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Original Research Article.

A Study on Comparison between WHO Protocol and Locally Adapted Dietary Protocol in the Management of Nutritional Marasmus At Hospital in Bangladesh

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ABSTRACT

Objectives: To compare the efficacy of locally adapted DMCH dietary protocol with the WHO protocol for the management of nutritional marasmus in Bangladesh.

Materials & Methods: A Hospital based Randomized controlled Trial (RCT) was conducted on Marasmic children (06-59 years) with weight for height/length ≤ 3SD of the median WHO references (n=62). Children treated with either WHO protocol (group-1, n=31) or DMCH protocol (Group-2, n=31). Clinical improvement, rate of weight gain, time taken to achieve target weight gain, return of appetite, return of smile and total cost of treatment were evaluated in both groups.

Results: In DMCH group the time taken to achieve target weight was 13.43 days which was around one day less than that of WHO group (14.33 days) and rate of weight gain was higher by around 2.6 gm/kg/day. Child receiving DMCH regimen took on average 3.47 days to return to smile the time was 4.47 in WHO group (P< 0.01). Most importantly daily treatment cost was higher by around 17 taka per day in WHO group. Neither of the group experienced any serious adverse effect or fatality.

Conclusion: Peanut based DMCH dietary regimen can be used effectively in the treatment of nutritional marasmus (without oedema) in the facility.

Keywords: Nutritional Marasmus, WHO, Randomized Controlled Trial.

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INTRODUCTION

Marasmus is a serious worldwide problem that involves more than 50 million children younger than 5 years. According to the World Health Organization (WHO), 49% of the 10.4 million deaths occurring in children younger than 5 years in developing countries are associated with PEM.[1]

According to 1990's estimate, the number of underweight children in developing countries is around 149 million.[2] In Bangladesh the percentage is 2.9% thus the total number of being 500,000[3]and in India the percentage is around 2.8% of children fewer than 5 are severely wasted.[4] Malnutrition is a contributing factor in nearly 60% of deaths in children for which infectious disease is an underlying cause.[5] Although no specific on the issue is available, evidence suggests similar or even more grave the situation in the country. 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%.[6] Nutritional deficiency is the one of the major problem in the developing world as well as in Bangladesh. Severely malnourished children require prompt treatment by properly dietary supplementation. Most of tertiary hospital in Bangladesh has no specific dietary formula for the management of nutritional marasmus. WHO has a management protocol for the management of severe malnutrition. The published evidence on this regard is scarce; particularly of well-designed trials.[7] 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. DMCH protocol is locally adapted (peanut based) easy to follow. The

calorie density is Low to high and micronutrient deficiency is corrected using locally available minerals and vitamins. This study was conducted to compare the outcome of management of severe malnutrition (without oedema) in children by DMCH protocol with the WHO protocol.

METHODS

The study was a randomized controlled trial (RCT), was conducted in Dhaka Medical College Hospital (DMCH) from July 2015 to June 2016.

Sampling

All the marasmic patients aged 06 years to 59 years who meet the inclusion criteria were enrolled in the study. Those who consented to participate were allocated with one of the dietary formula randomly by box of eight lottery method.

Sample Size

It was calculated considering efficacy of WHO dietary regimen, it takes on average 4 days to appear sign of improvement in terms of return of appetite and smiling face. We hypothesized that peanut based DMCH dietary formula would take similar or fewer days to achieve the treatment end point. Hence the effect size considered to be 1 day with one SD ± 1day. To detect the difference in two treatment of 1 day with ± 1SD, at power of 90%, level of significance is 0.05 with equal allocation, and the total number would be 62 including 10% inflation of the sample i.e. 31 in each group.

Estimated sample size for two-sample comparison in a trial STATA[i]

Sample size: m1 (4) m2 (3), SD1 (1) SD2 (1) alpha (.05)

Test Ho: m1 = m2, where m1 is the mean in WHO group and m2 is the forecasted mean in DMCH

Assumptions:

Alpha = 0.0500 (two-sided)
Power = 0.9000
m1 = 4
m2 = 3
sd1 = 1
sd2 = 1
n2/n1 = 1.00

To compare two means of two samples from normal populations with H0: m1 = m2 vs. HA: m1≠ m2 with significance level α and power 1 − β we need to specify the smallest detectable difference. We used σ1 ≈ S1 and σ2 ≈ S2 where S1 and S2 are the sample-based standard deviations of X1 and X2. As we have no idea about the population standard deviations, we used the range of the data divided by 4 to estimate the variance and then the standard deviations. 'n' is the sample size of each of the two samples. Then, for the two-tailed estimate, the smallest sample size we need is

$$n = \frac{\left(\sigma_1^2 + \sigma_2^2\right)\left(z_{1-\alpha/2} + z_{1-\beta}\right)^2}{\mu^2}.$$

Estimated required sample sizes:

n1 = 29; n2 = 29

Considering attrition 7% inflation of the sample is taken

The final sample would be

n1 = 29 + 7% of 29 ≈ 32 i.e. 29+2=31;

n2 = 29 + 7% of 29 ≈ 32 i.e. 29+2=31;

Hence 31 cases of nutritional marasmus were allocated with DMCH regimen and 31 cases got WHO regimen of treatment. In the end of the study complete data of 31 each cases of in DMCH and WHO group were available. Blinding was not possible as the identity of dietary ingredient could not be concealed.

Selection of Cases

Marasmus children (without oedema), aged six years to 59 years, whose weight for length/height equal and or less than 3SD of the median WHO references were included in the study. Children with major congenital anomalies, 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).

Pre-tested structured questionnaire was used. Anthropometric measurement and clinical finding was recorded in a structured checklist.

Study Procedure

The study was conducted at pediatric unit in Dhaka Medical College Hospital. During the study period marasmic children aged 06 years to 59 years were enrolled. After the eligibility screening based on inclusion a patient were approached for participation. Upon consent they were finally enrolled. Those who consented to participate were allocated with one of the dietary regimens randomly by box of eight lottery method.

For each child, a detailed history was recorded in a questionnaire from the mother or attendants. Information included the baseline assessment of the children, like the admission weight by baby scale, clinical condition, on admission like dehydration, skin condition, eye changes, ear nose throat condition, respiratory rate, heart rate and others (oral thrush, pallor, JVP, liver size and associated infection)

All the children were weighed and measured while wearing light weight clothing on admission and every day morning. Children aged less than 24 months of age were placed horizontally and weighed using an electronic weighing scale that has a precision of 0.05 kg. Their length was also measured by using an infantometer on admission that has a precision of 0.01m. Patients aged 24 to 59 years were weighed barefoot using a digital weighing scale with a precision of 0.05 kg. These children's height was also measured by using a stadiometer with precision of 0.01 m while standing straight on horizontal surface with heels together and eyes straight forward. 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.

Detail of each child's condition in hospital were recorded after thorough examination on arrival and followed up regularly. Heart rate, respiratory rate, temperature, heart, lungs, abdomen, liver, spleen and kidney, return of appetite, smiling face, weight gain daily and total amount of feeding were recorded. Physician, senior staff nurses working in the study unit were trained on the specific management protocol before starting the study. Senior staff nurses were involved for supervising feeding regimen and helping during anthropometric measurement. Follow-up was given twelve hourly daily. One nutritionist was involved for dietary advice.

Relevant investigations done whenever and wherever feasible or available for the clinical diagnosis and complications were included complete blood count, blood sugar, serum electrolytes, Mantoux Test (MT), x-ray chest. Certificate from the ethical review committee of DMCH was obtained before starting the study. Informed written consent was taken from the legal guardian of the patient.

DMCH Dietary Regimen (Pea-nut based)

Starter formula (F-75): Milk powder=30 gm, sugar=105gm, oil=20gm/ml, peanut=05gm and water up to 1000ml (Protein=0.9gm/100ml

Catch-up formula (F-100): milk powder=70gm, sugar=65gm, oil=35gm/ml, peanut=25gm water up to 1000ml (Protein=2.4gm/100ml)

WHO Dietary Regimen

Starter formula (F-75): Milk powder=35 gm, sugar=100gm, mineral mix=20ml, water=1000ml.

Catch-up formula (F-100): Milk powder= 110gm, sugar=50gm, oil=30ml/gm mineral mix=20ml, water=1000ml.

The electrolytes and mineral were supplied from locally available sources.

The electrolytes and mineral were supplied separately.

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 on days 7±1 and onwards.

Mineral mix contains Potassium Chloride 224gm, Tripotassium citrate 81gm, Magnesium Chloride 76gm, Zinc Acetate 8.2gm and Water 2500 ml. 20ml of electrolyte mineral solution was to added 1000ml of milk food.

Management

Management of all severely marasmic children were done on the basis of ten essential steps according to WHO Protocol. Enrolled children were randomized into two groups: one is DMCH another WHO group. Both groups were managed in two phase's i.e. initial phase and rehabilitation phase.

All the malnourished children are at risk of hypoglycemia; hence blood glucose should be measure immediately at admission by using glucometer strips. In case of suspected hypoglycemia 10% glucose was given either intravenously or through N-G tube and after improvement starts feeding two hourly day and night. Appropriate antibiotics were started.

Child was warmed by covering with clothes including hat, blankets and temperature measured half hourly. Children should be kept in room, not kept near windows. Diarrhoea with no sign of dehydration or some sign of dehydration treated with ReSoMol and N-G tube feeding with F-75.Every child with or without clinical deficiency was given vitamin A supplementation, Folic acid and other electrolytes initially, but iron supplement from the seven day or later. Here mineral was mixed with WHO dietary regimen but In DMCH Group minerals get from locally procured available medicine. Infection was controlled by as per WHO schedule.

In WHO group feeding was started with F-75 at 130 ml/kg/day (100Kcal/Kg) 2hourly orally or by N-G tube and later the frequency of feeding was reduced to 4houry. Whereas DMCH dietary regimen peanut based was made up of with whole milk powder, sugar, oil, peanut and water which also given in a same way. During rehabilitation phase both group of patient take extra food like fruits and eggs and also breastfeeding was encouraged. In this phase diet contains 100 Kcal / 100ml with protein 2.5 gm/100 ml and calorie were increased to 130 -200Kcal/Kg /day. A cheerful stimulation, structured play therapy for at least 30 minutes per day in Ashic play centre, physical activity and tender love care were allowed. We also gave health and nutritional education for mother and caregiver, Non immunized children were immunized and The baby was discharge from the hospital when clinically stable, complete antibiotic course, eating an adequate amount of nutritious food that mother can prepare at home, weight for height/ length -2SD, infections and other medical complications had been treated, regular follow-up checks, ensure vitamin A is given every six months, give structured play therapy.

Discharge on request when Completed antibiotic treatment, good appetite and weight gain, mother is motivated to follow advice given, give appropriate meals at least five times daily and high energy snacks between meals e.g. milk, banana, bread, and biscuits, give electrolyte and micronutrient supplements. Breastfeed as often as child wants.

Outcome Measures

1. Clinically return of appetite, return of smile, improvement of other associated medicinal conditions, and weight gain in gram per kg per day.

2. Time taken for gaining target weight (weight for height reaching -2SD of WHO median reference values), cost of treatment.

Formula for calculating weight gain:

$$\text{Weight gain in gm/kg/day} = \frac{(W2 - W1) \times 1000}{(W1 \times \text{Number of days from W1 to W2})}$$

W1: Initial or lowest weight in kg.

W2 = Weight in Kg on the day of calculation

Statistical Analysis

The collected data were analyzed thoroughly by SPSS program version of 20.0 software. In addition to descriptive statistics such as frequency tabulation, mean, standard deviation; statistical tests such as Chi-square test for qualitative variables and student's t tests for continuous variables were applied to determine statistical significance.

RESULTS

In the 62 samples from different areas of Bangladesh, the mean age of the patient was 19.3±SD 10.96 years, mean weight was 5.4±SD 1.43 kg, mean height was 69.24±SD 7.45 cm and mean MUAC was 9.99±SD 1.01 cm. Figure 1 shows the age distribution among patients in Bangladesh. From this figure, it is clear that maximum patients were aged less than 20 years. Some patients were between 21-40 years and a very few were more than 40 years.

Figure 2 depicts the parent of the patient's education level and occupation. Here it is clear that maximum parent were under high education level, maximum were just completed primary level of school and some of were illterate. Furthermore, most of the mothers were housewife and fathers were day laborer.

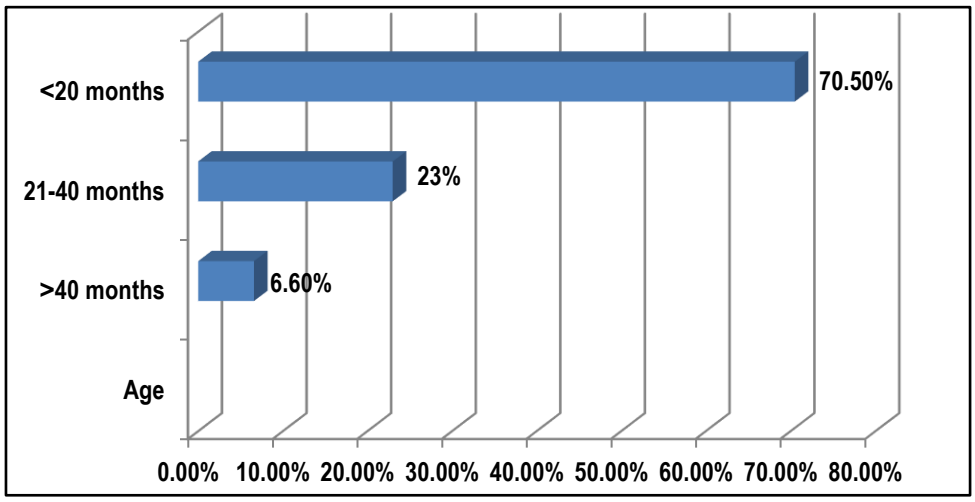

Figure 1: Age distribution of the patients

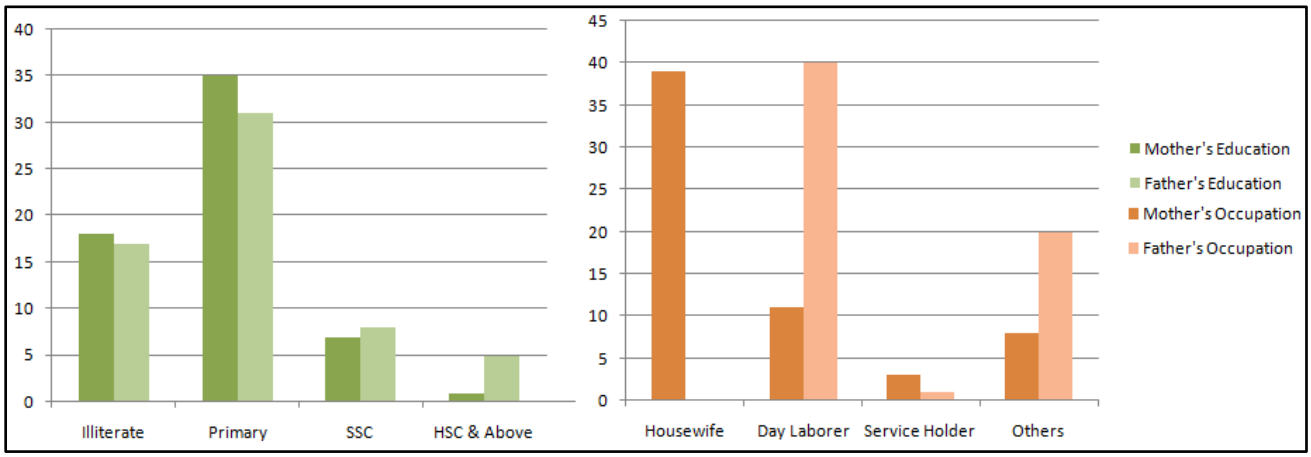

Figure 2: Education level and occupation of the parents of the patients.

Table 1: Frequency distribution of gender, residential place and socio-economic condition among 62 patients

	Male	Female	Others
Gender	28	34	0
	Urban	**Rural**	**Slum**
Residential Place	10	6	46
	Low	**Middle**	**High**
Socio-economic Condition	58	4	0

Table 2: Frequency distribution of various sorts of feeding formula

	Yes	No
Exclusive Breast Feeding	16	46
	Started after six months	**Started since after birth**
Formula Feeding	8	54
Animal Feeding	33	29
Family Feeding	50	12

Table 1 shows the frequency of gender, where 34 patients are female and 28 are male. This table also displays the residence and socio-economic condition of the patients. Maximum patients lived in the slum area and rest of the person lived in the urban and rural arena. Besides, almost every patient is under low socio-economic condition; only few are under middle range. Table 2 shows the frequency distribution of various type of feeding. Most of the patients started since after birth. Figure 3 illustrates the several types of risk factors like diseases and infections etc. Maximum patients had heart rate relevant problem, vitamin A supplementation, pallor, fever. Some had cough, respiratory rate and associated infections related problems. The baseline characteristics of the two groups were similar in both groups.

Table 3 compares outcome variables between the two groups, which were found to be comparable. Outcome of treatment was assessed in terms of, time to achieve target weight (hospital stay), rate of weight Gain, return to appetite and return to smile. Average time to achieve target weight after the intervention was not statistically significant.

In two group, however in DMCH group the time taken to achieve target weight was around one day less. With DMCH regimen rate of weight gain was higher by around 2.6 gm/kg. Child receiving DMCH regimen took less time to regain the appetite and smile, although the time difference in return to smile is highly significant ($P<0.01$).

Average treatment cost incurred in two groups was compared in the study. Both total treatment cost ($P<0.001$) and per day treatment cost ($P<0.001$) was significantly less in DMCH regimen.

Disposition of child after following treatment, ineach group total 32 patients were enrolled of which 30 (93.74%), 29(90.6%) survived, one each group were discharged on risk bond and one each left the study without prior information respectively in DMCH and WHO group. In Children receiving WHO dietary regimen one was discharged on request. None died in either of the groups.

Table 3: Outcome of treatment

Variables	DMCH		WHO		Analysis	
	Mean	SD	Mean	SD	t	P value
Time to achieve target weight in days	13.43	4.431	14.33	3.497	-1.18	0.245
Rate of weight gain in gm/ Kg/day	16.95	3.904	14.29	4.288	2.38	0.022*
Return of appetite in days	3.93	1.285	4.33	1.124	-1.91	0.062
Return of smile in days	3.47	1.167	4.47	1.252	-3.31	0.002*

*Statistically significant

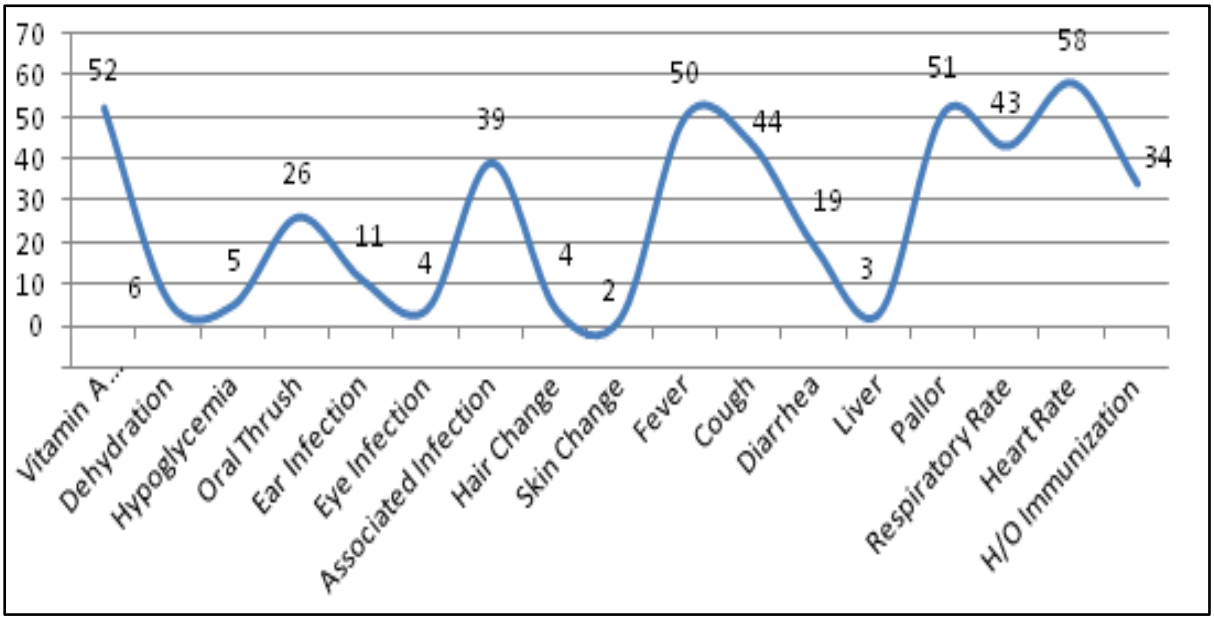

Figure 3: Risk Factors of the patients

DISCUSSION

Malnutrition is a major public-health problem throughout the developing world and is an underlying factor in over 50% of the 10–11 million children under 5 years of age who die each year of preventable causes.[8] 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 cases 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. Randomized controlled trial was conducted at pediatrics unit in Dhaka Medical College Hospital. During the study period marasmic 62 children aged 06 years to 59 years were enrolled. For each child, a detailed history was recorded in a questionnaire from the mother or attendants. The WHO standards were used to determine the nutritional status of children. Detail of each child's condition in hospital were recorded after thorough examination on arrival and followed up regularly.

A total of 62 children were enrolled and children were randomized into two groups: one is DMCH another WHO group. In DMCH group 30 continued till the end, one were discharged on risk bond and another one left the study without prior information. In Children WHO group 29 (90.6%) continued till the end, one was discharged on request, one left without any information and another one was discharged on risk bond. None died in either of the groups. Complete data of 30 children was available in DMCH group and in WHO group after including DOR complete data of 30 children was available.

Both groups were managed in two phase's i.e. initial phase and rehabilitation phase. Play therapy, nutritional education and discharge were same for both groups. The baby was discharged from the hospital when clinically stable, antibiotic course complete, taking full feed by spoon or sucking or orally and gaining weight daily until desired target weight -2SD.

Baseline characteristics showed that in the two comparing groups no statistically significant difference in age was seen. Anthropometric measure, in terms of weight, height/length and MUAC, were also in similar range in the two groups. No statistically significant difference exists in the distribution of gender and place of residence across two groups.

The intervention was given with Pea-nut based DMCH Dietary regimen. 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[9] 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. Outcome of treatment was assessed in terms of, time to achieve target weight (hospital stay), rate of

weight Gain, return to appetite and return to smile. Average time to achieve target weight after the intervention was not statistically different in two groups; however in DMCH group the time taken to achieve target weight was around one day less. With DMCH regimen rate of weight gain
was higher by around 2.6 gm/kg/day. Child receiving DMCH regimen took less tome to regain the appetite and smile, although the time difference in return to smile is highly significant. A study in Malwai[10] showed similar better response with peanut based regimen for the treatment of malnutrition.

In the current study DMCH group took considerably less time to show improvement in terms of returning to smile and appetite. Rate of weight gain was measured by researcher following up the patient every day in gm/kg/day. The growth rate was significantly more in DMCH group. In Malwai study the specific rate was not reported however in their study 66% achieved weight gain.

Disposition of child after following treatment is in DMCH group total 32 patients were enrolled of which 30 (93.75%) survived, one were discharged on Risk bond and another one left the study without prior information. In Children receiving WHO dietary regimen 29 (90.6%) survived, one was discharged on request, one left without any information and another one was discharged on risk bond. None died in either of the groups. Although WHO regimen was a considered slandered our study finding illustrates superiority of DMCH regimen over the WHO one. The inherent reason might be the inclusion of peanut and separate use of vitamins, minerals and electrolytes.

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 marasmus and kawarsiorkor. 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 however the difference is not statistically significant.

Treatment cost is an important determinant of compliance and feasibility in resource limited country like Bangladesh. Hence we compared the cost of treatment with two regimens. We considered both daily cost and total cost in Bangladeshi taka. Both total treatment cost and per day treatment cost ($P<0.001$) was significantly less in DMCH regimen. In DMCH group the average cost of treatment was less than 500 taka and daily cost of around 35 taka. In WHO group the total cost was around 765 taka and each day patients have to spend more than 50 taka. Malnutrition has to be treated with both food and drugs.

Locally available dried milk powder, Peanut, sugar, zinc, potassium, magnesium sulphate and multivitamins were used in DMCH protocol instead of imported skimmed milk and CMV based ReSoMal to correct dehydration. The service providers appreciated the simplicity of DMCH protocol depended on locally available products and duration of hospital stay was almost same, the cost would be lower in case of DMCH protocol.

The result obtained in this study has important implications in introducing protocol based management of severely malnourished children in hospitals with limited resources. DMCH protocol may appear to be a feasible alternative hospital of developing countries for management of severe malnutrition (without oedema).

CONCLUSION

Return of appetite was earlier in DMCH group. Return of smile and daily weight gain were significant in DMCH group than those in WHO group. The cost of treatment was also significantly less in DMCH group.

RECOMMENDATION

Peanut based DMCH protocol can be used in the treatment of nutritional marasmus in the age group 6 years to 59 years in the facility.

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