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Original Article

Acceptability of locally produced ready-to-use therapeutic foods in Ethiopia, Ghana, Pakistan and India

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Abstract

Successful treatment of severe acute malnutrition has been achieved with ready-to-use therapeutic food (RUTF), but only 15% of children with severe acute malnutrition receive RUTF. The objective of this study was to determine whether new formulations of RUTF produced using locally available ingredients were acceptable to young children in Ethiopia, Ghana, Pakistan and India. The local RUTFs were formulated using a linear programming tool that allows for inclusion of only local ingredients and minimizes cost. The study consisted of 4 two-arm, crossover, site-randomized food acceptability trials to test the acceptability of an alternative RUTF formula compared with the standard peanut-based RUTF containing powdered milk. Fifty children with moderate wasting in each country were enrolled in the 2-week study. Acceptability was measured by overall consumption, likeability and adverse effects reported by caregivers. Two of the four RUTFs did not include peanut, and all four used alternative dairy proteins rather than milk. The ingredient cost of all of the RUTFs was about 60% of standard RUTF. In Ethiopia, Ghana and India, the local RUTF was tolerated well without increased reports of rash, diarrhoea or vomiting. Children consumed similar amounts of local RUTF and standard RUTF and preferred them similarly as well. In Pakistan, local RUTF was consumed in similar quantities, but mothers perceived that children did not enjoy it as much as standard RUTF. Our results support the further investigation of these local RUTFs in Ethiopia, Ghana and India in equivalency trials and suggest that local RUTFs may be of lower cost.

Keywords: malnutrition, pre-school children, food consumption, child feeding, community-based, developed countries.

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Introduction

Malnutrition plays a causal role in over half of all deaths that occur in children under 5 years, and severe acute malnutrition (SAM) is attributed to one million of those deaths each year (Black *et al.* 2013). Since its programmatic advent in 2007, ready-to-use therapeutic food (RUTF) has facilitated home-based therapy for uncomplicated SAM (WHO 2006, 2007, 2013). RUTF has a low water activity, is shelf stable for up to 2 years and is difficult to contaminate because it does not support the growth of bacteria. Home-based therapy with RUTF for SAM is associated with increased treatment coverage in populations and higher recovery rates in affected individuals (WHO 2007). Despite RUTF's effectiveness, it is estimated that in 2015, globally only 15% of children with SAM will receive RUTF (UNICEF 2013). RUTF is often stigmatized as an imported food made with exogenous ingredients, and this is cited as a barrier to its widespread adoption.

In 2014, a spreadsheet formulation tool for RUTF was developed, which draws upon a database of almost all potential ingredients worldwide (Ryan *et al.* 2014). This linear programming (LP) tool targets the lowest-cost ingredients while assuring that the composition of the formulation meets the international specifications.

When this LP tool is coupled with a standardized food laboratory evaluation for physical properties and acceptability testing in the target populations, it was suggested that this would identify RUTF products that have utility in distinct cultural settings (Dibari *et al.* 2012; Ryan *et al.* 2014).

This study was subsequently undertaken to test the hypothesis that the LP tool, in conjunction with food laboratory assessment and acceptability testing, would identify candidate local RUTFs for clinical equivalency trials in Ghana, Ethiopia, Pakistan and India.

Subjects and methods

Subjects

Eligible subjects were children with a mid-upper arm circumference (MUAC) ≥ 11.5 and <12.5 cm, aged 8–24 months, presenting in local villages surrounding two health care sites in the identified regions. Exclusion criteria included children with chronic debilitating conditions, such as cerebral palsy or congenital malformations, or those having received a standard RUTF. Because this was an acceptability trial, children that presented with SAM, having a MUAC < 11.5 cm, were referred to health centres offering therapeutic feeding and were not be included in the study.

The studies were approved by the local institutional review boards, Jimma University Ethical Review Board, Noghuchi Memorial Institute for Medical Research Institutional Review Board, The Aga Khan University Ethical Review Committee, Indian Institute of Health Management Research Institutional Committee for Ethics and Review Research, and the Washington University Human Studies Committee.

Study design

The study was a 2×2 crossover, site-randomized, food acceptability study comparing a local RUTF with standard RUTF in four countries. Fifty children were enrolled in each country, 25 subjects per site.

The primary outcome of the study was the amount of therapeutic food consumed, consumption defined as percent of offered food consumed by the child. Secondary outcomes included the child's likeability of the foods as perceived by the caretaker and adverse events, defined as vomiting, rashes and diarrhoea, secondary to food allergy and mother's report of presumptive abdominal pain. This sample size was chosen assuming a 20% dropout rate to provide $\alpha = 0.05$ with 80% power to detect a difference in mean consumption of 5%.

The local RUTFs were developed using an LP tool, with locally procurable ingredients and produced on a small scale using pilot plant equipment. A 'local ingredient' was defined as the country having at least 500 metric tons of an ingredient available for purchase (Ryan *et al.* 2014). This definition did not take into account whether the ingredient was consumed by the local population to any appreciable extent. All local RUTFs met international safety criteria and nutrient recommendations, and organoleptic qualities were deemed acceptable by informal testing and were feasible for large-scale production.

Participation

Local implementing partners were identified in the four countries; Jimma University in Jimma, Ethiopia; University of Ghana in Legon, Ghana; Aga Khan University in Karachi, Pakistan; and Action Contre La Faim in Baran, Rajasthan, India. The locations of the health care sites used were Jimma and Serbo in the Oromia Region of Ethiopia, Kweiman and Danfa North of Accra in

Key messages

- Linear programming models are effective at accurately generating low-cost alternative ready-to-use therapeutic food (RUTF) formulations that meet all required specifications.
- There is a need to localize production and reduce the overall cost of RUTF to increase the coverage of this effective treatment.
- RUTF formulations using a local ingredients and production facilities are affordable and feasible.

Ghana, Matiari and Hala in the Matiari district of Pakistan, and Garda and Kawari Khurd in the Baran District of India. Lists of children residing in the study sites were obtained from health extension workers in each village. Community mobilizers and health care agents surrounding each study site screened all potential participants and identified 25 eligible children at two sites in each country.

On the day of enrolment, caretakers received an explanation of the study, had the opportunity to ask questions, indicated consent verbally and also signed a consent form if they chose to participate. For participants, a demographic questionnaire was given, and anthropometric measurements of the children were taken. The local RUTF was given to the children at the identified site for 7 days, while the standard RUTF was distributed at the other site. Dosing of the test foods was about 75 kcal/kg/day packaged in foil sachets or plastic bottles. This dose was chosen because it represented more than 50% of the typical supplementary ration for a wasted child, although not nearly the ration for a child with SAM.

After 3 days, the caretakers and children were asked to return to the site for assessment and to determine the amount of food consumed by the child to date. After 7 days, the caretakers and child returned for the child's anthropometric measurements and further assessment. Community mobilizers and trained staff followed up with the caregivers and children during home visits to assess the consumption and liking rate of the children in a more familiar setting. At the beginning of the second week, the type of RUTF that the child did not consume for the first 7 days was given. On day 10, the participants returned to the site and underwent the same assessment as on day 3. On day 14, the same assessment as day 7 was performed, with the addition of caregiver focus group discussions. Participation is summarized in Fig. 1.

Caretaker focus group discussions were also carried out to further understand the perception of RUTFs and local food consumption patterns (Phuka *et al.* 2011). Focus groups, conducted by community health care workers, consisted of three to eight caregivers and provided the opportunity for caregivers to express their opinions regarding the implemented system and study design, likeability of the trial foods and overall effect on their child (Barbour & Kitzinger 1999). The general effects monitored included the child's activity level before and during consumption, rate of consumption and observed adverse effects perceived by the caregiver. On day 0, community mobilizers received feedback from the caregivers regarding their opinion of RUTFs, the importance of local and imported ingredients, and processing methods such as fermentation to aid overall research on developing new, most cost-effective RUTFs. On day 14, community mobilizers received additional feedback regarding the local and standard RUTFs.

If a child remained with moderate malnutrition at the conclusion of the study, the caretaker was counselled about supplementary feeding and referred to treatment programmes if they were available.

RUTF formulation

A comprehensive, excel-based LP tool was used to develop nutritionally adequate RUTFs. National and international databases of ingredients were researched, and data regarding the nutrient composition, food safety, availability and costs associated with procuring, processing and distributing were compiled in the database (Ryan *et al.* 2014; Dibari *et al.* 2012). Individualized LP sheets were created for each of the four countries and used to generate formulations that were subsequently made in the laboratory.

Nutrient requirements were specified by WHO in 2007; a summary of the LP constraints that define the boundaries of the acceptable formulations is shown in the Supporting Information Table 1. The determined objective function of the LP tool was to solve for the least-cost ingredients, allowing for cost-effective novel ingredients to be introduced into the formulations without compromising the integrity of the final product. The identified nutrient specifications were upheld during production of all alternative formulations. Formulas were optimized for organoleptic properties, cost and fatty acid profile. Each RUTF was formulated such that it included an emulsifier at ~2% and a vitamin mineral premix at ~2%, respectively.

Laboratory preparation and assessment

Potential RUTFs were prepared at Washington University in the food preparation laboratory. Powered lipid emulsifier and the liquid oils present in the

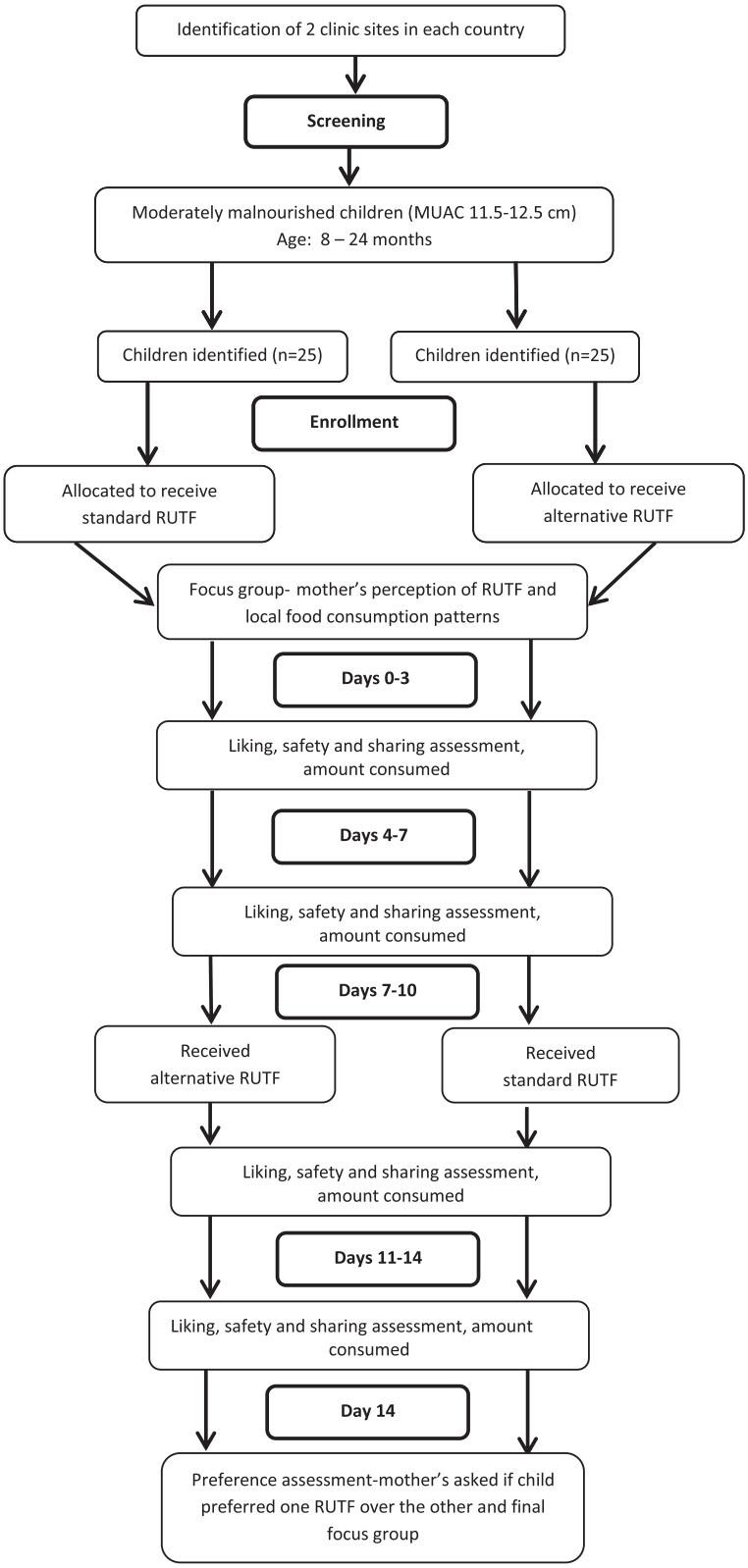

Fig. 1. Flow of subject participation; study screening, enrolment and assessment. MUAC, mid-upper arm circumference; RUTF, ready-to-use therapeutic food.

formula were blended while heating until the emulsifier was completely dissolved. Simultaneously, a portion of the dry ingredients and remaining vegetable oil were blended together. The dissolved emulsifier mixture and remaining dry ingredients were then combined and homogenized.

Qualitative analyses were performed on the identified formulation for each country as a method to predict production feasibility, product acceptance and overall liking. Informal sensory evaluations were conducted on each formulation at the Washington University Food and Nutrition Laboratory, evaluating texture, flavour, sweetness level and overall mouth feel in terms of child likability (Guinard 2001). Sweetness levels were altered to contain as much or less than the typical amount of sugar present in standard RUTF (Dibari *et al*. 2012). Water content (%) and pH were measured at the time of mixing. After internal qualitative analysis, products were sent to an accredited laboratory for macronutrient, micronutrient and microbial analyses. Upon receipt of the analyses, the formulas were determined to be safe and were produced at a larger scale for acceptability trials. After optimization of the extrusion and mixing processes, the most feasible, cost-effective and promising formulation for acceptability trials in Ethiopia, Ghana and Pakistan were prepared in bulk. All of these formulations were practical for large-scale production.

Preparation of study RUTFs

Final local RUTFs for Ethiopia, Ghana and Pakistan were produced by Purdue University (West Lafayette, IN, USA), and the RUTF used in India was produced by JVS, located in Jaipur, Rajasthan; Supporting Information Figure 1 outlines the production process.

Many ingredients used in the production of RUTF come in a pre-processed form (milk powder, refined vegetable oil and sugar); however, some ingredients need to undergo processing prior to being incorporated into the product (peanuts, legumes and cereal grains). The most widely available, effective processing methods are roasting and extrusion cooking. Extrusion cooking is the process of kneading a product or ingredient through a heat-safe barrel with a screw press. The generated pressure and friction create heat and subsequently cook the ingredient. All ingredients needing processing utilized either roasting or extrusion cooking in this study. Compositional testing was conducted on the identified final formulations to confirm that the test RUTFs complied with the WHO composition guideline.

Data analysis

The clinical data received were double entered into a Microsoft Excel spreadsheet (Redmond, WA, USA), cleaned and sealed. Summary statistics were calculated for each dietary group by country. Group measurements were expressed as means ± SD or n (%). A paired Student's t-test was used to compare continuous outcomes, and Fisher's exact test was used to compare categorical outcomes. Differences were considered significant if $P < 0.05$.

Results

Local RUTFs

The formulations for the four locations are described in Table 1. Compositional testing of these four local RUTFs shows that the macronutrient content predicted by the LP tool and the laboratory analyses is similar (Table 2). Additional calcium and phosphorus for the local RUTFs were added through the vitamin and mineral premix. Ingredient cost predicted by the LP tool for each alternative RUTF formula was $1.25/kg for Ethiopia and India, $1.14/kg for Ghana and $1.45/kg for Pakistan, compared with $2.18/kg for standard RUTF.

Acceptability study

From December 2014 to May 2015, 195 children completed the acceptability study (Table 3). All children enrolled had MUAC < 12.5 cm with the exception of those in Ghana. The reason for the alteration of the protocol in Ghana was that due to Ghana's participation in the '1000 Days Initiative', rates of moderate malnutrition are very low, such that enough children with low MUAC could not be found at the chosen study sites.

Table 1. Comparison of ready-to-use therapeutic food formulas

Ingredient	Standard	Ethiopia	Ghana	Pakistan	India
Legume, g/100 g					
Almond	—	—	—	10.00	—
Groundnut	27.00	10.00	—	—	15.00
Lentil	—	—	—	12.08	8.00
Soybean	—	6.50	7.10	—	—
Cereal/grain, g/100 g					
Maize	—	—	12.60	5.75	—
Oat	—	1.90	—	—	5.00
Milk, g/100 g					
Acid whey	—	14.40	—	—	17.50
Non-fat dry	25.00	—	—	—	—
WPC 34	—	10.50	12.38	21.05	—
WPC 80	—	5.50	6.10	—	7.02
Oil, g/100 g					
Canola, rapeseed	—	11.60	14.60	15.17	5.90
Coconut	—	—	5.00	—	20.08
Palm	15.80	15.50	5.00	—	—
Soybean	2.90	—	—	—	—
Sunflower	—	—	6.20	7.94	—
Sugar, g/100 g	26.00	20.00	25.00	24.00	18.00
Cocoa g/100 g	—	—	2.00	—	—
Total,* g	96.7	95.9	95.98	96	96.5
Ingredient cost, g/100 g	$0.230	$0.124	$0.108	$0.145	$0.117

WPC, whey protein concentrate. *Vitamin mineral powder (~2%) and emulsifier (~2%) per 100.0 g of product.

Table 2. Nutrient and physical properties of the four local RUTFs created

Nutrient characteristic	WHO specifications	Ethiopia	Ghana	Pakistan	India
Energy (kcal)	520–550	537	592	571	567
Energy (kcal) calculated*	—	553	548	547	567
Lipid (g)	26–36% by weight	34.8	33.4	32.6	36.8
Protein (g)	13–16% by weight	15.4	13.5	13.7	17.6
CHO (g)†	41–58% by weight	44.4	48.2	49.5	41.4
Dairy protein (g)	>50% protein	11.6	9.2	7.4	7.6
Fibre (g)	<5%	1.3	2.2	5	4.3
Calcium (mg)	300–600 mg/100 g	368	128	147	425
Phosphorus (mg)	300–600 mg/100 g	343	188	220	381
n-3% of total energy	0.3–2.5% total energy	2.4	2.4	2.4	0.9
n-6% of total energy	3–10% total energy	9.9	9.9	9.1	6.83
Water content (%)	2.5 max	1.3	1.5	1.1	2.09
pH	—	6.19	6.06	6.07	6.2
Water activity	<0.6	0.19	0.41	0.17	0.52

RUTFs, ready-to-use therapeutic food; CHO, carbohydrate. *Energy calculated from laboratory-analysed protein, CHO and lipid. Energy (kcal) = (g protein * 4) + (g CHO * 4) + (g lipid * 9); we observe a difference between the energy calculated by the tool and the one based on the laboratory data. †Carbohydrate calculated for laboratory-analysed samples (100 – ash–lipid–protein–water).

Consumption of either local or standard RUTFs ranged from 82% to 93%, and there were no significant differences when amounts of local and standard RUTF consumed were compared in any of the four countries. The Liking assessment differed only in Pakistan, where mothers perceived that their children preferred standard RUTF to local RUTF.

Table 3. Baseline characteristics of children that completed the study by country*

Characteristic†	Ethiopia	Ghana	Pakistan	India
	$n = 44$	$n = 50$	$n = 51$	$n = 50$
Male	18 (41)	23 (46)	19 (37)	27 (54)
Age (months)	16 ± 4.9	15 ± 4.9	14 ± 4.5	21.5 ± 9.8
Mother is caretaker	41 (93)	45 (90)	42 (82)	44 (88)
Father alive	42 (95)	50 (100)	51 (100)	50 (100)
Siblings	2.9 ± 1.6	1.8 ± 1.5	3.2 ± 2.8	1.7 ± 1.2
Breastfeeding	41 (93)	33 (66)	36 (84)	36 (72)
Mid-upper arm circumference (cm)	12.1 ± 0.3	14.7 ± 1.5	12.2 ± 0.2	12.2 ± 0.5
Weight-for-height, *z*-score	−1.5 ± 0.9	−0.6 ± 1.2	−1.4 ± 0.8	−2.2 ± 0.5
Height-for-age, *z*-score	−2.3 ± 1.4	−0.2 ± 1.2	−2.3 ± 1.6	−2.6 ± 1.3
Mother reports diarrhoea	0	11 (22)	1 (2)	10 (20)
Mother reports vomiting	0	7 (14)	1	2 (4)

*Values are mean ± SD or *n* (%). †Characteristics reported by the caregiver at the time of enrolment; time zero.

No child developed a rash suggestive of a food allergy. Upon enrolment, mothers reported almost no diarrhoea and vomiting in Ghana and Ethiopia, but in Pakistan and India, about 20% of mothers reported their child to have diarrhoea. There were no significant differences in mother's report of diarrhoea, vomiting or abdominal pain when local RUTF was compared with standard RUTF (Table 4). All children reported to have diarrhoea were assessed by team members, and none were deemed to have a significant gastrointestinal illness.

Focus group discussions

In general, the focus group discussion concluded that participants found the study to be an enjoyable experience. Although some caregivers were initially hesitant to feed their child the study foods, they believed that the food made their child stronger and healthier in the end. Caregivers also stated that they would be willing to walk a few miles or pay a small amount of money to continue having access to a similar programme.

Discussion

This study demonstrates that through the use of an LP tool, we were able to produce four low-cost optimized, country-specific, alternative RUTF products that met all nutritional requirements needed for SAM recovery in Ethiopia, Ghana, Pakistan and India. The alternative RUTFs were similar in their acceptability to standard RUTF, with the exception of the formulation for Pakistan.

A limitation was that the RUTFs were designed for the treatment of SAM but were tested among moderate acute malnutrition and healthy children (Guinard 2001). Several RUTF acceptability trials have also used moderate acute malnutrition and healthy children (Phuka *et al.* 2011; Ali *et al.* 2013; Owino *et al.* 2014; Iuel-Brockdorf *et al.* 2015). We could not ethically

Table 4. Outcomes of acceptability trials of ready-to-use therapeutic food by country*

Outcome	Ethiopia		Ghana		Pakistan		India	
	Alternative†	Standard‡	Alternative	Standard	Alternative	Standard	Alternative	Standard
Liking score§	4.6 ± 0.7	4.4 ± 0.7	3.5 ± 1.4	4.1 ± 0.9	3.8 ± 1.5¶	4.4 ± 1.0	4 ± 0.9	3.9 ± 0.9
Amount consumed, %	82 ± 23	87 ± 19	93 ± 16	92 ± 14	70 ± 28	83 ± 22	91 ± 19	90 ± 19
Days child consumed food	6.6 ± 1	6.2 ± 1.3	4.9 ± 2.0	5.7 ± 1.4	5.7 ± 0.7	5.6 ± 0.8	6 ± 1.5	6.2 ± 1.6
Coaxing	13	7	31	32	NA	NA	24	19
Diarrhoea	5	3	6	7	12	9	15	13
Vomiting	2	3	2	1	11	4	6	5
Abdominal pain	1	1	2	2	1	1	0	2

LP, linear programming; RUTF, ready-to-use therapeutic food. *Data presented at mean ± SD or *n*. †LP-generated formula; RUTF developed using local ingredients, country specific. ‡Standard RUTF formulation used as the control. §Score rated on a 0–5 scale (dislike–like). ¶Less than the score for standard RUTF, $P < 0.05$, paired Student's *t*-test.

withhold proper treatment for SAM from children for the purposes of participation in our acceptability study. Our extensive anecdotal experience in Africa has been that children with SAM are more willing to consume RUTF than well-nourished children. An appropriately powered clinical trial is needed to assess acceptability and effectiveness of these local RUTFs. Another limitation was that while caregivers were instructed to offer the RUTFs unadulterated to the child, the focus group discussions revealed that RUTF was mixed with other foods, including soups and porridges, at times. A child's willingness to consume RUTF may differ when it is mixed with other foods.

The local RUTF used in Pakistan needs further investigation before we can recommend that it be used in a clinical trial. While the amounts of RUTF consumed by our study population in Pakistan were comparable with those of the other three countries, mothers noted that their children did not enjoy consuming the RUTF as much as standard RUTF and reported more diarrhoea than upon enrolment. These findings may not indicate that this local RUTF in Pakistan was unacceptable or would be ineffective, but the large effort and expense of an effectiveness trial should not be undertaken without exploring this further in a preliminary manner.

The results of our work are encouraging that lower-cost RUTFs made with more local ingredients may be identified. The ingredient cost of the formulations we tested offers about one-third savings to producers.

Two of the four RUTFs did not contain peanut, and these were acceptable. This may allow for an RUTF to be used in some Asian societies where peanut is not appreciated as a staple food. Culturally accepted alternative RUTFs could be an avenue to address the unmet need as treatment for children with SAM in regions where the standard peanut-based RUTF has not been accepted. Multiple acceptability trials in South Asia have shown limited acceptability of RUTF and demonstrate a need for more culturally accepted ingredients and formulations (Ali *et al.* 2013; Nga *et al.* 2013).

The dairy ingredients used in all of the local RUTFs were forms of whey, while skimmed milk was used in the standard RUTF. The presence of lactose and/or sucrose in infant foods is associated with an increase in appetite, and this can be demonstrated in the very youngest infants, so it is thought not to be the result of habituation to sugar in the diet (Dessor *et al.* 1973; Khan *et al.* 2012). All of the RUTFs tested in this study contained substantial amounts of sucrose, but only the standard RUTF also contains large amounts of lactose. Whey protein may evoke a sour and bitter taste, more so than casein. Infants have intrinsic dislike for sour tastes. In spite of these theoretical reasons to suspect infants would have a greater appetite for standard RUTF, we found no difference in RUTF intake. Of course, these few observations in children from the developed world concern taste, diet composition and appetite may not be operative in malnourished children.

Infant and young child food acceptability is known to vary with cultures and settings. RUTFs are used in an age range when food preferences and eating habits are dynamic. Young child food preferences in the developing world are less studied and understood than those in countries where commercial processed foods are more available. In our study, children consumed each RUTF for a week; for therapy, they would be offered the RUTF for 6 weeks on average. There may be a change in acceptability seen after many weeks of feeding; thus, we cannot wholeheartedly recommend these RUTFs as acceptable without experience in larger effectiveness trial.

Overall, the results demonstrate the acceptance of alternative RUTFs. Future research of this work may include, but is not limited to, optimizing the programming tool to include acceptability parameters. The use of country-specific formulations has the potential to increase the practice of community-based treatments, therefore reducing the morbidity and mortality of SAM in settings where RUTF is not widely used.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

Contributions

MJM, SAV and KNR conceived the study and secured the funding. SAV created the food formulation tool. MO prepared the foods. MJM, KNR, JMW, RT, MM, TG, MSA, FS, SZ and SS enrolled the children, conducted the clinical portions of the study and collected the data. MJM and JMW analysed the data and wrote the first draft of the manuscript. All authors have read and approved the manuscript.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site.