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Effect of Locally Made Ready-to-Use Therapeutic Food -Mushpro Health Drink Powder (MHDP) for Treatment of Malnutrition on Children Aged 6 to 72 Months in Rural Area of Maharashtra, India: A Randomized Control Trial

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Abstract. Objective: To evaluate the effectiveness of a locally made Ready-to-use therapeutic food (RUTF) Mushpro Health Drink Powder in decreasing Severe and moderate malnutrition in Rural India. Participants: Children aged 6 months to 72 months. Interventions: Children with SAM, MAM and Normal in 17 Intervention Anganwadi centre received RUTF (MHDP) 3 gm/kg/per day (SAM) & 2 gm/kg/day MAM two times a day from December 2011 to February 2012. Children in the 17 Non-interventional Anganwadi centers' did not receive Mushpro supplementation. For both the groups the supplementations as per ICDS protocol were given & both arms included continuation of family diets. Results: Mean weight gain was found to be 710 gm in experimental group while 156 gm in control group. Mean weight gain in gm per day 11.8 gm in experimental group while 2.61 gm in control group . Mean height gain 0.65 cm per months in experimental group while 0.20 cm in control group. The weight gain per kg body weight was directly proportional to severity of the malnutrition. Conclusions: Community based treatment by locally made nutritious food MHDP showed significant weight gain and height gain in Experimental group and proved to be more effective in management of SAM and MAM.

Keywords: MHDP, SAM, MAM, Weight gain, Height gain

1. Introduction

The World Health Organization defines malnutrition as "the cellular imbalance between supply of nutrients and energy and the body's demand for them to ensure growth, maintenance, and specific functions. [1] Despite praiseworthy advances in economic prosperity and in the field of medical therapeutics, severe acute malnutrition (SAM) continues to be a significant public health problem in India. Approximately 8.1 million children under the age of 5 years (6.4%) suffer from severe acute malnutrition and it is one of the important co-morbidities leading to hospital admissions in our country [2]. The mortality associated with severe acute malnutrition is also high, ranging from 73 to 187 per 1000[.3] The third National Family Health Survey estimated that 45.9% of Indian children and 33.2% of children below 3 years of age are underweight. [4] Mild-to-moderate malnutrition has been associated with an increased risk of childhood morbidity [5], [6] Home-based treatment has been recommended during the rehabilitation phase of treatment for malnutrition in areas where follow up is possible.[7] The use of ready-to-use therapeutic foods (RUTF) for the treatment of moderate malnutrition has been reported to result in an average weight gain of 12.7% over a period of 28 days in moderately malnourished children.[8] Most children with SAM cannot be accommodated in hospitals; many families cannot afford their earning members to stay with their children in hospitals for many weeks. Efficacy trials will compare standard hospital care for SAM with community management far removed from real life situations of limited care.[9] Can we refuse to provide an alternative when we are unable to provide standard hospitalized care to millions of children with severe acute malnutrition? Currently available

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facilities for hospitalized care of children in India would be inadequate even if they were utilized exclusively for the treatment and rehabilitation of children with SAM. [10] Limitations in availability as well as access to facility based care, therefore, make community management of SAM a priority. This trial was designed to evaluate the effectiveness of community-based therapy with a locally produced RUTF (MHDP) for treatment of all grades malnutrition in children 6--72 months in rural area of Amravati District of Maharashtra, India.

2. Methods

This study was an open-labeled randomized controlled trial. The study was conducted from December 2011 to February 2012. Anganwadis centers were randomly assigned to Experimental group and control group. The study protocol was approved by Independent Ethical committee including ethical clearance. The study procedure was fully explained to the parents/caregivers and informed written consent was obtained from primary care givers.

A total of 120 children (60 in intervention group and 60 in non intervention group), assuming a 5% drop-out had 80% power to detect a difference of 50% of reduction in the proportion of malnutrition between groups, with an overall type I error of 5%. 270 children between the ages of 6 to 72 months were screened in 34 anganwadi centre. 126 children recruited after obtaining written informed consent. Six were later excluded. The unit of randomization was Anganwadi centre. Allocations into the study and control groups were done by lottery method. Baseline assessment of nutritional status was carried out immediately following recruitment. Children aged 6—72 months but not requiring hospitalization for severe malnutrition were considered eligible for study. Children less than 6 months were excluded as several of them were receiving breast milk. Also children having other diseases incriminated as a cause of severe malnutrition, including cerebral palsy, chromosomal malformation,known metabolic diseases, malignancies, congenital heart disorders, hemolytic anaemia,known malabsorption syndrome, or hepatic disorder were excluded.

Mushpro health drink powder is made up of perfect combination of mushroom (Ostreatus Pleurotus species) and other ingredients wheat flour and skimmed milk powder; some flavoring agents (cocoa powder etc) were added to make it palatable. Mushpro is approved by FDA Government of Maharashtra, Food Safety and Standards Authority of India. Nutritional composition of MHDP: Chemical analysis to determine proximate composition of sample was carried out. It was done by ISO certified laboratory given in Table-1.

Children with SAM & MAM in 17 Intervention Anganwadi centre received RUTF (Mushpro) 3 gm/kg/ for SAM & 2 gm/kg MAM two times a day. Children in the 17 Non-interventional Anganwadi centre did not receive MHDP supplementation. All children additionally continued to receive their normal diets, including one hot meal provided by the anganwadi every working day as part of ICDS Program & both arms included continuation of family diets.Active supervision for conditions requiring medical or nutritional treatment was conducted weekly in all 34 study anganwadi centre. MHDP was given during the mid morning and mid afternoon according to standard doses. Recruitment was done on 1st of December 2011 and the intervention started from the 14th of December 2011. Measurements were taken on day 1, day 15, day 30, day 45 and day 60. Anthropometric indices were calculated using WHO growth standard.The frequencies of follow-up visits were once a week .At each visit anganwadi worker, helper and parents were recounselled about quantity and frequencies of MHDP. Any medical problem identified during visit was treated.Measurment of weight and height was done at each visit.

The data obtained were analyzed using SPSS software version 16.0 for Windows. Numerical variables were compared between the two groups by using the independent student's test. For more than two groups ANOVA test was used.

3. Results

Of the 270 anganwadi children identified, 126 were recruited. Confirmation of dates of birth resulted in 6 children being excluded. 120 children were enrolled. At the end of the study, 120 children remained for follow-up, of whom 60 received nutritional supplementation (MHDP) and 60 did not receive nutritional supplementation. majority (32.5%) of the study subject were in age group 49-60 months followed by 25-36 months (20%), 13-24 months (15.8%) and 12.5% in 61-72 months. 55.8% were Male while 44.2 were

Female. 50% were SAM grade and 50 % were MAM grade. Table **2** show the Mean weight gain was found to be 710 gm in experimental group while 156 gm in control group. Mean weight gain in gm per day 11.8 gm in experimental group while 2.61 gm in control group and Mean weight gain gm per kg per day 1.21 gm/kg/day in experimental group while 0.27 gm/kg/day in control group. Mean height gain 0.65 cm per months in experimental group while 0.20 cm in control group.

Table 1: Chemical Analysis Showing Nutritional Composition Of MHDP By ISO Certified Laboratory.

Sr no	I Macro & Micronutrient	Contents	Sr no		Contents
1	Energy (kcal)	332.67	10	Vitamin B 5(mg)	21
2	Carbohydrate(gm)	59.30	11	Vitamin C(mg)	0.1
3	Preoteins(gm)	27.5	12	Dietary fibre	0.87
4	Fats (gm)	1.76	13	Calcium(mg)	456
5	Iron (mg)	2.7	14	Magnesium(mg)	175
6	Vitamin A(mg)	550	15	Phophorus(mg)	587
7	Vitamin B1(mg)	2.5	16	Folic acid (mg)	60
8	Vitamin B2(mg)	7.2	17	Sodium	0.18
9	Vitamin B 3(mg)	0.13	18	Potassium	0.88
Sr no	Essential amino acids	Contents	Sr no		contents
1	Lysine	0.97	12	Histidine	0.40
2	Amino buteric acid	0.02	13	Phenelamine	0.51
3	Proline	0.18	14	Trytopher	0.12
4	Threonine	0.3	15	Arginine	0.05
5	Isoleucine	0.55	16	Glutamic acid	0.03
6	Aspertic acid	0.28	17	Methionine	0.13
7	Thyrosine	0.54	18	Alamine	0.14
8	Valine	0.43	19	Serine	0.14
9	Dihydroxyphenelamine	0.42	20	Cysteine	0.25
10	Hydroxyproline	0.36	21	Cystine	0.005
11	Leucine	0.53	22		
Sr no	Essential Fatty acids	Contents	Sr no		Contents
1	Caproic acid	0.03	6	Palmitic acid	0.24
2	Caprylic acid	0.02	7	Heptadecanoic acid	0.02
3	Capric acid	0.22	8	Oleic acid	0.11
4	Myristoleic acid	0.01	9	Linoleic acid	1.28
5	Pentadecanoic acid	0.12	10	Stearic acid	0.15

Table 2: Mean Weight Gain and Height Gain in Both Study Groups

Weight gain	Group		t	p	95% CI
	Experimental	Control			
Mean weight gain	710	156	8.5	0.0001	425-681
Mean weight gain gram per day	11.8	2.61	8.5	< 0.001	7.09-11.3
Mean weight gain gram /kg/day	1.21	0.27	8.1	< 0.001	0.71-1.16
Mean height gain	0.65	0.20	3.7	< 0.001	0.21-0.69

The age wise Mean weight gain per day in experimental group was found to be higher than control group and found to be highly significant in all age group except 6-12 months. The age wise Mean height gain per month in experimental group was found to be highly significant in all age group except 13-24 months. The age wise Mean weight gain per day and mean height gain in experimental group was found to be higher than National and International standards shown in (Table-3).

Table 4 shows the mean weight gain in SAM 790 gm, MAM 630 gm in Experimental group while among control group weight gain in SAM 150 gm, MAM 163 gm. The mean weight gain gm per day in SAM 13.1 gm /day, MAM 10.5 gm/day gm in Experimental group while control group in SAM 2.5 gm/day, MAM 2.7 gm/day. The mean weight gain in gm per kg per day in SAM 1.36 gm/kg/day, MAM 1.06 gm /kg/day in Experimental group while control group in SAM 0.28 gm/kg/day, MAM 0.27 gm/kg/day. Weight gain was found to be statistically significant in study group. The Weight gain was found to directly proportional to the severity of malnutrition.

Table 3: Mean Weight among Study Subjects with Comparison to National & International Standard.

Age (months)	Mean Weight gain in Study group (Gm/day)		CSSM*	NRC**
	Experimental	Control		
6-12	8.6	4.5	12.4	13.5
13-24	9.50	0.55	6.9	8
25-36	11.6	3.0	6.9	8
37-48	12.3	0.23	5.57	6
49-60	13.1	5.0	5.57	6
61-72	13	0.01	5.57	6

* Govt of India CSSM review A newsletter on child survival and safe motherhood Programme Jan 1995, No25

** Nelson text book of Pediatric ,18th Edition Vol 1,Part 1-XVI adopted from National Research Council, Food and Nutrition Board ,Washington D.C ,Contemp Pediatr 1993,10;11

Table 4: Weight Gain In Relation To Severity of Malnutrition among Study Subjects

Weight gain	Grade	Study Group		ANOVA
		Experimental	Control	
Mean weight gain	SAM	790	150	F=73.5
	MAM	630	163	p< 0.001
Mean weight gain gram per day	SAM	13.6	2.5	F=73.5
	MAM	10.5	2.7	p< 0.001
Mean weight gain gram per kg per day	SAM	1.36	0.28	F=66.2
	MAM	1.06	0.27	p< 0.001

4. Discussion

It was found that the Mean weight gain in 2 months was as follows: MHDP (n=60): The Mean weight gain at 2 months was higher in the Intervention group (n=60): 1.21 gm per kg per day as compare to control group (n=60): 0.27 gm per kg per day ($p < 0.001$). The mean weight gain in our study 1.12 kg was more than that of Azara Sneha Singh et al[11] (0.54kg), Sandige H et al[12] & Diop EI et al[13]Meta analysis report (Weight gain = 0.07 g/kg/d), Michael H Golden[14] weight gain on the CSB was 1.2 g/kg/d.The mean weight gain in our study (1.2 g/kg/d) was less than that by Manary MJ et al[15].Meta-analyses (WMD= 2.10 g/ kg/day) , Bhutta ZA et al[16] (meta-analysis showed an advantage of weight gain of 3.0 g/kg/day), Amthor RE et a [17], Jilcott SB et al[18] Linemann Z et al[19] , Ciliberto MA at al[20] 4 studies metaanalytic methods the pooled mean weight gain with the use of RUTF was 3.2 g/kg/day (95% CI 3.06, 3.34 g/kg/d), Khanum et al[21]. (4 gm/kg/day). The Mean Height gain in our study is more than National and International Standard in the age group more than two years that is among Experimental group (0.93 cm per month) than Control group (0.22 cm per month).However it is less than in the age group less than two years. The appetites of children given zinc supplements improved and they started to catch up in height [22]from the realizations of catch up in height by the supplementation of zinc the theory of type I (functional nutrients) and type II nutrients was generated[23][,24][,25]..The study had limitations. The study is not ideal in that it was not blinded, but blinding would have been difficult for acceptable interventions. To summarize, locally made Supplementary nutritious food MHDP showed significant weight gain in Experimental group. More effective in management of SAM and MAM. This study showed that immediate therapeutic treatment for short duration of period is a feasible, effective and well-accepted intervention to combat moderate & severe malnutrition.As weight gain and height gain are most sensitive indicators for monitoring of Malnutrition,so these two anthropometric indiacators are enough to show the effect of MHDP in malnutrition children.Competing interests: There does not exist any conflict of interest what so ever. Funding: NGO named Bahu-uddeshiya Arogya Va Samaj Kalyan Sanstha, Amravati, Maharashtra, India.

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