

Efficiency and Safety of Therapeutic Nutrition Products for Home Based Therapeutic Nutrition for Severe Acute Malnutrition: A Systematic Review

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Context: Severe acute malnutrition (SAM) in children is a significant public health problem in India with associated increased morbidity and mortality. The current WHO recommendations on management of SAM are based on facility based treatment. Given the large number of children with SAM in India and the involved costs to the care-provider as well as the care-seeker, incorporation of alternative strategies like home based management of uncomplicated SAM is important. The present review assesses (a) the efficacy and safety of home based management of SAM using 'therapeutic nutrition products' or ready to use therapeutic foods (RUTF); and (b) efficacy of these products in comparison with F-100 and home-based diet.

Evidence Acquisition: Electronic database (Pubmed and Cochrane Controlled Trials Register) were scanned using keywords 'severe malnutrition', 'therapy', 'diet', 'ready to use foods' and 'RUTF'. Bibliographics of identified articles, reviews and books were scanned. The information was extracted from the identified papers and graded according to the CEBM guidelines.

Results: Eighteen published papers (2 systematic reviews, 7 controlled trials, 7 observational trials and 2 consensus statements) were identified. Systematic reviews and RCTs showed RUTF to be at least as efficacious as F-100 in increasing weight (WMD=3.0 g/kg/day; 95% CI -1.70, 7.70) and more effective in comparison to home based dietary therapies. Locally made RUTFs were as effective as imported RUTFs (WMD=0.07 g/kg/d; 95% CI=-0.15, 0.29). Data from observational studies showed the energy intake with RUTF to be comparable to F-100. The pooled recovery rate, mortality and default in treatment with RUTF was 88.3%, 0.7% and 3.6%, respectively with a mean weight gain of 3.2 g/kg/day. The two consensus statements supported the use of RUTF for home based management of uncomplicated SAM.

Conclusions: The use of therapeutic nutrition products like RUTF for home based management of uncomplicated SAM appears to be safe and efficacious. However, most of the evidence on this promising strategy has emerged from observational studies conducted in emergency settings in Africa. There is need to generate more robust evidence, design similar products locally and establish their efficacy and cost-effectiveness in a 'non-emergency' setting, particularly in the Indian context.

Key words: Efficacy, Management, Severe acute malnutrition, Therapeutic nutrition product.

Despite praiseworthy advances in economic prosperity and in the field of medical therapeutics, malnutrition 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 (SAM) and it is one of the important co-morbidities leading to hospital admissions in our country(1). The mortality

associated with severe acute malnutrition is also high, ranging from 73 to 187 per 1000(2). Needless to say, control and prevention of severe acute malnutrition should be one of the important priorities of the health planners. The current recommendations on the management of SAM by WHO involve initial management at a referral centre for initial stabilization followed by home therapy(3). Given the number of severely malnourished children in India

and the state of health infrastructure in the country, particularly in the peripheries, these strategies do not seem to be logistically feasible. Also, given the complex interplay between social exclusion, poverty and SAM, inpatient treatment is associated with un-acceptable costs to the family. In such a situation, uncomplicated malnutrition is not considered a health problem by the family leading to delayed institution of appropriate management. This leads to seeking of health care when the problem is associated with other co-morbidities, leading to increased mortality.

Given the grimness of the current situation, there is clearly a need to improve and improvise the current standard guidelines for the management of SAM in children. One of the suggested methods has been the use of 'therapeutic nutrition products' administered at home to children with uncomplicated SAM(4). A review was planned to study the efficacy and safety of various therapeutic nutrition products for home based management of SAM in children and to critically review the extendibility of this strategy to India with the following objectives:

- (a) to study the efficacy and safety of home based management of SAM using 'therapeutic nutrition products' in children; and
- (b) to compare the efficacy of these products with F-100 formulation or home based dietary therapy.

Trials: Systematic Reviews; before and after observational studies; Individual, cluster, and quasi randomized and non-randomized controlled trials; consensus statements.

Participants: Children with severe acute malnutrition.

Intervention: Therapeutic nutrition product, basically derived from F-100 formulation, which is an integral part of the WHO Management Protocol for SAM but should have these additional properties: (i) does not need to be prepared in any form before consumption; (ii) resists microbial contamination; and (iii) can be stored at ambient temperature.

Control: No intervention or alternative intervention such as home based dietary management or facility based standard treatment.

Outcome Measures: For efficacy: (a) Recovery rate (as defined by the authors); (b) Weight gain (g/kg/day); and (c) Relapse.

For Safety: (a) Morbidities like diarrhea, malaria and respiratory infections; and (b) Mortality.

Identification of studies: An exhaustive literature search was done in the Cochrane Library and Pubmed using the search terms 'severe malnutrition', 'therapy', 'diet', 'ready to use foods' and 'RUTF' on April 20, 2010.

REVIEW OF EVIDENCE

A total of 4073 citations were scanned to identify relevant studies. The bibliography of identified articles was also scanned and lateral search strategy in Pubmed was utilised to identify any additional trials. A total of 18 published studies(4-21) were identified and the information extracted was graded according to the CEBM guidelines(22) and is presented in **Table I**. Wherever possible and where the data from the published studies was extractable, the data was pooled statistically to get a precise quantitative estimate. The pooled estimates of the weighed mean difference (WMD) of the weight gain between the control and intervention group and the mean pooled weight gain in observational studies were calculated by meta-analyses using random effects model assumptions with the "metan" command in STATA software.

Systematic Reviews

A 2008 systematic review(4) on severe malnutrition identified 276 articles on management of SAM, of which 21 were eventually included in the final analyses. Of these, nine studies evaluated the efficacy of WHO guidelines for facility based management of severe acute malnutrition; pooled data from these trials showed a reduction in mortality (Risk Ratio 0.45; 95% CI 0.32, 0.62). The authors could not identify any randomized controlled trials studying the effect of RUTF on mortality. However, obtaining the observational data collected from 21 field programs on 23,511 children on community based management of SAM, the authors showed the case fatality rate to be 4.1%, recovery rate was 79.4% and default was 11%; figures which were

TABLE 1 ROLE OF THERAPEUTIC NUTRITION PRODUCTS IN HOME BASED MANAGEMENT OF SEVERE ACUTE MALNUTRITION IN CHILDREN: SUMMARY OF EVIDENCE

Author, Year of Publication, Country, Type of Study, Age, Inclusion Criteria	Intervention, Sample Size, Duration of Study	Salient Findings	Conclusion, Grade of Evidence
Systematic Reviews			
Bhutta, <i>et al.</i> , 2008(4), Pediatric age group	Intervention to reduce mother and child undernutrition and survival; Analyzed data from 21 studies on management of SAM	The overall case-fatality rate in 23, 511 unselected severely malnourished children treated in 21 programs of community-based therapeutic care in Malawi, Ethiopia, and Sudan, between 2001 and 2005, was 4.1%, with a recovery rate of 79.4% and default of 11.0%. This compares favourably with case-fatality rates that are typically achieved with facility-based management.	Use of prepared balanced foods such as spreads and ready-to-use supplementary foods is feasible in community settings. Grade: 2a
Ashworth, <i>et al.</i> , 2006(5), Systematic Review, Malnourished children in non-emergency situations	Community based rehabilitation for treatment of severe malnutrition, Analyzed data from 33 studies of community based rehabilitation	Eleven (33%) programs were considered effective. Of the subsample of programs reported since 1995, 8 of 13 (62%) were effective. None of the programs operating within routine health systems without external assistance was effective.	When done well, rehabilitation at home with family foods is more cost-effective than inpatient care, but the cost effectiveness of ready-to-use therapeutic foods (RUTF) versus family foods has not been studied. Where children have access to a functioning primary health-care system and can be monitored, the rehabilitation phase of treatment of severe malnutrition should take place in the community. Grade: 2a
Controlled Trials RUTF versus Standard Practice			
Gaboulaud, <i>et al.</i> , 2007; Niger(6), Controlled trial, purposive selection, 6-59 mo; Inclusion: a) WHZ < -3 z or bilateral pitting edema b) MUAC < 11 cm	Management at therapeutic feeding centre (TFC) versus TFC and home based care versus home based care alone using RUTF; Total: 1937 TFC: 660; TFC and home: 937; Home based: 340	(Order: TFC, TFC plus home, home) Recovery: 52.7, 83.2 and 92.7; Mortality: 18.9, 0.0, 1.7; Default: 28.1, 16.8, 5.6 Transferred: 0.3, 0, 0; Wt gain: 20.8, 10.1, 9.7 g/kg/d	Satisfactory treatment of SAM can be achieved using a combination of home and hospital strategies. Children without complications and preserved appetite may be directly managed at home. Grade: 2b
Ciliberto, <i>et al.</i> 2005; Malawi(7); Quasi-randomized controlled trial; 10-60 mo; Inclusion a) Moderate and Severe wasting and/or kwashiorkor	RUTF versus standard practice (WHO guidelines) at NRU; Total = 1178; RUTF: 992; Standard Therapy: 186; Duration: 8 weeks of therapy; follow up till 6 mo.	Recovery (WFH z > -2): 79% versus 46%; Mean wt. gain: 3.5 g/kg/d versus 2.0 g/kg/d; Mortality and relapse: 8.7% versus 16.7%; Lower morbidity in RUTF group	Home-based therapy with RUTF is associated with better outcomes for childhood malnutrition than is standard therapy Grade: 1b

Author, Year of Publication, Country, Type of Study, Age, Inclusion Criteria	Intervention, Sample Size, Duration of Study	Salient Findings	Conclusion, Grade of Evidence
b) Absence of severe edema, evidence of systemic infection, or anorexia			
Diop, <i>et al.</i> , 2003; Senegal(8); Randomized controlled trial; 6-36 months; Inclusion: WFH < -2z without edema or after edema had resolved	RUTF versus F-100 (received F-75 for 1-4 days prior to enrolment); Total: 70, RUTF: 35, F-100: 35	Wt gain: 10.1 g/kg/d in F-100 versus 15.6 g/kg/d in RUTF group, Mean duration to recovery: 17.3 days in F-100 versus 13.4 days in RTUF	RTUF can be used efficiently for the rehabilitation of severely malnourished children. Grade: 1b
<i>Commercial or Indigenous Medical Nutrition Products versus Home based Foods</i>			
Manary, <i>et al.</i> , 2004; Malawi(9); Quasi randomized controlled trial >12 months; Inclusion: a) Children discharged from NRU after initial treatment of infectious and metabolic problems, b) HIV negative	RUTF versus RUTF supplement versus maize-soy flour; Total: 282, RUTF: 69	Recovery: 95% in RUTF versus 78% in others; Wt Gain: 7.0 versus 4.9 g/kg/d	Home based therapy of malnutrition with RUTF is successful. Grade: 1b
c) Tolerated test dose of RUTF	RUTF supplement: 96 Maize soy: 117 Duration: Till recovery/death/infection	Morbidity: 3.8% diarrhea in RUTF versus 5.6% in others	
Simpore, <i>et al.</i> , 2006; Burkina Faso (10); Randomized controlled trial; 6-60 months; Inclusion: Undernourished children after initial stabilization using NG feeds	Spirulina, <i>Misola</i> (made of Millet, soya, peanut kernel, sugar, salt) versus traditional foods; Total: 550 Spirulina: 170, <i>Misola</i> : 170 Spirulina+ <i>Misola</i> : 170, Control: 40	All groups showed significant wt gain; maximum in spirulina and <i>Misola</i> group	Rehabilitation by Spirulina plus <i>Misola</i> seems synergically favour the nutrition rehabilitation better than the simple addition of protein and energy intake. Grade: 1b
<i>Local versus Imported Therapeutic Nutrition Products</i>			
Sandige, <i>et al.</i> , 2004; Malawi(11); Quasi-randomized controlled trials: 1-5 years; Inclusion: a) Initial stabilization at NRU; b) WHZ < -2z for non-hospitalized subjects	Imported RUTF (Plumpy nut) versus Recovery (Local): 80%, locally produced RUTF; Total: 260, Local RUTF: 135; Imported RUTF: 125; Duration: 14 weeks	Recovery (imported): 75%, Wt gain: 5.2 versus 4.8 g/kg/d, Default: 5% Failure, mortality and relapse: 11%	Home-based therapy with RUTF was successful. Locally produced and imported RUTF have similar efficacy. Grade: 1b
Diop, <i>et al.</i> , 2004; Senegal(12); Randomized controlled trial; 6-59 months; Inclusion: a) Severe malnutrition (WFH <70% and/or edema); b) Initial stabilization for 7 days at facility	Local RUTF versus Imported RUTF; Total: 61, Individual sample sizes not mentioned	Mean energy intake comparable: 3434.2 vs 3181.2 kJ; Mean wt gain: 7.9 vs 8.1 g/kg/d; Mean duration of rehabilitation: 35 vs 33 days	Home-based rehabilitation with locally made RUTF was successful in promoting catch-up growth. Locally produced RTUF was, at least as well accepted as the imported version and lead to similar weight gain. Grade: 1b
Cohort Studies			
Amthor, <i>et al.</i> , 2009; Malawi(13);	RUTF to provide 175 kcal/kg/d	Recovery (WFH 100%): 93.7%	Home-based therapy with RUTF

Author, Year of Publication, Country, Type of Study, Age, Inclusion Criteria	Intervention, Sample Size, Duration of Study	Salient Findings	Conclusion, Grade of Evidence
Prospective cohort study; Inclusion: a) WFH < 70% or Kwashiorkor b) Good appetite	and protein 5.3g/kg/d; N = 826 Duration: 8 weeks	Mean wt gain: 2.7 g/kg/d Failure: 1.8%; Mortality: 0.9% Default: 3.6% Relapse: Not Mentioned	administered by village health aides is effective in treating malnutrition during food crises in areas lacking health services Grade: 2b
Jilcott, <i>et al.</i> , 2010; Uganda(14); Evaluation study of a feeding program; 6-59 months; Inclusion: a) WFA < 3 rd percentile; b) MUAC < 12 cm	Locally produced RUTF; N=20 Duration: 5 weeks	Energy intake: 684 kcal/day Mean wt gain: 2.5 g/kg/day	Locally-produced RUF is a promising strategy for community-based care of malnourished children.
Linemann, <i>et al.</i> , 2007; Malawi(15); Prospective cohort study; 6-60 months; Inclusion: a) Moderate and severe malnutrition b) Good appetite	Locally produced RUTF; treatment by medical professionals versus community health aides; Total: 2131 SAM Duration: 8 weeks	Recovery: 89%; Mean wt gain: 3.5g/kg/d Default: 7%; Mortality: 1.4%; No differences in recovery rate based on training of the staff	Home-based therapy with RUTF yields acceptable results without requiring formally medically trained personnel. Grade: 2b
Ciliberto, <i>et al.</i> , 2006; Malawi(16); Prospective cohort study; 1-5 years; Inclusion: a) Edematous malnutrition, b) Good appetite, c) No complications	Administration of RUTF at home; Total: 219; Duration: 8 weeks	Recovery: 83%, Mortality: 5%, Mean wt gain: 2.8g/kg/d	Children with edematous malnutrition and good appetite may be successfully treated with home-based therapy. Grade: 2b
Chaiken, <i>et al.</i> , 2006; Ethiopia(17); Prospective cohort study; Age not mentioned; Inclusion: a) WFH < 70% or bilateral edema or MUAC < 11 cm	RUTF; N=5799 Followed up till recovery	Recovery (WFH 80%) : 66% Default: 2.3%, Transferred: 8.8% Mortality 0.2%	Recovery rates comparable with international standards, coverage far exceeded that of traditional center-based care. Grade: 2b
Collins, <i>et al.</i> , 2002; Ethiopia(18); Retrospective Cohort Study; 6-120 months; Inclusion: a) WFH < 70% or bilateral pitting edema	RUTF Oral antibiotic Vitamin A, FA Education; N=170 Followed up till recovery	Recovery: 85%, Mean wt gain: 3.2 g/kg/d Mortality: 4%; Default: 5%, Relapse: 6%; Mean time to recovery: 42 days	Outpatient treatment exceeded internationally accepted minimum standards for recovery, default, and mortality rates. Time spent in the program and rates of weight gain were not satisfactory. Outpatient care could provide a complementary treatment strategy to therapeutic feeding centres. Grade: 2b
Briend, <i>et al.</i> , 1999; Chad(19); Prospective Cohort study; >12 mo Inclusion: a) WFH < 70% b) Gaining wt for 3 days	Alternative F100 feeds were replaced by RUTF; 203 meals	Energy intake 40.2 (SD 20.9) kcal/kg per feed for RUTF versus 20.2 (11.5) kcal/kg per feed for F100 (p < 0.001); Total mean energy intake for the day was same	RUTF might be useful in contaminated environments or where residential management is not possible. Grade: 2b

Author, Year of Publication, Country, Type of Study, Age, Inclusion Criteria	Intervention, Sample Size, Duration of Study	Salient Findings	Conclusion, Grade of Evidence
Consensus Statements			
WHO, UNICEF, SCN informal consultation on community based management of SAM, 2006 (20)		<ol style="list-style-type: none"> 1. It is highly desirable to manage the treatment of severely malnourished children with no complications at home without an inpatient phase. 2. RUTFs are useful to treat severe malnutrition without complications in communities with limited access to appropriate local diets for nutritional rehabilitation. 3. When families have access to nutrient-dense foods, severe malnutrition without complications can be managed in the community without RUTF by carefully designed diets using low-cost family foods, provided appropriate minerals and vitamins are given. 4. Treatment of young children should include support for breastfeeding and messages on appropriate feeding practices for infants and young children. Children under 6 months of age should not receive RUTF or solid family foods. These children need milk-based diets, and their mothers need support to reestablish breastfeeding. They should not be treated at home. 	
Grade of Evidence: 5			
National Workshop on Development of Guidelines for Home Based Care and Standard Treatment of Children suffering from Severe Acute Malnutrition, 2006(21)		<ol style="list-style-type: none"> 1. Home based management could be feasible, acceptable, and cost effective option for those children categorized as “uncomplicated”. 2. Experience indicates that home management of SAMN is likely to be successful in closely monitored conditions with protocols, motivated staff and parents. An effective home based care and treatment program should be comprehensive and simultaneously address nutritional, medical, social, and economical aspects. 3. Energy dense therapeutic diets with low bulk are essential in the initial phase of management. However, these should be economical, available, and acceptable. These diets could be (i) home based (prepared/modified from the family pot) or (ii) ready to use therapeutic food (RUTF). Feeding should be frequent (6 to 8 times per 24 hours), active, and hygienic. 4. Commercially available international RUTF may not be suitable (acceptable, cost effective and sustainable) for Indian settings. 5. Multiple micronutrient and mineral supplementation should be provided orally as per the WHO guidelines for inpatient management of SAMN children. 	
Grade of evidence: 5			

noted to be comparable to data from facility based trials. The authors also conducted two meta-analyses of RCTs conducted in children recovering from SAM as part of this review. The first one compared the use of RUTF with F-100, and revealed an advantage of weight gain of 3.0 g/kg/day (WMD = 3.0; 95% CI= -1.70, 7.70) in favour of RUTF; however, the results were not statistically significant ($P=0.21$). Meta-analyses comparing RUTF with maize/soy flour included only one study(9) and found significantly increased weight gain (WMD= 2.10 g/kg/day; 95% CI= 1.97, 2.23; $P<0.001$).

Another review, conducted by Ashworth, *et al.*(5), studied the effectiveness of rehabilitating severely malnourished children in community settings. Effectiveness was defined as mortality of less than 5% or weight gain of more than 5 g/kg/day. 16 trials of home based management of SAM children were identified; of these, seven were considered to be effective. Amongst these, two programs were home based programs where no food was distributed, while 5 trials utilised RUTF. The authors noted that all successful programs aimed at providing the child with high protein, high energy diet at frequent intervals. None of the programs within the existing health systems was effective without external assistance. Home based treatment with nutrition education was shown to be effective in Bangladesh, even without the provision of RUTF or any other food. However, this involved considerable effort in educating the mothers.

Controlled Trials

A total of seven controlled trials were identified. Three trials compared home based management of RUTF with the standard practise using F-100 formula at therapeutic centres. Of these, two studies started home therapy after initial stabilization at a facility(6-8). A previously conducted meta-analysis showed an advantage of weight gain of 3.0 g/kg/day (WMD = 3.0; 95% CI= -1.70, 7.70) in favour of RUTF against F-100; however, the results were statistically not significant(4). The third study(8) in this group followed a purposive selection method, where more sick patients and those with complications were referred to a facility; subjects without complications and with good appetite were

selected for home based management using RUTF. Expectedly, the mortality in the F-100 group was much higher (18.9% versus 92.7%) because of the unequal baseline status between the two groups.

Two studies were identified that compared the efficacy of therapeutic nutrition products with traditionally available foods at home. Manary, *et al.*(9) compared RUTF with maize soy flour and observed higher weight gain and recovery, and lower morbidity in RUTF group, in comparison to home based foods. The study had been included in the systematic review mentioned above and details are given in that section. The second study(10) used *Misola* (a local product made from millet, soya, peanut kernal, sugar and salt) that supplies energy almost equivalent to conventional RUTFs. The authors found that *Misola* fortified with Spirulina led to higher weight gain, in comparison to use of traditional foods.

Two trials(11,12) compared the efficacy of a locally made RUTF with imported RUTF. A meta-analysis was done from the data derived from the two studies doing a comparative assessment of the impact of locally made RUTF and imported RUTF. The pooled data from the two studies done amongst 321 subjects, of whom 165 received locally made RUTF and 156 received imported RUTF, showed no difference in the weight gain between the two groups (WMD = 0.07 g/kg/d; 95% CI = -0.15, 0.29, 1.244, $P=0.15$) (**Fig 1**).

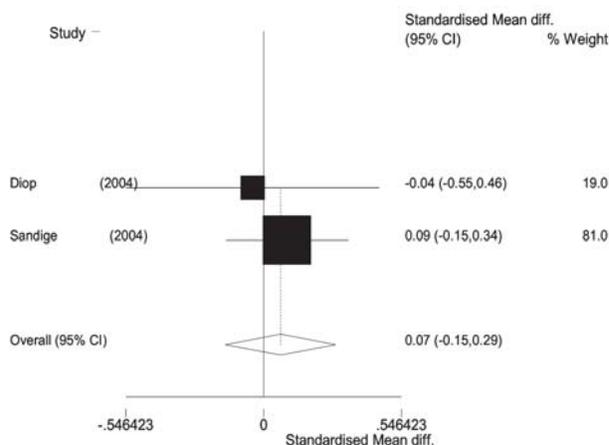


FIG. 1 Forest Plot showing the effectiveness of imported RUTF in comparison with local RUTF in weight gain of severe malnourished children.

Observational Trials

A total of 7 observational trials(13-19) were identified. Of these, one trial(19) estimated the adequacy of energy intake with ready to use foods in comparison to F-100 and found them to be comparable. Most of the trials (4 out of 5) reported a recovery rate (recovery variably defined by the authors) of more than 80%.

A pooled analysis of data from 5 studies (giving information on 9145 severely malnourished children) reveals a recovery rate of 88.3%, mortality of 0.7%, default rate of 3.6% and 6.7% babies had failure of treatment or needed referral to a facility. Using meta-analytic 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) (**Fig 2**). Of these trials, one(14) used a locally designed RUTF and found weight gain comparable, as with the use of commercially available RUTFs in other trials.

Consensus Statements

Two consensus statements(20,21) were identified from published literature. Both the statements emphasized the need to treat uncomplicated severely malnourished children at home, and on the efficacy of therapeutic nutrition products like RUTF for this purpose. They also stated the need for micronutrient supplementation as per WHO guidelines, exclusive breastfeeding in the first 6 months of life, monitoring of the children to ensure compliance and adequate response to treatment and need to develop local products to increase acceptability and decrease cost.

DISCUSSION

Review of presently available published peer reviewed literature shows that the use of 'therapeutic nutrition products' like RUTF are efficacious in treating children with severe acute malnutrition, who do not have any associated complications, and during the rehabilitation phase when prolonged hospitalization may not be desirable. Systematic reviews and randomized controlled trials on the topic show that this modality of treatment may be as efficacious as standard (WHO) treatment using F-100. Furthermore, these products are more effective than home based foods with lower energy

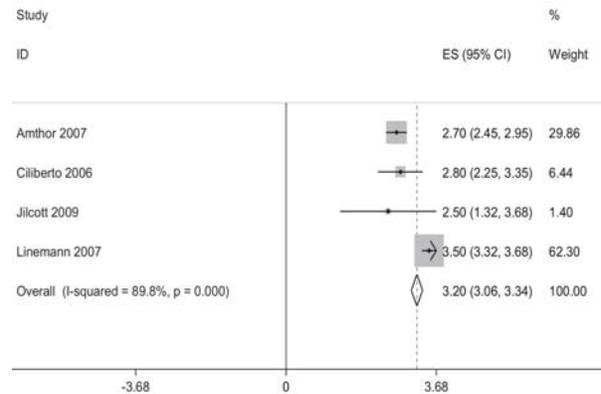


FIG. 2 Forest Plot showing the pooled estimates for weight gain in severe malnourished children using RUTF.

density in treating SAM. Locally designed ready to use foods are as effective as the commercially available products. The overall recovery rate with the use of RUTF is more than 85% with a mortality of less than 1%.

However, the currently available level of evidence does have some drawbacks that preclude the direct incorporation of such a strategy into a program or a policy, and even its extendibility to India. First is the fact that there is paucity of data, that too of robust quality, available on the topic. Most of the information is available from observational studies conducted in disaster situations, where no other alternative strategy was feasible. The other noteworthy issue is the fact that all the studies available so far were conducted in Africa. The results of extending it to countries like India, in non-emergency situations, with unknown efficacy and acceptability, are at present unpredictable.

A number of studies, especially the controlled trials which constitute a higher level of evidence are conducted in controlled situations, under the supervision and monitoring of health care workers. No doubt, this enables early identification of complications and institution of early treatment, wherever indicated but digresses from the basic rationale of using this strategy in areas where the health infrastructure is poor or non-existent. Such supervised management also increases the cost of management of SAM children. Based on the cost of RUTF alone, Ashworth, *et al.*(5) estimated the cost

EURECA CONCLUSION IN THE INDIAN CONTEXT

- The presently available evidence, drawn from limited number of studies, all conducted in Africa, on home based management of severe acute malnutrition using therapeutic nutrition products suggests that it is safe and efficacious.
- There is need for further research, particularly in product innovation and operational issues to establish its efficacy and cost effectiveness in the Indian context.

to rehabilitate a SAM child to be \$55; for a HIV positive child it would double to \$110. To put it in perspective, in 2006, the per capita health care cost spent by India was \$39(23). These are substantial costs for the health system of any developing country to absorb and emphasize the need for product innovation at a local level.

The use of home treatment, using medical nutrition products, as a public health strategy, therefore, should be treated as a possibility in infancy, with its need to study its feasibility and cost effectiveness in the Indian setting in an operational research format, before suggesting its integration into the current health programs. The effectiveness of cheaper locally designed ready to use foods is encouraging, and should stimulate the scientific community to design appropriate food(s) which are culturally acceptable in various parts of our large country, as well as cost-effective.

Most important is the need to communicate to the policy planners the urgency to address the problem of severe acute malnutrition. Despite the fact that severe malnutrition is often a co-morbidity in large proportion of avoidable child mortality, it does not get the attention it deserves. It should be emphasized that the treatment of SAM is cost effective – in fact, even hospital based management of SAM is more cost effective in reducing mortality than many other child survival intervention programs including the extremely visible vitamin A supplementation program(24,25). The availability of alternative strategies like home based management using locally made therapeutic nutrition products is likely to add to the cost effectiveness. India needs multi-pronged strategies to address the problem of severe malnutrition, given the geo-graphic, cultural and financial barriers that exist across this large

country; home based management is likely to be one of them.

Funding: None.

Competing Interests: None stated.

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