Effectiveness of Indigenous Ready-to-Use Therapeutic Food in Community-based Management of Uncomplicated Severe Acute Malnutrition: a Randomized Controlled Trial from India

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Summary

A randomized controlled trial was conducted in Chandigarh, India (2011), to determine the effectiveness of indigenous ready-to-use therapeutic food (RUTF) in community-based management of uncomplicated severe acute malnutrition (SAM). Intervention was through outpatient therapeutic program site (OTP). Study and control group children (6 months–5 years) were followed up weekly for 12 weeks, in OTP and at home. All children received supplementary nutrition through anganwadis under integrated child development scheme. Study children, in addition, received therapeutic dose of RUTF in OTP. Primary outcome, 115% of baseline weight, was attained in 6 of 13 (46.2%) and 1 of 13 (7.7%) children among study and control group, respectively [odds ratio: 10.28, 95% confidence interval (CI): 1.02–103.95]. Compared with control group, addition of RUTF in study group resulted in average additional increase in weight by 13 g/kg of baseline weight/week/child (95% CI: 2–23). Indigenous RUTF was effective in community-based management of uncomplicated SAM.

Key words: ready-to-use therapeutic food (RUTF), severe acute malnutrition (SAM), community-based management.

Introduction

Severe acute malnutrition (SAM) remains a major killer of children <5 years of age and is a neglected health condition. [1]. SAM is diagnosed when the child has any one of the following criteria: weight for height Z (W/HZ) score < −3SD, mid upper-arm

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circumference (MUAC) < 115 mm, bipedal edema or visible severe wasting [2].

According to National Family Health Survey (NFHS III), 6.4 % of children <5 years of age in India suffer from SAM. Facility-based management of all these children is not practical, and it has not been able to tackle SAM as a public health problem [3, 4]. Community-based management of acute malnutrition involves provision of treatment for uncomplicated SAM with energy dense ready-to-use therapeutic foods (RUTF), in therapeutic doses for short term, through an outpatient therapeutic program site (OTP) [5] and/or other nutrient-dense foods at home.

However, most of the evidence on effectiveness of RUTF has emerged from observational studies conducted in emergency settings in Africa. There is need to generate more robust evidence, design similar products and protocols locally and establish efficacy and cost-effectiveness in a ‘non-emergency’ setting, particularly in the Indian context [6–8]. Hence, this intervention study was planned with the objective of determining the effectiveness of introduction of locally prepared RUTF in therapeutic doses in community-based management of uncomplicated SAM.

Materials and Methods

Indira colony, Chandigarh, is a densely populated urban resettlement colony with a population of 22,000, and <5-year-old population of approximately 3000. Urban Health and Training Center, Indira colony, was the OTP. The investigators screened all the children registered under the 12 anganwadi centers of Indira Colony for SAM. Operational definition of SAM was children between 6 months to 5 years of age (as on date of registration) with W/HZ score < 3SD or MUAC < 115 mm (any one). An exception to this was for infants where the MUAC criterion was not used. Age was confirmed through immunization cards. Salter electronic baby and toddler scale (model 914), Seca 214 portable stadiometer and Infantometer (Mfd. by ISO 9001:2000 Co.) were used to measure weight, height and length, respectively. Weight was measured to the nearest 10 g and height/length to the nearest millimeter. Mean of two measurements was taken. Calibration was done once every week using standard weights and rods. World Health Organization’s (WHO’s) Anthro software v3.2.2 was used for calculation of Z scores.

Uncomplicated SAM children were the units of study. Inclusion criteria included the following: SAM child with all of the following: good appetite, alert and clinically well. Child had to be resident of the area for at least 6 months. Complicated SAM—SAM with any one of the following: anorexia, not alert, high fever (>104 F), severe pallor, severe dehydration, lower respiratory tract infection, bipedal edema, visible severe wasting—formed the exclusion criteria. SAM children without complications who passed the ‘appetite test’ as recommended by WHO/The United Nations Children’s Fund (UNICEF) were accepted for outpatient care. (Supplementary Annexure 1, RUTF distribution protocol).

RUTF (Supplementary Annexure 2) was locally prepared by trained personnel in the kitchen of the institution to which the investigators were affiliated. RUTF was microbiologically tested based on quantitative spread plate methodology using suitable solid and enrichment media. Identification was carried out as per standard protocols [9] to test for a shelf life of minimum 8 days. Macronutrient contents (Supplementary Annexure 3) and microbiological cutoffs (Supplementary Annexure 4) were adhered to as suggested by UNICEF [10]. Fresh supply of groundnut, used to prepare RUTF, was physically verified for fungal contamination.

Children with uncomplicated SAM were randomized into study and control group by one of the doctors of the OTP, on the day of registration, by using a computer-generated randomization sequence. Allocation concealment was done using numbered, opaque, sealed envelopes. An independent statistician prepared random sequence using block randomization (block size 4) by randomly selecting the blocks. Open-labeled parallel randomized controlled study design was used with an allocation ratio of 1:1 (Fig. 1). Blinding of study and control group could not be done for obvious reasons.

First day of OTP (2 July, 2011) was considered as the date of registration in the study. Children were followed up throughout the study period at OTP (once a week for 12 weeks) by an Out Patient Department (OPD) team that included two doctors and one medical social worker. During OTP visit, all children (study and control) underwent anthropometry, individual case management and counseling for feeding. We tried to limit bias by asking the medical social worker to measure the children in a separate room before the start of the weekly OTP. RUTF in therapeutic dose of 200 kcal/kg/d was prescribed for study group by the doctor (Supplementary Annexure 1). Weekly requirement of RUTF packets was given to the family during OTP visit. Objective assessment of RUTF compliance was done by noting down the amount of RUTF consumed in previous week. In case the child was absent from the OPD, weekly requirement of RUTF was sent to their home through the anganwadi workers (AWWs).

Both study and control groups also received supplementary nutrition from the anganwadi as per guidelines for management for malnutrition under the Integrated Child Development Scheme (ICDS). ICDS uses weight for age criterion to classify malnutrition. Under ICDS, children received 500 kcal of energy and 12–15 g protein per day through anganwadi centers. Those with severe malnutrition received
800 kcal of energy and 20–25 g protein per day. No mechanism was put in place for monitoring supplementary nutrition through Anganwadi centers.

Follow-up home visits of all children was done according to a predefined protocol: once a week by doctor and twice a week by AWW. AWWs were trained by the investigator well in advance. SAM complications, if any, were noted, and family was motivated and counseled with respect to feeding the child. In study group, RUTF compliance (complete/partial/nil) was also noted. Data were recorded in OTP booklet (parent and office copy).

RUTF was stopped in the study group once the child attained 115% of the baseline weight (primary outcome variable); a predefined discharge criterion was used for the same (Supplementary Annexure 5). At the end of the study period, children in control group satisfying the inclusion criteria were given RUTF for 4 weeks.

Sample size was calculated for hypothesis testing for difference between two proportions. The following assumptions were made: expected percentage of children who will attain the primary outcome in study group—60; in control group—10, power 0.80, α error 0.05 and dropout rate 0.10. Sample size of 11 in each arm was finalized by n-master 1.0 sample size software, considering a one-sided test. Both the study and control groups received similar intervention but for RUTF in study group. It is expected that children in study group will fare better than those in control group.

A review of various studies on effectiveness of RUTF in community-based therapeutic care between 2000 and 2005 in Africa showed a recovery rate between 61.5 and 88% [11]; primary outcome used in these studies was different from the one used in our study. No study is available to date that has used the primary outcome as used in this study; hence, the lower range (60%) was taken as the primary outcome in study group, i.e. percentage of children who would attain 115% of baseline weight. In control group, an assumption of 10% was made arbitrarily. Data were entered and analyzed by original assigned groups in SPSS v17.0.

Institute ethics committee approval was obtained. Informed consent was taken from the parents before including their children in the study. Permission and support from the concerned authorities of the respective programs were taken before the start of the study. The trial was registered with Clinical Trials Registry of India (CTRI/2011/12/002259).

Results

Thirty-two children were indentified with uncomplicated SAM; parents of 26 children gave consent. Study and control groups both had 13 children each (Fig. 1). Baseline characteristics of participants are shown in Table 1. No child showed signs and
symptoms of complicated SAM. No complications as a result of RUTF consumption were noted. There was no loss to follow-up (Supplementary Annexure 1). Follow-up in OTP by SAM children was 70% of expected person-days follow-up. Follow-up home visits by AWWs were 52% of the expected person-days follow-up. Both were not significantly different between study and control group. The doctor made all home visits in both groups. At the end of the intervention, 10 out of the 26 children [study (6), control (4)] fulfilled the operational definition for uncomplicated SAM.

Primary outcome was attained in 6 out of 13 (46.2%) among study group and 1 out of 13 (7.7%) among control group; the difference was statistically significant [odds ratio: 10.28, 95% confidence interval (CI): 1.02–103.95]. Longitudinal data analysis (parametric curve: curvilinear) showed that change in the Z score was statistically significant over time: baseline W/HZ score did not affect the weight gain (low power cannot be ruled out). Younger age was found to be associated with greater weight gain (Table 3). This is expected because young children have less weight to gain/kg than old children.

To our knowledge, this is the first randomized controlled trial in Indian setting that has studied the effectiveness and feasibility of indigenous RUTF in community-based management of uncomplicated SAM. This study has tested the model of using a primary health center as the OTP along with the assistance of AWWs in providing community-based care in non-emergency settings. We have used protocols that can be replicated in other sites.

Weight gain of 3 g/kg/d was lower than 8 g/kg/d among moderate acute malnutrition children in a study in Niger [12] where fixed dose of RUTF (1000 kcal/day/child) was given, unlike our study where individualized therapeutic dose was given. Even with a RUTF dose of 175 kcal/kg/day, substantial differences in rates of weight gain were apparent: in Senegal, the mean rate with RUTF was 8 g/kg/day; in Malawi, where there was high level of edema, it was 5 g/kg/day [13, 14] and <3.5 g/kg/day in further two studies [15, 16]. Clinically, a weight gain of 8 g/kg/d is expected in uncomplicated SAM children who are put on RUTF therapy [17]. Our study has shown a lower recovery rate (46.7%) than from Bangladesh (91.9%) [18].

Assuming prevalence of SAM to be 6.4%, approximately 170 uncomplicated SAM cases were expected to be detected. With low registration in anganwadi centers, followed by application of inclusion criteria, only 32 cases were detected. We did not collect information with respect to sociodemographic profile. Bias in allocation to two intervention arms cannot be ruled out in a scenario where first two children were allotted to the same intervention. Varying block size could have been a better option. Despite anthropometry being done in a separate room before the start of the OPD, bias cannot be ruled out as it would have been obvious for the social worker to know the group (study/control) of the child. Same OTP OPD team was involved in medical checkup, anthropometry, counseling and follow-up home visits.

Attainment of 115% of baseline weight was used as discharge criterion despite using W/HZ score as one of the recruitment criteria; the reason being some SAM with MUAC < 115 mm can have discharge W/H of 90% at admission [2]. Similar numbers of uncomplicated SAM in both groups at the end of the study should be interpreted with caution as

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**TABLE 1**

*Baseline characteristics of study participants*

<table>
<thead>
<tr>
<th>Serial no</th>
<th>Baseline characteristics</th>
<th>Overall [mean (SD)]</th>
<th>Study group [mean (SD)]</th>
<th>Control group [mean (SD)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Age in months</td>
<td>29 (15)</td>
<td>28 (16)</td>
<td>30 (14)</td>
</tr>
<tr>
<td>2</td>
<td>Male (%)</td>
<td>50</td>
<td>23</td>
<td>77</td>
</tr>
<tr>
<td>3</td>
<td>Z score for weight for height</td>
<td>−3.33 (0.67)</td>
<td>−3.47 (0.88)</td>
<td>−3.18 (0.32)</td>
</tr>
<tr>
<td>4</td>
<td>Z score for weight for age</td>
<td>−3.95 (0.98)</td>
<td>−4.28 (0.90)</td>
<td>−3.63 (0.96)</td>
</tr>
<tr>
<td>5</td>
<td>Z score for height for age</td>
<td>−3.13 (1.62)</td>
<td>−3.44 (1.36)</td>
<td>−2.81 (1.85)</td>
</tr>
</tbody>
</table>

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**Discussion**

When compared with control group, proportion of children attaining primary outcome was significantly higher in study group. Average weight gain in study group was 3 g/kg/d, out of which 2 g/kg/d was attributable to RUTF. Differential distribution of sex and baseline W/HZ score did not affect the weight gain (low power cannot be ruled out). Younger age was found to be associated with greater weight gain (Table 3). This is expected because young children have less weight to gain/kg than old children.

To our knowledge, this is the first randomized controlled trial in Indian setting that has studied the
study group had lower average Z score at the beginning of the study. Many factors like low average consumption of RUTF/child and low follow-up home visits by AWWs could not be controlled owing to systemic deficiencies. Although an appetite test was performed, an acceptability test was not conducted among caregivers and family heads to determine the acceptance of the product as a therapy. Non-significant results in subgroup analysis should be interpreted with caution owing to small sample size. In our study, change in W/H Z score was not significantly different between study and control group (Table 2); it is to be noted that sample size was not calculated for change in W/HZ score. Owing to logistic constraints, aflatoxin testing was not performed. We were not able to procure mineral vitamin mix; instead, a multivitamin tablet was used to supplement micronutrients. The micronutrient content of multivitamin tablet was less than that of mineral vitamin mix (especially Zinc and Iron) used in WHO-UNICEF RUTF (Supplementary Annexure 3). Thiamin, riboflavin, folic acid and retinol content were satisfactory. This difference of micronutrients could be another reason for poor weight gain. In such a scenario, micronutrient level measurement in children may be included in future studies to identify potential deficiencies. In our study, RUTF was tested for a shelf life of minimum 8 days; however, experience has shown that RUTF without air tight packaging has a shelf life of 3–4 months. Many locally prepared foods that are culturally acceptable and low cost have been used by reliable academic and medical institutes of India. Most of them, with a short shelf life, have been used for community-based supplementation rather than therapy. Indigenous RUTF was effective in community-based management of uncomplicated SAM. Because of lower recovery rate and average weight gain in our study, we would recommend that future studies incorporate larger sample size, acceptability testing in community, aflatoxin testing of RUTF and mineral vitamin mix procurement. Appropriate Information/Education/Communication (IEC) activities and system strengthening must be carried out to ensure high compliance.

### Table 2

*Longitudinal data analysis (parametric curves: curvilinear) of WHZ score over the period of intervention (12 weeks)*

<table>
<thead>
<tr>
<th>Type III test of fixed effects&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Numerator df</th>
<th>Denominator df</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>1</td>
<td>34.29</td>
<td>0.000</td>
</tr>
<tr>
<td>Treatment group (study/control)</td>
<td>1</td>
<td>34.29</td>
<td>0.620</td>
</tr>
<tr>
<td>Week</td>
<td>1</td>
<td>192.29</td>
<td>0.000</td>
</tr>
<tr>
<td>Week square</td>
<td>1</td>
<td>192.21</td>
<td>0.002</td>
</tr>
<tr>
<td>Treatment group * week</td>
<td>1</td>
<td>192.29</td>
<td>0.125</td>
</tr>
<tr>
<td>Treatment group * week square</td>
<td>1</td>
<td>192.21</td>
<td>0.119</td>
</tr>
</tbody>
</table>

<sup>a</sup>Dependent variable: WHZ score.

### Table 3

*Linear regression (forward method) to determine the effect of group, baseline W/H Z score, age and gender of the child on weight gain*

<table>
<thead>
<tr>
<th>Model</th>
<th>Unstandardized coefficients</th>
<th>95% CI for β</th>
<th>t</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>β</td>
<td>Standard error</td>
<td>Lower</td>
<td>Upper</td>
</tr>
<tr>
<td>1</td>
<td>Constant</td>
<td>0.031</td>
<td>0.006</td>
<td>0.018</td>
</tr>
<tr>
<td></td>
<td>Age in months</td>
<td>−0.001</td>
<td>0</td>
<td>−0.001</td>
</tr>
<tr>
<td>2</td>
<td>Constant</td>
<td>0.011</td>
<td>0.01</td>
<td>−0.010</td>
</tr>
<tr>
<td></td>
<td>Age in months</td>
<td>−0.001</td>
<td>0</td>
<td>−0.001</td>
</tr>
<tr>
<td></td>
<td>Group (Ref: Control)</td>
<td>0.013</td>
<td>0.005</td>
<td>0.002</td>
</tr>
</tbody>
</table>

Dependent Variable: weight gain per kg baseline weight per week. Gender and baseline W/H Z score not included by the model.
Key Messages

What is already known?
1. In Africa, community-based management of acute malnutrition has been proven to be highly effective; RUTF is as effective as F100, and locally made RUTF is as effective as imported RUTF.

What the study adds?
1. This study has generated evidence by preparing RUTF locally and establishes its effectiveness and feasibility in management of uncomplicated SAM in a ‘non-emergency’ community-based setting, in the Indian context.
2. We have devised and tested practical algorithms for community-based management, in addition to formulation of criteria for selecting children.

Supplementary Data
Supplementary Data are available at *Tropej* online.

References