

A study to assess the impact of medical nutrition therapy compared to standard nutrition therapy in children with severe thinness in the age group of 5 to 10 years

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Abstract

Aim: The aim of our study was to study and compare the impact and efficacy of medical nutrition therapy (MNT) with that of the standard nutrition therapy (SNT) in children diagnosed with Severe thinness in the age group of 5-10 years and diagnosed as severely thin. **Study Design:** It was a prospective comparative study, conducted over a period of 18 months at the Nutrition Rehabilitation, Research and Training Centre (NRRTC) associated with a tertiary care hospital in India. **Methods and Materials:** A total of 113 children in the age group of 5 to 10 years with severe thinness were enrolled and divided into 2 groups—58 were placed in the MNT group and 55 in the SNT group for a period of 8 weeks. The children in both groups received MNT and SNT diet over the said period of 8 weeks. Primary outcome variables were weight gain and body mass index (BMI) (i.e., change in nutritional status). **Results:** At the end of 8 weeks, the rate of weight gain (gm/kg/day) was significantly greater in the MNT group, that is, 2.35 gm/kg/day as compared with the SNT group, that is, 0.73 gm/kg/day, and the change in nutritional status was significantly better in the MNT group ($p < 0.001$) with 62.1% achieving normal nutritional status, 32.8% remaining thin, and 5.2% remaining severely thin as compared to the SNT group in which 9.1% achieved normal nutritional status, 65.5% remained thin, and 25.5% remained severely thin. **Conclusion:** To conclude, MNT is superior to SNT for the treatment of severe thinness (ST).

Keywords: BMI (body mass index), MNT (medical nutrition therapy), SAM (severe acute malnutrition), severe thinness (ST)

INTRODUCTION

The World Health Organization (WHO) describes nutrition as “the intake of food, considered in relation to body’s dietary needs” and good nutrition is the key determinant of health.^[1] When food intake is not in balance with body’s dietary needs, malnutrition occurs. Malnutrition can be expressed in terms of thinness or obesity. Thinness is defined by WHO as the percentage of defined population with a body mass index (BMI) between < -2 SD and ≥ -3 SD below the median according to the WHO child growth standards. A BMI < -3 SD or presence of bipedal edema were designated as severe thinness (ST).^[2] Globally, the incidence of thin and severely thin cases was 192 million in 2016.^[3]

The incidence of children who were stunted and severely wasted were 38.4% and 7.5%, respectively, as per National Family Health Survey (NFHS-4).^[4] The prevalence and

demographic characteristics of severely thin children above 5 years have not been studied widely. Thinness in school children and adolescents is largely understudied, contrasting with the vast amount of literature on infant malnutrition.

Ready-to-use therapeutic food (RUTF) or medical nutrition therapy (MNT) contains nutrients in required amounts that can be used in malnourished children. Optimal nutritional

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status supports immune system and reduces the risk of frequent infection. MNT has shown promising results in the management of severe acute malnutrition (SAM). The effect of MNT on severely thin children is not well evaluated, and it is a research gap that has to be filled.

METHODS AND MATERIALS

This prospective comparative study comparing the efficacy of MNT with that of standard nutrition therapy (SNT) in children diagnosed as severely thin was conducted for a period of 18 months (May 2015 to November 2016) at the Nutrition Rehabilitation, Research and Training Centre (NRRTC) associated with a tertiary care hospital in India. The study was conducted after the Institutional Ethics Committee clearance was obtained. The study was registered in Clinical Trials Registry India (CTRI/2018/03/012440). The subjects were admitted during the first 2 weeks of the study and were followed up weekly over a period of 8 weeks. The study was hospital-based and included a follow-up home-based care under the supervision of NRRTC.

The study details were explained to the subject's parent/guardian along with a patient information sheet. Written informed consent from parent/guardian and assent of subject was taken. Demographic details and chief complaints like fever, weight loss, cough, diarrhea, and any other issue were noted in predesigned proforma. Past history of tuberculosis/contact was enquired.

Clinical examination was done with special attention to anthropometry, that is, weight and height. The weight was recorded using a standard electronic weighing scale with an accuracy of 10 gm. The height measurement was performed using a 1-mm precision portable stadiometer. The BMI was measured using the formula: weight (kg)/height (meter),^[2] and nutritional status was categorized as per WHO 2007 standard growth charts.^[2] Malnutrition was classified according to the WHO guidelines taking only the BMI parameter provided those in the age group 5 and 12 years. BMI <-3 SD or bipedal edema were designated as ST and comprised the potential study population.

Detailed history of the subjects was obtained. A complete clinical examination of subjects at the time of admission, including vitals, general examination, and a detailed anthropometry with WHO classification for malnutrition and systemic examination, was done. All admitted children were subjected to anthropometry, that is, weight and height. BMI was calculated and scrutinized as per WHO standard growth charts 2007. These details were filled in a predesigned case record form.

After obtaining the informed consent/assent, the children were subjected to an appetite test. They were given the amount of MNT food to be eaten in one sitting as per the appetite test chart.^[5] If they ate the minimum necessary amount of MNT food, they were considered as *pass*. All Severely thin children were enrolled

in the study on their passing the appetite test.^[5] The amount of MNT food to be consumed to pass the appetite test is shown in Table 1.^[5] Those with chronic illness, on nutritional supplements, known immune-compromised state, TB, and those who failed the appetite test were excluded from the study. The demographic characteristics of both study groups were comparable.

A total of 113 children were enrolled in the study and were divided into two groups: MNT group ($n = 58$) and SNT group ($n = 55$). As per WHO-UNICEF 2009 protocol, the MNT group children were given MNT food daily for a period of 8 weeks based on an MNT delivery chart along with nutritional counseling. Those in the SNT group were given SNT food daily for a period of 8 weeks. Both groups received nutritional counseling.

SNT counseling was structured on the following principles.

- Minimum meal frequency.
- Minimum dietary diversity.
- Emphasis on family-based low-cost, high-protein, and energy-yielding food appropriate to the community and socioeconomic background.

SNT consisted of a high-protein and high-calorie diet comprising boiled eggs, banana, rice-green gram porridge with vegetables, jiggery, vegetable paratha, and cooking oil. The diet provided 175 kcal/kg/day with a total nutritional value of 100 kcal with a protein content of 3 gm per 100 gm.

MNT food was prepared indigenously in the production unit. The equipment used for the production included a motorized grinder, planetary mixer, and a filling and sealing machine. The constituents of the MNT food included peanut paste (25%), skimmed milk powder (24%), powdered sugar (28%), soya bean oil (20.8%), micronutrients (1.6%), and emulsifiers (0.6%) as per WHO recommendations on RUTF composition. MNT food is rich in various micronutrients like calcium, magnesium, selenium, and fat-soluble and water-soluble vitamins.^[6] Then the food was ground to achieve a particle size up to 300 micron and packaging with nitrogen flush. The nutritional value of a 92-gm sachet was 560 kcal and 14.6 gm of protein.^[6]

Table 1: Appetite test. To pass the appetite test the MNT consumed has to at least in moderate range

Body weight (KG)	Poor	Moderate	Good
3-3.9	≤ 15	15-20	>20
4-5.9	≤ 20	20 - 25	>25
6-6.9	≤ 20	20 - 30	>30
7-7.9	≤ 25	25 - 35	>35
8-8.9	≤ 30	30 - 40	>40
9-9.9	≤ 30	30 - 45	>45
10-11.9	≤ 35	35 - 50	>50
12-14.9	≤ 40	40 - 60	>60
15-24.9	≤ 55	55 - 75	>75
25-39	≤ 65	65 - 90	>90
40-60	≤ 70	70 - 100	>100

MNT group children were given MNT food daily for a period of 8 weeks along with nutritional counselling. The compliance of MNT was noted at each follow-up visit. The quantity of MNT food to be consumed is as per the MNT delivery chart given in Table 2.^[5]

The SNT group children were given SNT food and nutritional counselling. All the children enrolled in the study were shifted to home-based diet after 8 weeks of either SNT or MNT.

The subjects were monitored and followed up every week for a period of 8 weeks (duration of MNT received). A detailed anthropometric examination along with clinical examination and nutritional counseling were given to children at each visit during follow-up. Details were maintained in our case record form.

Statistical analysis

Data were analyzed using the SPSS software (version 15.0). Data were given as mean and standard deviation (SD) for quantitative variables and number and percentage for qualitative variables. A Student's unpaired *t* test was applied to compare between group 1's and group 2's quantitative data. Chi-square test was applied to compare percentages of qualitative data. Chi-square test with continuity correction was applied to compare values in 2 X 2 Tables. If the cell values in 2 X 2 values are small, Fisher Exact Probability test was applied. Students paired *t* test was applied to compare means at two time points. All tests were two-tailed. Level of significance was taken as $P < 0.05$ (S = significant, NS = not significant, P = probability value, *df* = degrees of freedom, NA = not applicable).

RESULTS

The detailed baseline demographics of subjects enrolled in the study are depicted in Table 3. Of the total 113 subjects

enrolled in the study, 58 were placed in the MNT group and 55 in the SNT group. The children in both the MNT group and SNT group were severely thin with a BMI of less than -3 SD. The mean weight of those in the MNT group at the time of enrolment and at 8 weeks post-MNT was 14.28 ± 2.67 kg and 16.65 ± 3.19 , respectively. The mean weight of SNT group at the time of enrolment and 8 weeks post-SNT was 14.74 ± 2.91 kg and 15.46 ± 3.00 kg, respectively. The mean weight gain (grams/day) was more in MNT group (i.e., children who received the MNT diet) compared to the SNT group throughout the 8-week study period. The mean weight gain (grams/day) was maximum in the first 2 weeks from the time of enrolment (67.86 ± 38.76 gm), which was statistically significant ($t = 8.9$, $P < 0.001$). The mean rate of weight gain values (grams/kg/day) recorded between enrolment (or the start of the study period) and up to 2 weeks, 4 weeks, 6 weeks, and 8 weeks into the study period were statistically significant as depicted in Table 4. The MNT group had a statistically significant higher weight gain in grams/kg/day at all timeframes except between weeks 5 and 6 of the study period, during which time the weight gain continued to be high but statistically nonsignificant [Table 4]. The mean height in cm recorded for the MNT group and the SNT group was, respectively, 111.32 cm and 112.99 cm on enrolment; 111.80 cm and 113.33 cm after 4 weeks; and 112.32 cm and 113.58 cm after 8 weeks. The overall increase in height (cm) measured from the time of enrolment up to the completion of the 8-week study period for the MNT group and the SNT group was 1.00 ± 0.45 cm and 0.59 ± 0.27 cm, respectively, which was statistically significant with $t = 6.0$ and $P < 0.001$ [Table 5].

There was a statistically significant increase in BMI between enrolment and the completion of the 8-week study period in the MNT group as compared to the SNT group, except between enrolment and 4 weeks into the study as shown in Table 6.

A flow chart of all subjects, including those lost to follow-up, is depicted in [Figure 1]. The change in nutritional status was highly significant in the MNT group ($P < 0.001$) with 62.1% achieving normal nutritional status as compared to 9.1% in the SNT group and only 5.2% remained severely thin as compared to the 25.5% in the SNT group, as depicted in [Figure 2].

The compliance rate of the MNT group was compared with its rate of weight gain between enrolment and the cessation of the 8-week study period. The increase in the percentage of consumption in the MNT group, from low to 30%, 30% to 40%, 40% to 50%, and greater than 50% showed a faster rate of weight gain, as depicted in Table 7.

DISCUSSION

The present study was conducted to assess the effectiveness of MNT in children with ST on the basis of its effect on the anthropometric parameters such as weight, height, and BMI. Blanket as well as targeted supplementary feeding program, midday school meal program, food fortification, micronutrient supplementation, and take-home ration have been studied

Table 2: Recommended MNT chart for SAM child as per present weight

Class of weight (kg)	Total amount of MNT/day (grams)	8 Feeds (grams)	6 Feeds (grams)	5 Feeds (grams)
3.0-3.4	125	15	20	25
3.5-3.9	130	15	22	30
4.0-4.9	175	20	28	35
5-5.9	195	25	35	35
6.0-6.9	225	30	40	45
7.0-7.9	275	35	45	55
8.0-8.9	330	40	60	60
9.0-9.9	330	40	55	65
10.0-11.9	385	50	65	75
12.0-14.9	480	60	80	95
15.0-19.9	600	75	100	120
20.0-24.9	710	90	120	140
30-39.9	930	115	160	180
40-60	1090	135	180	220

Table 3: Baseline demographics and anthropometric values recorded at the time of enrolment

		Group 1 (MNT group) (n=58)	Group 2 (SNT group) (n=55)	t, significance, and P
Demographics	Age (months)	85.02±18.79	87.85±15.04	t=0.9, ns, P=0.35
Gender (n [%])	Male	30 (51.7%)	23 (41.8%)	F=0.35, df=1, ns, P=0.35
	Female	28 (48.3%)	32 (58.2%)	
Anthropometric measures	Weight (Kg)	14.28±2.67	14.74±2.91	t=0.9, ns, P=0.4
	Height (Cm)	111.32±9.80	112.99±10.23	t=0.9, ns, P=0.4
	BMI	11.48±0.65	11.53±0.48	t=0.2, ns, P=0.8

Table 4: Weight parameters during study**Comparison of mean rate of weight gain (gm/kg/day) between the MNT group and the SNT group**

Time period	MNT group	SNT group	t and P
Enrolment to 1 week	5.03±3.41	0.87±2.32	t=6.8, significant, P<0.001
1 week to 2 weeks	4.33±3.67	1.52±1.38	t=5.3, significant, P<0.001
2 weeks to 3 weeks	2.77±2.73	0.68±1.66	t=4.9, significant, P<0.001
3 weeks to 4 weeks	1.84±2.97	0.77±1.36	t=2.5, significant, P=0.02
4 weeks to 5 weeks	2.89±3.89	0.90±1.28	t=3.6, significant, P<0.001
5 weeks to 6 weeks	1.96±2.89	1.13±1.70	t=1.9, nonsignificant, P=0.07
6 weeks to 7 weeks	1.92±2.81	0.42±1.79	t=3.4, significant, P=0.003
7 weeks to 8 weeks	2.93±3.06	0.93±1.31	t=4.5, significant, P<0.001
Enrolment to 2 weeks	4.68±2.61	1.19±1.41	t=8.8, significant, P<0.001
Enrolment to 4 weeks	3.49±1.63	0.96±0.99	t=9.9, significant, P<0.001
Enrolment to 6 weeks	3.14±1.43	0.98±0.89	t=9.6, significant, P<0.001
Enrolment to 8 weeks	2.35±1.08	0.73±0.67	t=9.6, significant, P<0.001

Table 5: Height changes recorded for the two groups during the study period**Overall increase in height in centimeters during study period of 8 weeks in the MNT group and the SNT group**

Time period	MNT group	SNT group	t and P
Enrolment to 4 weeks	0.48±0.27	0.33±0.15	t=3.4, significant, P<0.001
Enrolment to 8 weeks	1.00±0.45	0.59±0.27	t=6.0, significant, P<0.001

in children in large numbers, and these studies were carried out for the entire population group without classifying them into *thin* or *severely thin* categories based on anthropometric parameters. Studies on RUTF targeted severely malnourished children below 5 years of age and in adults who were severely thin, but we haven't come across any study so far that targeted

children in the age group of 5 to 10 years who were severely thin and with risk factors similar to those observed in cases of severely acute malnutrition.

The rate of weight gain (grams/kg/day) is an important criterion used by various studies and national programs to determine the efficacy of nutritional supplementation (RUTF/home-based supplementation). One study that compared home-based therapy with RUTF with standard therapy in the treatment of malnourished Malawian children aged below 5 years showed a weight gain of 3.5 gm/kg/day in the RUTF group as compared to the weight gain of 2 gm/kg/day observed in the standard therapy group over a period of 8 weeks.^[7] In our study, we recorded a weight gain of 2.5 gm/kg/day in the MNT group and 0.73 gm/kg/day in the SNT group over a period of 8 weeks. The standard rate of weight gain decreased after the age of 2 years. In our study, the mean age of participants was more than 85 months, and a lower rate of weight gain is expected therefore, which is still significant. Similar observations were also noted by Patel MP *et al.* (3.1 gm/kg/day),^[8] Ciliberto MA *et al.* (2.8 gm/kg/day),^[9] Diop EHI (15.6 gm/kg/day),^[10] Manary MJ (5.2 gm/kg/day),^[11] and Thakur *et al.* (9.59 gm/kg/day).^[12]

The MNT improved the nutritional status of children from the status of *severely thin* to *normal* in 62.10% of the study group, with only 5.2% remaining *severely thin* at the end of the 8-week study period. This is in sharp contrast to children in the SNT group, where only 9% of them attained a normal BMI and 25% remained *severely thin* at the end of the study. We consider this a very significant achievement and can attribute it to energy-dense lipid-rich content of RUTF which plays an important role in recovering the wasted lean tissue. RUTF requires minimal parental supervision and it is easy to consume with fewer chances of contamination. It can be easily stored at home. RUTF provides all the nutrients to regain appetite, has a good shelf life, and easy to deliver, administer, and use. It is safe to use and doesn't need refrigeration for storage at home. It can be stored in various climatic conditions and is resistant to bacterial contamination. It provides an array of micronutrients that help in the restoration of appetite and counteracts free radical damage caused by malnutrition. It is culturally acceptable and can be served in single-serve packets.^[13] An MNT food packet costs Rs. 75, and spending Rs. 75 per MNT food packet to improve the nutritional and functional status in malnourished population is a way more sensible and cost-effective option than incurring huge

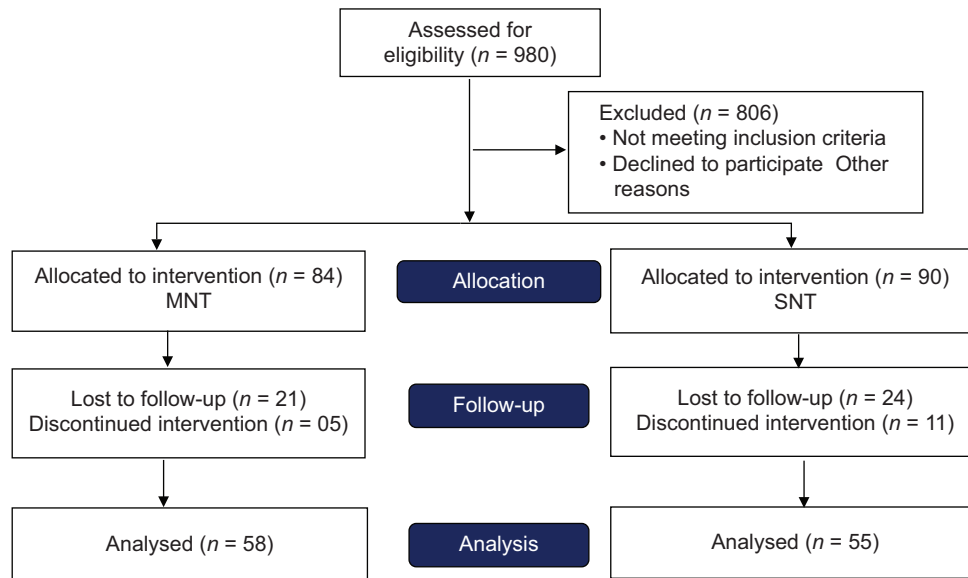


Figure 1: Flowchart for subject assessment, including lost to follow-up

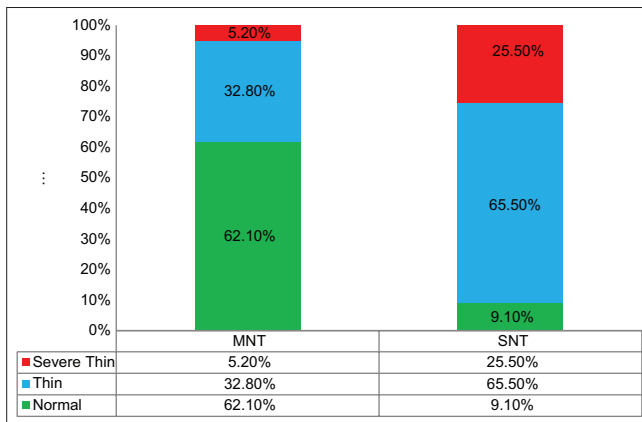


Figure 2: Nutritional outcome between the MNT group and the SNT group at the end of the 8-week study period

expenses via hospitalization to restore their nutritional status comparable to that of an average healthy individual. Children have an additional advantage of frequent contact with nutrition specialists when targeted for nutritional supplement interventions. This might improve their malnourished status through closer monitoring, follow-up, and nutritional and hygienic counselling. Thus, children on MNT showed a better rate of nutritional recovery than their counterparts in the SNT group. Long-term effects of RUTF on anthropometric parameters and metabolic syndrome are not known. A detailed assessment of malnourished children's antioxidant levels, biochemical levels, and changes in body composition assay needs to be carried out. Not using randomization of subjects is a limitation in this study.

CONCLUSION

We conclude that indigenously prepared MNT/ready-to-use therapeutic food (RUTF) is definitely superior in promoting

Table 6: BMI changes

Gain in BMI recorded for the MNT group and the SNT group from enrolment to the end of the 8-week study period

Time period	MNT group (n=58)	SNT group (n=55)	P
Enrolment to 2 weeks	0.72±0.45	0.21±0.20	t=7.8, significant, P<0.001
Enrolment to 4 weeks	1.07±0.59	0.64±1.69	t=1.8, nonsignificant, P=0.07
Enrolment to 6 weeks	1.37±0.75	0.50±0.44	t=7.5, significant, P<0.001
Enrolment to 8 weeks	1.71±0.94	0.74±0.45	t=6.9, significant, P<0.001

Table 7: Compliance of MNT with the rate of weight gain

Percentage of MNT food consumed	Mean rate of weight gain
Low to 30% (n=7)	0.14
30 to 40% (n=26)	0.16
40 to 50% (n=17)	0.18
>50% (n=8)	0.19

rapid weight gain and has a significantly better nutritional outcome (achieving normal nutritional status).

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Conflicts of interest

There are no conflicts of interest.

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