Original Article

Efficacy of Locally Adapted Dietary Regimen in the Treatment of Nutritional Marasmus: A Randomized Control Trial

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Abstract:

Food-based strategies are currently in practice to meet the challenges of micronutrient malnutrition in malnourished children. World Health Organization (WHO) proposed a dietary regimen for such therapy. In resource limited country like Bangladesh, it is difficult to implement the WHO protocol properly. Current study aimed at evaluating the locally adapted peanut based Dhaka Medical College Hospital (DMCH) dietary formula in the treatment of nutritional marasmus. The trial was conducted in Dhaka Medical College Hospital (DMCH) from July 2009 to June 2010. Sixty marasmic patients (based on WHO criteria) admitted in the hospital aged 06 to 59 months who meet the inclusion criteria were enrolled. Children with major congenital anomalies, children having feeding difficulty and bi-pedal edema, severe anemia, severe dehydration, TB, congestive heart failure with shock, critically sick child were excluded. Children were allocated with one of the dietary formula (DMCH regimen or WHO regimen) randomly by box of eight randomization protocol. Both groups were managed in two phase's i.e. initial phase and rehabilitation phase. In the initial phase starter formula was used and during the rehabilitation phase catch-up formula was given. Heath and nutritional education for mother and caregiver was given, Non-immunized children were immunized and discharge was given after fulfilling the criteria. Independent t tests were applied to compare outcome of treatment. Child receiving DMCH regimen took on average 3.47 days to return to smile the time was 4.47 in WHO regimen group (P< 0.01). Rate of weight gain was also higher in the group by around 2.66 gm/kg/day. In DMCH group the time taken to achieve target weight was 13.4 days which was around one day more than that of WHO group (14.3 days). Total amount of F-75 was also required less in WHO group. Most importantly daily treatment cost was higher by around 17 BDT per day in WHO regimen group. Neither of the group experienced any serious adverse effect or fatality. Locally made peanut based DMCH protocol is more efficacious than the WHO regimen for treatment of treatment of nutritional marasmus in the age group 6 months to 59 months.

Key word: Malnutrition, Nutritional marasmus, Peanut based regimen, DMCH regimen, DMCH regimen, RCT

Introduction:

Rates of malnutrition in Bangladesh are among the highest in the world. More than 54% of preschool-age children, equivalent to more than 9.5 million children, are stunted, 56% are underweight and more than 17% are wasted.[1] Malnutrition is a major contributing factor in nearly 60% of deaths in children[2] and those who are severely malnourished and admitted to hospital face a 30-50% case fatality rate.[3] The evidence base for effective prevention and treatment is incontrovertible, but it is not put into practice. Several studies worldwide show that the median case fatality rate has not changed for the past five decades, and that one in four severely malnourished children died during treatment in the 1990s. In any decade, however, some centers obtained good results with fewer than 5% dying, whereas others fared poorly with a mortality rate of approximately 50%.[4] With appropriate treatment, as described in these guidelines, this unacceptably high death rate can be reduced to less than 5%. The evidence base for effective prevention and treatment is incontrovertible, but it is not put into practice. Several studies worldwide show that the median case fatality rate has not changed for the past five decades, and that one in four severely malnourished children died during treatment in the 1990s.

The challenging nutritional management is often overlooked and underestimated, resulting in an impairment of the chances for recovery. The social and economic implications of PEM and its complications are incalculable. Severely malnourished children have a high mortality rate. Even in the 1990s, mortality rates as high as 49% have been reported for malnourished children in hospitals.[5] Optimum management of these acutely ill children and a good outcome depends on an evidence based prescriptive regimen of care.[6] Almost all severely malnourished children have infections, impaired liver and intestinal function, and problems related to imbalance of electrolytes when first admitted to hospital. Because of these problems, they are unable to tolerate the usual amounts of dietary protein, fat and sodium. It is important, therefore, to begin feeding these children with a diet that is low in these nutrients and high in carbohydrate, WHO proposed a dietary regimen for such therapy. In resource limited country like Bangladesh, it is difficult to implement the WHO protocol properly. Dhaka Medical

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College Hospital has its own protocol for the management of severe malnutrition. This study was conducted to determine effectiveness of locally adapted DMCH dietary regimen (F-75 and F-100 peanut based) as compared to WHO regimen for the management of marasmus in a selected tertiary care centre.

Materials and Methods:

The trial was conducted in Dhaka Medical College Hospital (DMCH) from July 2009 to June 2010. Sixty marasmic patients (Weight for length/height equal and or less than -3SD of the median WHO references) admitted in the hospital aged 06 months to 59 months who meet the inclusion criteria were enrolled in the study. Children with major congenital anomalies, Children having feeding difficulty and bi-pedal edema, severe anemia, severe dehydration, TB, Congestive heart failure with shock, Critically sick child (who needs of assistant ventilation, Cyanosis with 40% oxygen, RR > 80/ min, Severe chest indrawing, audible grunting at the time of admission) were excluded from the study. The WHO standards were used to determine the nutritional status of children. The standard deviation or Z- scores of weight for height/length (WHZ) was calculated using the following calculation = (individual value - median value of the reference population)/SD value of the reference population.

Dietary regimen

	DMCH Dietary regimen Peanut based	WHO Dietary regimen Standard regimen
Starter formula (F-75)	Milk powder=30 gm, Sugar=105gm Oil=20gm/ml, peanut=05gm Water up to 1000ml (Protein=0.9gm/100ml)	Milk powder=35 gm, Sugar=100gm, Mineral mix=20ml, Water=1000ml.
Catch - up formula (F-100)	Milk powder=70gm, Sugar=65gm, Oil=35gm/ml, Peanut=25gm Water up to 1000ml	Milk powder= 110gm, Sugar=50gm, Oil=30ml/gm Mineral mix=20ml Water=1000ml.

The electrolytes and mineral

Mineral was mixed with WHO dietary regimen. Electrolytes and mineral were supplied separately from locally available sources in DMCH group. Potassium 3-4 mmol/kg/day, Magnesium 0.4-0.6 mmol /kg/day, Multivitamin supplementation, Folic acid 1mg/day(5mg on day one), Zinc 2mg/kg/day, Elemental iron 3mg/kg/d only once child starts gaining weight usually for day 7 1 and onwards. 20ml of electrolyte mineral solution was to added 1000ml of milk food.

Enrolled children were randomized into two groups, and were allocated with one of the dietary formula (DMCH regimen or WHO regimen) randomly by box of eight lottery method. Both groups were managed in two phase's i.e. initial phase and rehabilitation phase. In the initial phase starter formula was used and during ther rehabilitation phase catch-up formula was given. During rehabilitation phase both group of patient take extra food like fruits and eggs and also breastfeeding was encouraged. A cheerful stimulation, structured play therapy for at least 30 minutes per day in Ashic play centre, physical activity and tender love care. Heath and nutritional education for mother and caregiver was given, Non immunized children were immunized and discharge was given after fulfilling the criteria. Senior staff nurses working in the study unit were trained on the specific management protocol before starting the study. Three senior staff nurses were involved for supervising feeding regimen and helping during anthropometric measurement. Follow-up was given twelve hourly by the author himself. One nutritionist was involved for dietary advice. Infection was controlled by using syp. Cotrimoxazole, inj. Ampicillin, Syp. Amoxicillin and inj. Gentamycine. Inj. Chloramphenicol and occationally inj. Metronidazole and ciprofloxacillin as and when needed.

Discharge criteria was for child absence of infection, eating at least 120-130 Kcal/Kg/d, weight for height/ length is -2SD, persistent weight gain on exclusive oral feeding, caretakers are sensitized to home care. The baby was discharged from the hospital when clinically stable, antibiotic course complete, taking full feed by spoon or sucking or taking food orally and gaining target weight -2SD, i.e. Weight for height /length = -2SD.

Formula for Weight gain in gm/kg/day=

$$\frac{(W2 - W1) \times 1000}{(W1 \times \text{Number of days from W1 to W2})}$$

W1: Initial or lowest weight in kg. W2 = Weight in Kg on the day of calculation

The collected data were analyzed thoroughly by SPSS program version of 16.0 software. In addition to descriptive statistics such as frequency tabulation, mean, standard deviation; Chi-square test for qualitative variables and student's t tests for continuous variables were applied to determine statistical significance.

Results:

Baseline characteristics

A total of 60 children were enrolled for the trial, 30 in each group. In DMCH group 30(93.74%) continued till the end, one withdrew from the study. Children in WHO group 29 (90.6%) continued till the end, one was discharged on request. None died in either of the groups. No statistically significant different was found in baseline characteristics and demography in two randomly allocated groups. (Table 1&2) Among the mothers in DMCH group around one third are illiterate, half studied up to primary level and 16.7% had SSC or above level of education. In WHO group around two third studied up to primary level, around one fourth had no formal education and only 6.7% studied up to SSC or above level of education.

Table 1: Baseline characteristics

Parameters	DMCH		WHO		Analysis	
	Mean	SD	Mean	SD	t	P value
Age(Months)	17.39	8.58	21.50	12.78	1.46	0.150
Wight (Kg)	0506	1.28	5.83	1.51	2.13	0.057
Length/Height(Cm)	67.53	6.19	71.05	8.34	1.85	0.069
MUAC(Cm)	09.82	1.12	10.18	0.89	1.35	0.182

Table 2: Distribution of sex and residence

	DMCH	WHO	Total	Analysis
Sex				
Male	14 (46.7%)	13 (43.3%)	27 (45.0%)	$Ç^2$=.07 p=.79
Female	16 (53.3%)	17(56.7%)	33 (55.0%)	
Residence				
Urban	5 (16.7%)	3 (10.0%)	8 (13.3%)	$Ç^2$=.59 p=.75
Slum	22 (73.3%)	24 (80.0%)	46 (76.7%)	
Rural	03 (10.0%)	3 (10.0%)	6 (10.0%)	

Characteristics of the child

In both DMCH and WHO group most had two or less siblings. Prevalence of exclusive breastfeeding was also similar in both groups. Similar inference goes to age of complementary feeding. Distribution of formula feeding is indifferent in two groups (P>0.05). Almost similar fraction of subjects in two groups has completed immunization and majority in both groups had received Vitamin A supplementation. (Table 3). Around eighty percent in both the group had mild pallor; Majority had respiratory rate and heart rate within normal limit in both DMCH and WHO group. And in both groups most cases had Liver not palpable. Similar proportion of subjects in both the group had dehydration, Hypoglycemia, Oral thrush, eye infection and hair change. Regarding clinical conditions similar proportions of child have suffered from diarrhea, Fever and cough.

Table 3: Child characteristics

Values	DMCH	WHO	Total	Analysis
Number of child				
2	26(86.6%)	28(93.4%)	27(90.0%)	$Ç^2$=2.07;
>2	04(13.4%)	02(06.7%)	06(10.0%)	p=.56
Exclusive breastfeeding				
Yes	11(39.7%)	13(43.3%)	24(40.0%)	$Ç^2$=5.08;
No	19(60.3%)	17(56.7%)	36(60.0%)	p=.21
Age of complementary food				
3 month	06(20.0%)	11(367%)	17(28.3%)	$Ç^2$=2.39;
4-6 month	11(36.7%)	07(23.3%)	18(30.0%)	p=.30
>6 month	13(43.3%)	12(40.0%)	25(41.7%)	
Formula Feeding				
From 6 month	09(30.0%)	19(66.7%)	25(41.7%)	$Ç^2$=4.86;
Since birth	21 (70.0%)	10(33.3%)	31(51.7%)	p=.073
Immunization				
Complete	17(58.6%)	16(53.3%)	33(55.9%)	$Ç^2$=.783;
Incomplete	12(41.3%)	14(46.7%)	13(44.0%)	p=.676
Vit A supplementation				
Yes	25(83.3%)	26(86.7%)	51(85.0%)	$Ç^2$=.313;
No	05(16.7%)	04(13.3%)	09(15.0%)	p=.717

Outcome of treatment and logistic requirement

In DMCH regimen rate of weight gain was higher by around 2.6 gm/kg and they took less time to regain the appetite and smile. Time taken to achieve target weight was not statistically different however average time required to gain target weight was around one day less DMCH. Total amount of F -75 required was significantly less in DMCH group (P<0.05). Amount of F-100 was also required less in the DMCH group although the difference is not statistically significant. Both total per-capita treatment cost (P<0.001) and per day treatment cost (P<0.001) was significantly less in DMCH regimen. (Table 4)

Table 4: Comparison of outcome and logistics requirement

Variables	DMCH		WHO		Analysis	
	Mean	SD	Mean	SD	t	P value
Outcome indicators treatment						
Time to gain target weight (days)	13.4	4.4	14.3	3.5	-1.2	0.245
Rate of weight gain in gm/ Kg/day	16.9	3.9	14.3	4.3	2.4	*0.022
Return of appetite in days	3.9	1.3	4.3	1.1	-1.9	0.062
Return of smile in days	3.5	1.2	4.5	1.3	-3.3	*0.002
Total amount offeeding required/ patients						
F- 75 in ml	2390.3	907.1	3075.5	1312.8	2.514	*0.015
F- 100 in ml	9564.0	4020.6	10700.0	4743.1	1.625	0.110
Cost of treatment (taka/patient)						
Total cost	498.7	214.5	763.7	309.2	4.278	*0.001
Per day cost	352	9.3	52.3	13.2	6.022	*0.001

*Statistically significant

Discussion:

Current study finding confirmed suitability of DMCH dietary regimen over WHO regimen for the research of severe malnutrition. DMCH group took considerably less time to show improvement in terms of returning to smile and appetite. The growth rate was also significantly higher in DMCH group. Total amount of F-75 was significantly less in DMCH group than the WHO group. Regarding the amount of F-100, in the DMCH group the amount is slightly less.

Malnutrition has to be treated with both food and drugs. It is therefore necessary to regard provision of nutrients as essential for recovery, and to organize and ensure nutrient supply in the same way as the supply of essential drugs. To maintain dietary requirement we tested the regime based on peanuts, and it was found as well tolerated none experienced any adverse event. Although WHO regimen was a considered standard our study finding illustrates superiority of pea nut based DMCH regimen over the WHO one. The inherent reason might be the inclusion of peanut and separate use of vitamins, minerals and electrolytes.

Peanut has traditionally been used as a source, of oil. In recent years, several cereals and legumes-based foods using peanuts as protein supplements have been developed to alleviate protein calories malnutrition problem. Peanut in the form of flour, protein isolates, and meal in a mixed product have been found to be very desirable from a sensory quality point of view. Peanut protein is deficient with respect to certain essential amino acids, but its true digestibility is comparable with that of animal protein. A study by Devdas[7] reported that the children fed with peanut fortified millet and rice diet experience greater height and weight growth greater arm and chest development and higher hemoglobin concentration.

A study[23] conducted at ICMH and a local private hospital compared the efficacy of WHO dietary regime with another locally adopted regime called ICMH regimen. In their study 30 each patients were enrolled with malnutrition. They reported almost similar time for target

weight gain. However the study enrolled both marusmus and kawarsiorkor. A study in Malwai[8] showed similar better response with peanut based regimen for the treatment of malnutrition. In their study although the specific growth rate was not reported however in their study 66% achieved weight gain. In the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B), after the introduction of a standardized protocol, based on the WHO guidelines, fatality rate decreased to 9% and subsequently to 3.9% from an earlier 17%.[9] Severely malnourished children require prompt treatment by properly dietary supplementation. WHO has a management protocol for the management of severe malnourished child. The WHO protocol for the management of severe malnutrition has some limitations. There are phases of feeding from low to high calorie density. Treatment includes dose of a combined mineral and vitamin mix, which is difficult to procure locally. In Bangladesh, especially in government facility settings, it is rather difficult to implement the WHO protocol properly due to lack of necessary logistics support. Now majority hospitals are working with traditional local dietary regimen. The DMCH Protocol based on peanut tried to make the management easy and convenient.

A review[10] of Current guidelines for the management of severe malnutrition showed that the protocols are mainly based on new concepts regarding the causes of malnutrition and on advances in our knowledge of the physiological roles of micronutrients. In contrast to the early 'protein dogma', there is a growing body of evidence that severely malnourished children are unable to tolerate large amounts of dietary protein during the initial phase of treatment. Similarly, great caution must be exercised to avoid excessive supply of iron and sodium in the diet, while keeping energy intake at maintenance levels during early treatment. Because severely malnourished children require special micronutrients, a mineral-vitamin mix is added to the milk-based formula diets, which are specially designed for the initial treatment and the rehabilitation phase. To further improve nutritional rehabilitation and reduce cases of relapse, 'ready-to-use therapeutic food' and 'ready-to-eat nutritious supplements' with relatively low protein and high fat content have been developed. Although current dietary recommendations do not differentiate between edematous and nonoedematous forms of malnutrition or between adults and children, there are indications that further clarification is still needed for applying dietary measures for specific target groups.

Study done in the department of Pediatrics, Washington University, St Louis, USA[11] examined the effectiveness of locally made ready to use food for treatment of severe malnutrition to determine the operational effectiveness of treating. Children aged 6-59 months were recruited in rural southern Malawi. Each child received 65 kcal/kg/d of locally produced soy/peanut RUSF, a product that provided about 1 RDA of each micronutrient. Anthropometric measurements were taken every 2 weeks and additional rations of RUSF were distributed at this time if the child remained wasted. Study participation lasted up to 8 weeks. The intervention proved to be robust, maintaining high recovery rates and low default rates when instituted without the additional supervision and beneficiary incentives of a research setting.

Treatment cost is an important determinant of compliance and feasibility in resource limited country like Bangladesh. In practice, inpatient units treating severe malnutrition are commonly confronted by extremely ill patients who need intensive medical and nursing care. Most of these units are have severe capacity constraints, in particular, very few skilled staff. In addition, most careers of malnourished patients come from the poorest families and have great demands on their time. To achieve an impact at a population level, management protocols must take these socioeconomic realities into account, balancing the potentially conflicting demands and ethics of clinical medicine with those of public health. We compared the cost of treatment with two regimens.

Cost is considered an important parameter of treatment successes. Effect of a Low-Cost Food on the Recovery and Death Rate of Malnourished Children was done in Uganda.[12] The low-cost regimen was more effective in treating malnutrition. Widespread use of the cheaper option resulted in better outcomes than the costly one, and could produce a savings in the medium- to long-term, thereby releasing resources for other uses. We considered both daily cost and total cost in Bangladeshi taka. In DMCH group the average cost of treatment was less than 500 BDT and daily cost of around 35 BDT. In WHO group the total cost was around 765 taka and each day patients have to spend more than 50 taka.

One major limitation of the study was the smaller sample size, the number of children treated with this regime was small to allow for definitive conclusion about efficacy. Blinding couldn't be done as the information regarding the dietary ingredient could not be concealed leaving potential for observation bias. Considering the limitation still the study concludes that peanut based DMCH protocol can be used in the treatment of nutritional marasmus in the age group 6months to 59 months in the facility.

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