital inpatient/ outpatient department diagnosed as Severe Acute Malnutrition by WHO definition.

Intervention: All subjects received either Indigenous Ready-to-use Therapeutic Food (Medical Nutrition Therapy) or Standard Nutrition Therapy (protein calorie rich diet) for eight weeks and followed up for next four months.

Main outcome measures: Mean rate of weight gain (g/kg/day), target weight, change in nutritional status.

Results: Rate of weight gain was higher (P<0.05) at 2 weeks on indigenous Ready-to-use Therapeutic Food (Medical Nutrition Therapy) (5.63 g/kg/day) as compared to Standard Nutrition Therapy (3.43 g/kg/day). 61.2% subjects achieved target weight compared to 47.7% controls. At 8 weeks, 82.8% subjects recovered from Severe Acute Malnutrition compared to 19.3% controls (P<0.005). The results obtained in community were comparable to facility-based indigenous Ready-to-use Therapeutic Food (Medical Nutrition Therapy). The morbidity was less in study group at follow-up.

Conclusions: Indigenous Ready-to-use Therapeutic Food (Medical Nutrition Therapy) appeared to be superior to Standard Nutrition Therapy in promoting weight gain in children with Severe Acute Malnutrition.

Keywords: *Medical Nutrition Therapy, Micronutrients, Nutritional rehabilitation, Protein energy malnutrition. Ready-to-use-food*.

Trial Registration: CTRI/2014/04/004523 (Retrospecitive registration)

Malnutrition is a major health concern in Indian children, not only in rural areas, but also in urban slums. Every third malnourished child in the world lives in India [1]. Globally, around 20 million children under 5 years of age have Severe acute malnutrition (SAM) and 40 percent of these (8 million) are in India. This accounts for 6.4% of all Indian children under five years of age.

Conventionally malnutrition was attributed to protein and/or energy deficiency. Newer research reveals that it is primarily due to deficiency of type II nutrients leading to loss of appetite, growth cessation, reductive adaptation to environmental stress, oxidative stress or infection [2]. Most of these children also have deficiency of type I nutrients that affect specific physiologic functions.

Accompanying Editorial: Pages 277-8

The standard of care recommended by WHO in management of SAM is Ready-to-use Therapeutic Foods (RUTF) containing balanced amounts of all necessary nutrients (Type 1 and 2) in the bioavailable form. Evidence for feasibility, acceptability, safety and efficacy of RUTF is lacking in India. We decided to address this by devising a locally produced RUTF termed Indigenous Ready to Use Therapeutic Food [RUTF-I (Medical Nutrition Therapy, MNT)] [3]. This study was undertaken to analyze the various aspects of use of RUTF-I (MNT) in facility- and community-based management of children with SAM.

METHODS

The Department of Pediatrics, LTMG Hospital established an RUTF-I (MNT) production unit as part of its state-of-the-art Nutrition Rehabilitation, Research and Training Centre (NRRTC) at Urban Health Centre (UHC), Dharavi. The ingredients of RUTF-I (MNT) were peanut butter (25%), skimmed milk powder (24%), powdered sugar (28%), soya bean oil (21%), and micronutrients (1.6%) with emulsifier (0.4%), which meet the WHO recommendations on RUTF composition. 100 g of RUTF-I (MNT) provides 540 kcal and 16 g proteins [3]. Caloric value of 100 g Standard Nutrition Therapy, SNT (comprising of milk with sugar and oil, boiled eggs, banana, rice green gram porridge with vegetables, jaggery and oil) was 100 kcal with 3 g proteins. Regular batch-testing of RUTF-I (MNT) was done for Aflatoxin assay and bacterial and fungal culture.

All children aged 6-60 months in the community (Doorstep Childcare Center, DCC/Community Management of Acute Malnutrition, CMAM model) or in the hospital inpatient or outpatient department (facility-based model) diagnosed as SAM by WHO definition (weight-for-length/height <-3 SD or mid-upper arm circumference (MUAC) <11.5 cm and/or bilateral pitting pedal edema) were enrolled [4]. Children unable to take oral feeds or already on nutritional supplements or with any pre-existing chronic illness were excluded. Ethics clearance was obtained from the Institutional Ethics Committee of the institute.

The study was planned to assess four models:

First model: RUTF-I (MNT) *vs* SNT (April 2011 – June 2013): A prospective randomized controlled open trial was undertaken to compare the efficacy of RUTF-I (MNT) with SNT in hospitalized SAM children at NRRTC. NRRTC consisted of 15 bedded indoor unit, an outdoor unit and an indigenous production unit for preparing RUTF-I (MNT). The study was monitored by a dedicated medical officer along with a nutritionist-cum-counseler.

We carried out an interim analysis to compare the efficacy of RUTF-I (MNT) over SNT, which proved the superiority of RUTF-I (MNT) over SNT. Hence, we dropped out the SNT arm of the study and continued to give only RUTF-I (MNT) to all our SAM children as a policy decision.

Second model: Only RUTF-I (MNT) (June 2013 – June 2015) – We continued management only with RUTF-I (MNT) and studied its effectiveness in a facility-based model (NRRTC).

With an aim to study the feasibility of RUTF-I (MNT) use in uncomplicated SAM children in the community, we planned Model 3 and Model 4 of the study simultaneously. We coordinated with the NGO SNEHA (Society for Nutrition Education and Health Action) for these two models.

Third model: DCC model (August 2012 – December 2013) – 27 DCCs were established in Dharavi, M East and L wards. DCCs were day care centers having one trained teacher and helper each. All eligible subjects were examined by a Medical Officer and registered for intervention. Throughout the treatment duration, RUTF-I (MNT) was administered under observation from Monday to Friday and RUTF-I (MNT) for remaining two days was given at home. A community organizer (CO) from the NGO SNEHA along with Anganwadi Sevika conducted and recorded the monthly anthropometry. The data was then submitted to the intervention team.

Fourth model: CMAM model (August 2013 – August 2015) – This was applied in the same geographical areas as the DCCs. One community organizer (CO) along with one community helper was appointed for 1000 population. The process of identification and enrolment was similar to that of DCC. The CO visited the child daily in first week followed by alternate days for next seven weeks. Weight was monitored fortnightly during the treatment period and then monthly for four months.

In the first model, 321 children were enrolled after an informed written consent by caretakers. Detailed socio-demographic data were obtained. After initial resuscitation and stabilization with F75 and F100 respectively, children were subjected to the appetite test. Those who passed the test (based on the WHO appetite test chart [5]), were allocated into intervention and control groups to RUTF-I (MNT) or SNT diet exclusively. The randomization was done using a computer generated random number table by Microsoft Excel.

The intervention group received RUTF-I (MNT) at 175 kcal/kg present weight/ day for eight weeks. Caregivers received nutritional counseling and children shifted to home diet after eight weeks. The control group received SNT (175 kcal/kg/day). This was given through the hospital kitchen during hospital stay and the caregiver was trained to prepare the same at home after discharge. All children were hospitalized for a period of two weeks or till they satisfied the WHO discharge criteria, whichever was later.

Weight was monitored daily during hospital stay, once a week for next six weeks, and monthly for next four months. Height/Length and MUAC was recorded weekly for 8 weeks and then monthly for next 4 months. The

proportion of RUTF-I (MNT) consumed and morbidity parameters (respiratory infections and diarrhea) were recorded.

Primary outcome variables were mean rate of weight gain (gm/kg/day), proportion of children achieving target weight and recovery from SAM status. The mean rate of weight gain (g/kg/day) was calculated as weight gain over a defined time period divided by the number of days. Target weight is defined by UNICEF as 15% weight gain above the baseline weight. Recovery from SAM is defined as weight for height more than – 3 SD or MUAC >115 mm, for the purpose of this study.

Statistical analysis: Children who completed at least two weeks of treatment were included in the analysis. Data from baseline, day 14, day 28, day 42, day 56, and day 180 were used for analysis. Data were analyzed using SPSS 15.0. Distribution of the rate of weight gain was not normally distributed. Hence non parametric test [Friedman test for several related data (non-parametric 2 way ANOVA)] was applied to compare mean weight gain and mean rate of weight gain at all time points. As per the requirement of the statistical test, data with all time point values were included in the analysis (Per protocol population). After getting significant difference by Friedman test, Wilcoxon Signed Rank test was applied to rate of weight gain values between two time points. All tests were two tailed. Level of significance was taken as P=0.05.

RESULTS

A total of 880 children who completed at least two weeks of intervention were included in the analysis. The details of follow up at each point in time are depicted in ***Fig*.1**. Detailed demographic data are presented in ***Table* I**. The rise in the mean weight at every follow up during intervention was more in all the RUTF-I (MNT) models as compared to the SNT model.

Model 1 (RUTF-I *vs* SNT)

A total of 129 children on RUTF-I (MNT) and 113 on SNT completed two weeks of treatment. The cumulative mean rate of weight gain was 4.5 g/kg/d in RUTF-I (MNT) group and 2.9 g/kg/day in SNT group during intervention. The mean rate of weight gain throughout the first 8 weeks was significantly higher in the RUTF-I (MNT) group compared with the SNT group (P<0.05), and it was highest in the initial 14 days (5.63 g/kg/day for RUTF-I (MNT) and 3.43 g/kg/day for SNT). It almost equalized at the end of 6 months (***Table* II**). 60.4% (78) children in the RUTF-I (MNT) group achieved the target weight as compared to 47.8% (54) in the SNT group. Of the 78 children who achieved the target weight in the RUTF-I (MNT) group, 25 (32.1%) did so in the first 2 weeks itself. In comparison, of the 54 children who achieved the target weight in the SNT group, only 2 (3.7%) did so in the first 2 weeks (***Table* III**). Recovery rate at the end of 8 weeks was 82.8% in RUTF-I (MNT) group. At the end of 8 weeks, only 17.1% children on RUTF-I (MNT) (model 1) were non-responders as against 35.4% on SNT. At the end of 6 months, only 15.1% children on RUTF-I (MNT) (model 1) were non-responders as against 33.3% on SNT (***Table* IV**). On follow up, incidence of infections were 17.1% in RUTF-I (MNT) and 30.8% in SNT (P=0.056).

Model 2 (Only RUTF-I)

Three-hundred and fifty-five children completed two weeks of treatment. The cumulative mean rate of weight gain was 3.25 gm/kg/d during intervention. The mean rate of weight gain was highest in the initial 14 days (5.67 gm/kg/day) (***Table* II**). A total of 54.3% children achieved the target weight (***Table* III**). Only 17.5% and 16.4% children were non-responders at the end of 8 weeks and 6 months, respectively (***Table* IV**).

Model 3 (Only DCC)

Seventy-one children completed two weeks of treatment. The cumulative mean rate of weight gain was 5.15 gm/kg/d during intervention. The mean rate of weight gain was highest in the initial 14 days (11.14 gm/kg/day) (***Table* II**). A total of 77.5% children achieved the target weight (***Table* III**). Only 20.7% and 17.1% children were non-responders at the end of 8 weeks and 6 months, respectively (***Table* IV**).

Model 4 (Only CMAM)

Two-hundred and twelve children completed two weeks of treatment. The cumulative mean rate of weight gain was 3.2 gm/kg/d during intervention. The mean rate of weight gain was highest in the initial 14 days (9.2 gm/kg/day) (***Table* II**). A total of 64.7% children achieved the target weight (***Table* III**). Only 18.3% and 22.4% children were non-responders at the end of 8 weeks and 6 months, respectively (***Table* IV**).

DISCUSSION

In this study, the rise in mean weight on initiation of RUTF-I (MNT) was significantly more rapid as compared to SNT. The mean rate of weight gain was maximum and statistically significant at 2 weeks in all RUTF-I (MNT) models as compared to the SNT model. It was maximum for DCC, probably due to the supervised feeding throughout the intervention period, followed by

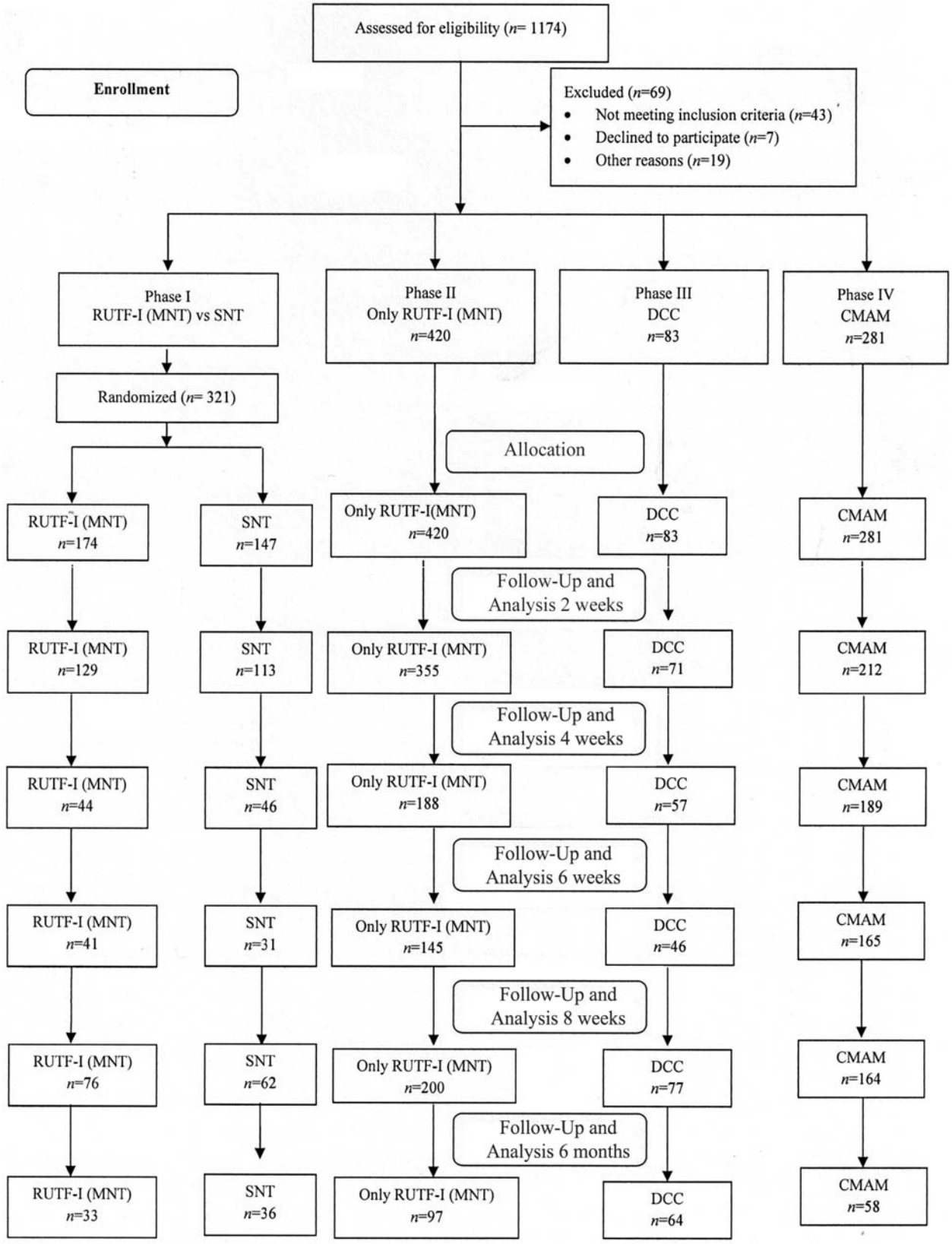

FIG. 1 *Flow of participants in the study.*

TABLE I DEMOGRAPHIC AND ANTHROPOMETRIC PARAMETERS

	RUTF-I (MNT) with SNT		*Only RUTF-I (MNT)(n=420)*	*DCC (n=127)*	*CMAM (n=281)*
	RUTF-I (MNT) (n=174)	*SNT (n=147)*			
Age					
Median (mo)	23.28	29.01	19.83	20	26
6 mo - 1 y	52 (29.8%)	54 (36.7%)	158 (37.6%)	46 (36.2%)	64 (22.7%)
1-3 y	91 (52.2%)	59 (40.1%)	212 (50.4%)	57 (44.8%)	151(53.7%)
3-5 y	31 (17.8%)	34 (23.1%)	50 (12%)	24 (18.8%)	66 (23.4%)
Male sex	85 (48.8%)	67 (45.5%)	213 (50.7%)	60 (47.2%)	141 (50.1%)
Anthropometry					
Weight (kg), mean (SD)	6.7 (1.8)	6.76 (2.9)	6.53	7.25	7.46
Height (cm), mean (SD)	73.6 (10.2)	75.4 (13.4)	71.4	74.2	77.3
MUAC (cm), mean (SD)	11.2 (1.2)	11.6 (1.7)	11.4	-	-

RUTF-I (MNT): Indigenous Ready to use therapeutic food; SNT: Standard nutrition therapy; DCC: Day care centre; CMAM: Community management of acute malnutrition.

TABLE II MEAN WEIGHT AND RATE OF WEIGHT GAIN

	Groups	*Parameters monitored*	*On admission*	*2 wks*	*4 wks*	*6 wks*	*8 wks*	*6 mo*
Model 1	RUTF-I (MNT)	Mean weight (kg)	6.70	7.22	7.26	7.67	7.93	8.92
		Rate of weight gain (g/kg/d)		5.63	4.72	4.22	3.45	1.75
	SNT	Mean weight (kg)	6.76	7.07	6.83	7.18	7.29	8.05
		Rate of weight gain (g/kg/d)		3.43	2.82	2.98	2.38	1.67
	P value (rate of weight gain)			<0.05	<0.05	<0.05	<0.05	
Model 2	Only RUTF-I (MNT)	Mean weight (kg)	6.54	6.95	7.24	7.36	7.65	8.36
		Rate of weight gain (g/kg/d)		5.67	2.25	3.01	2.01	1.65
	P value (rate of weight gain)		<0.001					
Model 3	DCC	Mean weight (kg)	7.25	8.25	8.52	8.89	8.68	8.32
		Rate of weight gain (g/kg/d)		11.14	4.92	3.77	0.82	0.06
	P value (rate of weight gain)		<0.001	0.01				
Model 4	CMAM	Mean weight (kg)	7.45	8.42	8.61	8.69	8.78	9.38
		Rate of weight gain (g/kg/d)		9.20	1.56	0.91	1.12	0.44
	P value (rate of weight gain)		<0.001					

Only significant P values are mentioned.

TABLE III PROPORTION OF CHILDREN ACHIEVING TARGET WEIGHT AT DIFFERENT TIME INTERVALS

	Model 1		*Model 2*	*Model 3*	*Model 4*
Time frame	*RUTF-I (MNT)* (*n*=129)	*SNT* (*n*=113)	*Only RUTF-I (MNT)* (*n*=355)	*DCC* (*n*=71)	*CMAM* (*n*=212)
2 weeks	25 (19.3%)	2 (1.8%)	49 (13.8%)	32 (45.1%)	59 (27.9%)
4 weeks	11 (8.5%)	8 (7.1%)	37 (10.4%)	10 (14.1%)	24 (11.3%)
6 weeks	13 (10.0%)	10 (8.8%)	32 (9.0%)	2 (2.8%)	21 (9.9%)
8 weeks	9 (6.9%)	7 (6.2%)	36 (10.1%)	7 (9.8%)	20 (9.4%)
6 months	20 (15.5%)	27 (23.9%)	39 (10.9%)	4 (5.6%)	13 (6.1%)
Total	78 (60.4%)	54 (47.8%)	193 (54.3%)	55 (77.5%)	137 (64.7%)

WHAT IS ALREADY KNOWN?

- RUTF is a medical treatment for Severe Acute Malnutrition recommended by UNICEF and WHO.

WHAT THIS STUDY ADDS?

- Indigenously prepared RUTF is feasible and effective in SAM management, not only in facility-based but also in community-based care, both in supervised and unsupervised settings.

TABLE IV NUTRITIONAL STATUS AT 8 WEEKS AND 6 MONTHS

	Groups	*Nutritional status*	*8 wks*	*6 mo*
Model 1	RUTF-I	*n*	76	33
	(MNT)	SAM	13 (17.1%)	5 (15.1%)
		MAM	32 (42.1%)	9 (27.3%)
		Normal	31 (40.7%)	19 (57.6%)
	SNT	*n*	62	36
		SAM	22 (35.4%)	14 (33.3%)
		MAM	28 (45.1%)	8 (22.2%)
		Normal	12 (19.3%)	16 (44.4%)
Model 2	Only RUTF-I	*n*	200	97
	(MNT)	SAM	35 (17.5%)	16 (16.4%)
		MAM	90 (43.5%)	47 (48.4%)
		Normal	75 (37.5%)	34 (36.0%)
Model 3	DCC	*n*	77	64
		SAM	16 (20.7%)	11 (17.1%)
		MAM	33 (42.8%)	29 (45.3%)
		Normal	28 (36.3%)	24 (37.5%)
Model 4	CMAM	*n*	164	58
		SAM	30 (18.3%)	13 (22.4%)
		MAM	72 (43.9%)	23 (39.6%)
		Normal	62 (37.8%)	22 (37.9%)

SAM: Severe acute malnutrition; MAM: Moderate acute malnutrition.

CMAM and facility-based models. It decreased steadily over 8 weeks and furthermore till 6 months, but remained generally higher in the RUTF-I (MNT) group compared with the SNT group. After the initial rapid weight gain in the first 2 weeks, there was a plateau effect, which was reflected as the decrease in the rate of weight gain beyond 2 weeks. This was observed in all four study models. Target weight was achieved in a larger proportion of children on RUTF-I (MNT) throughout with statistical significance up to 6 weeks. Majority of children on RUTF-I (MNT) achieved their target weight in the first two weeks itself, whereas among children on SNT, majority achieved their target weight at the end of 6 months. The rate of recovery from SAM status was higher in all RUTF-I (MNT) groups as compared to SNT group throughout.

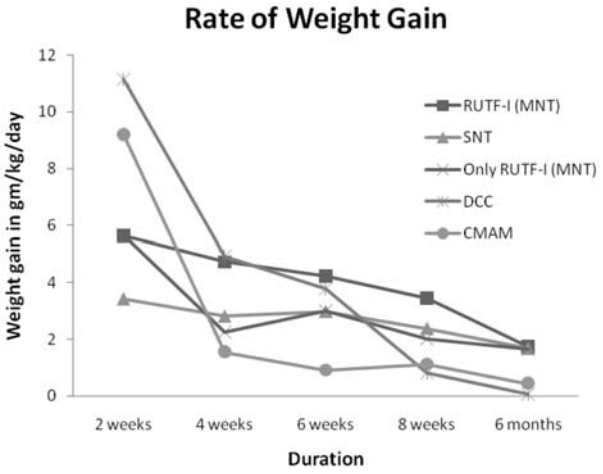

Fig. 2*: Rate of weight gain in children with SAM managed with different models of nutrition therapy.*

Limitations of our study were: (*i*) children in the facility-based model were not supervised daily for RUTF-I (MNT) consumption after discharge from hospital; (*ii*) no ration/ financial assistance were provided in SNT group; (*iii*) the default rate at 8 weeks was high; (*iv*) average RUTF-I (MNT) consumption was less (20%- 60%); and (*v*) the duration of hospital stay was not analyzed.

The cumulative mean rate of weight gain in our study was more than that reported by Cliberto, *et al.* [7] (2.8 g/kg/d), but lesser than that reported by other authors [8-10]. Patel, *et al.* [11] showed a weight gain of 9 g/kg/day during hospital stay and 3.2 g/kg/day during home-based follow-up, comparable to our study. Recovery rate at the end of 6 months in RUTF-I (MNT) group (84.8%) was comparable to 88.5% reported by Gera, *et al.* [12].

We conclude that RUTF-I (MNT) has an early, rapid and sustained impact in improvement of nutritional status in a community setting as well as in a facility-based model.

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Contributors: AJ: designed the study, .supervised the trial and contributed to preparation of manuscript; PK: supervised the

trial and wrote the first and final draft of manuscript; LF: supervised the functioning of the production unit and assisted in final draft of manuscript; SF: data collection, assisted in statistical analysis; NS: designed the study trial and setting up of production unit; MM: designed the study trial and supervised the trial.

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