Jayatissa R., Silva B. G., Amaratunga Y. N. 2024. "Acceptability of locally produced Ready-to-Use Therapeutic Food (RUTF) among children aged 2-4 years in Sri Lanka." *World Nutrition, 15*(3), September, 56–62. https://doi.org/10.26596/wn.202415356-62

Research

Acceptability of locally produced Ready-to-Use Therapeutic Food (RUTF) among children aged 2-4 years in Sri Lanka

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Keywords: RUTF, SAM, wasting, hedonic scale, children under five

https://doi.org/10.26596/wn.202415356-62

World Nutrition 2024;15(3):56-62

Background

Although child wasting is preventable, it is a significant public health problem in Sri Lanka. Imported ready-to-use therapeutic food (RUTF), called BP-100, is part of the locally used treatment of severe acute wasting. However, Sri Lanka has faced economic barriers in providing this product. Two RUTF bars were developed in our laboratory based on global nutrient and other specifications (RUTF-1 and RUTF-2). Nutrient and microbiological analyses were within acceptable limits and shelf life was determined. This observational study was conducted to test the acceptability of locally produced RUTFs among children aged 2-4 years old, a first step in its possible use in place of imported versions. 56 children aged 2-4 years old in two preschools located in poor urban settings were included. These two RUTF bars and BP-100 were given to the children for a total period of three weeks (3 days of each product), with 3 to 4 days of interval in between. At the beginning, weight and height of the children were measured. A five-response hedonic scale was used to test acceptability. Mean daily intakes, and any apparent adverse effects were recorded. A taste test on the acceptability of RUTF and BP-100 among mothers or guardians was carried out on the last day of the trial. The colour, taste, smell, and texture of both RUTF bars were compared to BP-100. Overall acceptability of RUTF-1 (p=0.000) and RUTF-2 (p=0.02) was observed compared to BP-100 among both children and mothers. No adverse effects were reported. Further analysis indicated that there was no significant difference between locally produced RUTFs and BP-100 on acceptability in relation to sex, age, wasting, or stunting; however, a difference was noted related to ethnicity (p=0.000). In conclusion, locally produced RUTFs are as acceptable as BP-100. There is a need to assess the effectiveness of RUTFs while building partnerships with the food industry for sustainable production.

INTRODUCTION

WHO published its first guidelines in 1990 for treating children affected by severe acute malnutrition (SAM) in resource-limited settings using F-75 and F-100 milk-based formulas (WHO, 2013). Nearly a decade later, ready-to-use therapeutic food (RUTF) was innovated for use in nutrition emergencies to address SAM in children under five years old (Briend et al., 1999). It became popular and widely used by many countries due to its long shelf life, readiness to eat with no cooking, ease of storage at room temperature, etc. Considering the success of RUTF programmes, WHO, UNICEF, and WFP have recommended its use in managing SAM within community based (CMAM) programmes (WHO et al., 2007). Barriers to scale-up include cost and regular supply (IFPRI, 2016).

BP-100, similar to F-100, has been used as the RUTF in Sri Lanka, through a community-based program alongside family food, particularly in areas of conflict, initially supported by UNICEF (Jayatissa et al., 2012). It is imported and was selected to ensure cultural acceptability. RUTF programmes have been integrated into the routine health and nutrition programme in the Ministry of Health from the beginning and included as policy to treat SAM children aged 6-59 months. Currently, it is funded by the Government of Sri Lanka (MoHN, 2007 & MoH, 2023). However, there is no specific food product for children with moderately acute malnutrition (MAM). Locally produced supplementary food, 'Thriposha,' manufactured by the Ministry of Health, is distributed to underweight children, and used to treat MAM (Ministry of Health, Nutrition & Indigenous Medicine, 2016; Institute of policy studies of Sri Lanka, 2020).

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Despite the many nutritional programmes implemented in Sri Lanka, there has been no significant improvement for 25 years in under-five wasting, considered to be a significant public health problem by successive governments, with the rate remaining around 15% (Central Bank of Sri Lanka, 2022). According to WHO specifications, this level of under-five wasting is considered to be an emergency problem. Furthermore, this rate is higher than the Asia region average of 8.9%, and Sri Lanka has been identified as one of the countries with a very high level of wasting (Development Initiatives, 2022).

With the COVID epidemic, Sri Lanka has undergone a severe economic crisis and faced many issues, including fuel, food, gas shortages, and restrictions on imports due to foreign currency depreciation, causing civil unrest (FAO, 2023). This has caused ripple effects on the health, nutrition, and wellbeing of the population (Weerakoon et al., 2022). A national study conducted in 2022 highlighted the rise of malnourished children, with the prevalence of wasting among children aged 6-59 months reaching 19.8%. Out of these, SAM was 2.5%, and the rest was MAM (Jayatissa et al., 2023).

Making the scale-up of severe wasting treatment a priority. However, the affordability of BP-100 became an issue. Furthermore, the focus has shifted towards sustainable and locally produced RUTF to reduce dependency on imports and ensure a stable supply. UNICEF supported the Ministry of Health's efforts on research and development to explore locally produced RUTF. Emphasis was placed on using alternative ingredients to make RUTF more cost-effective and to make programmes more sustainable. Hence, this study was conducted to develop and test the acceptability of locally produced RUTF in comparison to the imported RUTF, BP-100.

METHODS

This was an observational study. The study participants were children aged 2-4 years regardless of their nutritional status due to low number of SAM children in one location. Study sites were purposively selected two preschools in a poor urban community. The inclusion criteria were children attended preschools aged 24-48 months with SAM, MAM, or normal nutritional status who provided consent from a parent or guardian. The exclusion criteria were children with chronic diseases under medical care and known allergies to ingredients in the RUTF or BP-100 (Adams et al., 2017).

The sample size was calculated using an online calculator (https://hedwig.mgh.harvard.edu/sample_size/js/js_crossover_quant.html) assuming a 0.2 mean difference on acceptability (between the RUTF formulas and BP-100, a significance level 5%, an estimated standard deviation of the difference of acceptability of 0.5 and a power of 80%. Considering a 10% dropout rate, the calculated sample size was 55 children (Serdar et al., 2021).

Two RUTF formulas (RUTF-1 and RUTF-2) were developed in the laboratory using locally available different ingredients with a nutrition composition similar to BP-100, based on global specifications as shown in Table 1 (WHO, 2021) to be comparable to BP-100, as shown in Table 1. Recipe formulation was done theoretically using the Sri Lankan food composition database (Jayatissa et al., 2021). Soya, green gram, rice, peanut powder, and coconut butter were used as ingredients. Extrusion cooking of the soya, maize, and green gram blend was done, followed by mixing with coconut butter, peanut powder, Kithul Treacal, and dates to form a paste, which was then converted into a bar. Each bar was wrapped separately. As shown, the cost of production of this RUTF was far below the price of BP-100.

Table 1. Nutrition values and cost of RUTF-1 and RUTF-2 compared to BP-100

Nutrition Parameters	RUTF_1		RUTF_2		BP-100	
	100g	Per 1 bar (20g)	100g	Per 1 bar (20g)	100g	Per 1 tablet (28g)
Energy (kcal)	518	104	501	100	527	125
Carbohydrates (g)	35	7	36	7	47.5	11.9
Protein (g)	19	4	19	4	14.5	3.6
Fat (g)	31	6	27	5	31.0	7.5
Fiber (g)	6	1	6	1	5	1.2
Cost (US $)		0.45		0.47		3.3
Ingredients (combinations were considered to improve palatability, reduce cost and local availability)	Rice (white, medium-grain, raw unenriched)		Rice (white, medium-grain, raw unenriched)		Wheat flour (baked)	
	Soybeans (mature seeds, raw) and Green gram (deshelled)		Soybeans (mature seeds, raw) and Green gram (deshelled)		Soy protein	
	Whole-milk powder		Whole-milk powder		Milk solids	
	Coconut Butter and coconut meat		Coconut Butter		Vegetable oils (palm, rapeseed)	
	"Kithul" Treacle and Dates		"Kithul" Treacle and Dates		Sugar	
	Minerals and vitamins		Minerals and vitamins		Minerals and vitamins	

The RUTF-1 and RUTF-2 formulas were microbiologically analysed (Aerobic plate, presumptive Coliform, Escherichia coli, Staphylococcus aureus, Salmonella species, Yeast, Mould counts), to confirm the acceptability limits as specified in the food regulation. The shelf life of both formulas was determined to be beyond 3 months. Both formulas were similarly packed to blind the study participants in a simple appealing way to try new foods and in 20g portions making it easy for children to try. However, investigators were able to differentiate between the two formulas for allocation. The test was conducted in the preschool to ensure comfortable and familiar environment for children to ensure reliable responses. Parents or caregivers were present and were briefed not to influence the child's responses. The children were provided with RUTF prior to their snack interval.

At the beginning, a baseline survey was conducted to collect demographic information and medical history using an interviewer-administered structured questionnaire. Weight and height were measured using a Seca electronic weighing scale (minimum 50g) and stadiometer (minimum 1cm) by a trained measurer using standardised procedure. Standard WHO protocols for measuring weight and height of children were applied (WHO, 1995).

As shown in Table 2, each child received each of the three products (RUTF Formula 1, RUTF Formula 2, BP-100). One preschool was given RUTF-1, and the other school was given RUTF-2. In the second week, products were crossed over.

Table 2. Allocation of study subjects in two primary schools (n=56)

Day 1	Day 2	Day 3	Day 4-6	Day 7	Day 8	Day 9	Day 10-13	Day 14	Day 15	Day 16
RUTF_1	RUTF_1	RUTF_1	X	RUTF_2	RUTF_2	RUTF_2	X	BP100	BP100	BP100
RUTF_2	RUTF_2	RUTF_2	X	RUTF_1	RUTF_1	RUTF_1	X	BP100	BP100	BP100

In the third week, all children were given BP-100 as a control. There was a 3–4-day washout period each week to prevent carryover effects. The total duration of the study was 3 weeks, conducted in February 2023.

The children were explained the process clearly ("you are going to try new food, and I want you to tell me, if you like it or not, by pointing to the faces"). First day practice round was carried out for children to get familiar with Hedonic scale (Lim, 2011). Five bars (100g) were provided to each child to assess the consumption rate.

Acceptability was measured daily based on the consumption rate (amount of food consumed compared to amount offered), the child's willingness to eat (assessed by a 5-point visual hedonic scale using smiley faces to represent different scales liking to simplify understanding: 5 = very good, 4 = good, 3 = neutral, 2 = bad, 1 = very bad) (Lim, 2011), observed adverse effects for new foods (vomiting, diarrhoea, allergic reactions), and the mother's/caregiver's perception of the child's preference. Trained investigators observed the children and rated their acceptance (willingness to eat, facial expressions, etc.) on third day of the supply for each of the three types of RUTF. Daily logs were maintained by the teachers and investigators.

On the last day, a taste test was conducted with 22 mothers or guardians to understand children's acceptance and any barriers to RUTF usage. They were provided all three products to consume one after another, with mouth rinsing in between, and marked their preferences a 5-point hedonic scale for each product.

Ethical approval was obtained from the Lady Ridgeway children's hospital review committee. Written consent was obtained from parents or guardians. It was ensured that all data were anonymised, and regular monitoring for adverse effects was conducted.

STATISTICAL ANALYSIS

Anthropometric indicators of height-for-age, weight-for-age and weight-for-height were determined for all children using 2006 WHO growth standards (WHO, 2009). Data were analysed using SPSS (version 22.0, IBM, Inc) software package. Consumption rates between the three products were compared using repeated measures ANOVA. Likert scale responses were analysed using the chi-square test. Ordinal regression analysis was performed considering the 5-scale Likert scale on acceptability, which was taken as dependent variable. Independent variables were identified as mean age, sex (control=male), ethnicity (control=Sinhala ethnicity), type of RUTF (control=BP-100), mean amount of RUTF bars consumed, wasting (control=non-wasted) and stunting (control=non-stunted). A statistically significant level was chosen as $p<0.05$.

RESULTS

A total of 30 children from each preschool was enrolled and 56 children participated in the study. Table 3 presents the basic characteristics of the children.

Table 3. Basic characteristics of sample children (n=56)

Age in years	No (%)
2	7 (12.5)
3	20 (35.7)
4	29 (51.8)
Sex	
Male	26 (46.4)
Female	30 (53.6)
Ethnicity	
Sinhalese	25 (44.6)
Tamil	31 (55.4)
Nutritional status	
SAM (<-3SD weight-for-height)	1 (1.8)
Wasting (<-2SD weight-for-height)	10 (17.9)
Stunting (-2SD height-for-age)	7 (12.5)
Underweight (<-2SD weight-for-age)	12 (21.4)

The children consumed a higher number of bars from RUTF-2 than from RUTF-1, while the lowest was from BP-100. RUTF-1 had significantly higher sensory scores compared to RUTF-2 and BP-100 ($p<0.05$), indicating better acceptance of colour, taste, texture, and smell. RUTF-1 was also significantly more acceptable overall compared to RUTF-2 and BP-100 (P=0.000). The highest percentage of children liked RUTF-1 (Table 4).

Table 4: Sensory evaluation among sample children for RUTF formulas and BP-100

Sensory component	RUTF-1 (n=56)	RUTF-2 (n=56)	BP-100 (n=56)	P value*
Mean (SD) amount of RUTF consumed in grams	43.6 (23.4)	54.9 (74.2)	38.6 (107.4)	0.513
Colour - Mean (SD)	4.2 (0.9)	4.0 (1.0)	3.7 (0.9)	0.024
Taste - Mean (SD)	4.2 (0.9)	3.9 (1.1)	3.5 (1.0)	0.003
Texture - Mean (SD)	4.5 (0.6)	4.3 (0.8)	3.8 (0.9)	0.000
Smell - Mean (SD)	4.3 (0.8)	4.1 (1.0)	3.8 (0.9)	0.035
Overall acceptability - Mean (SD)	4.3 (0.9)	4.0 (1.0)	3.6 (1.1)	0.001
% of children like it (very good/good)	87.5	73.2	57.1	0.002

*The Anova statistical test was used in these comparisons

RUTF-2 had significantly higher overall acceptability of mothers than RUTF-1 and BP-100 (p=0.000). A similar percentage of mothers liked RUTF-1 and RUTF-2 (Table 5).

Table 5. Sensory evaluation among mothers or guardians for RUTF formulas and BP-100

Sensory component	RUTF-1	RUTF-2	BP-100	Statistics
Colour - Mean (SD)	4.8 (0.5)	5.0 (0.2)	4.9 (0.3)	0.203
Taste - Mean (SD)	4.5 (0.7)	4.7 (0.8)	2.5 (1.4)	0.000
Texture - Mean (SD)	4.6 (0.7)	4.7 (0.5)	4.5 (0.7)	0.582
Smell - Mean (SD)	4.9 (0.4)	4.9 (0.3)	4.0 (1.4)	0.002
Overall acceptability - Mean (SD)	4.2 (0.6)	4.7 (0.7)	2.6 (1.5)	0.000
% of them like it (very good/good)	95.2	95.7	27.3	0.000

Direct observation recordings by the teachers on the acceptability of RUTF among children showed that 92.8% of

children had good acceptance, 2.9% had poor acceptance, and one child refused it from the first day. There were no adverse effects reported. In the discussion, mothers or guardians reported that they did not observe any adverse effects, children liked the new food, and there was no reduction in food intake at home due to consumption of RUTF.

Ordinal regression model was estimated to investigate whether age, sex, ethnicity, type of RUTF, wasting and stunting at baseline predict acceptability of RUTF ("very good", "good", "neutral", "bad" and "very bad") as shown in Table 6. Children from Tamil ethnicity accepted RUTFs better than children from Sinhalese ethnicity (B=1.36, P=0.000). The children accepted RUTF-1 and RUTF-2 better than BP-100 (B=1.49, P=0.000 and B=0.81, P=0.02). There was no significant relationship between RUTF and BP-100 acceptability in relation to the age, sex, stunting, wasting of children, or number of bars consumed.

Table 6. Results of ordinal multiple regression analysis

Variable	B	SE	Wald	df	p-value	95% CI
Mean age in years	-0.93	0.21	0.19	1	0.663	-0.5, 0.3
Mean amount of bars consumed	0.09		3.36		0.067	0.0-0.2
Sex (Ref: Male)						
Female	-0.45	0.05	1.97	1	0.161	-1.1, 0.2
Ethnicity (Ref: Sinhalese)						
Tamil	1.36	0.32	19.09	1	**0.000**	0.8, 2.0
Baseline nutritional status						
Wasting	-0.53	0.31	1.87	1	0.171	-1.3, 0.2
Stunting	0.17	0.47	0.13	1	0.717	-0.8, 1.0
Type of RUTF (Ref:BP-100)						
RUTF-1	1.49	0.38	15.79	1	**0.000**	0.8, 2.2
RUTF-2	0.81	0.36	4.98	1	**0.026**	0.1, 1.5

(Model = x^2 = 39.98, df=8, P=0.000; R^2=0.23)

DISCUSSION

The two locally produced RUTF were well accepted by children aged 2-4 years. Acceptance is an important factor in the success of nutritional interventions, and our results suggest that the local RUTFs we developed met this criterion effectively. High acceptability directly influences the likelihood that children will consistently consume RUTF. The good acceptability of this locally accepted RUTF may be attributed to the palatability of local ingredients, closeness to local cultural appropriateness, and easiness of consumption. Previous studies on locally produced RUTFs have shown similar findings (Weber et al., 2017; Owino et al., 2014; Selvaraj et al., 2022; Bahwere et al., 2009; Manary, 2006; Choudhury et al., 2018)

An important finding of this study is that there were no reported adverse effects associated with the consumption of the locally produced RUTFs. This is an important component for the safety and well-being of children, ensuring that RUTF can be consumed without additional health risks. This result aligns with previous research indicating that RUTFs, in general, are safe for consumption when produced under proper guidelines (Isanaka et al., 2009; Latham et al. 2011).

The analysis revealed that the type of RUTF significantly predicted degree of acceptability. Ethnicity also played a role, with Tamil ethnicity showing higher acceptability compared to Sinhalese ethnicity. This may be due to different food preferences and palatability between ethnicities (Jayawardena et al., 2013). Sex, age, wasting, and stunting did not significantly influence acceptability. Previous studies reported similar findings (Patel et al., 2005; World Bank, 2022).

BP-100 has been used in Sri Lanka to treat SAM children for many years with good outcome (Jayatissa et al., 2012). However, its higher cost has been a limiting factor for widespread use. One of the significant advantages of locally produced RUTF is its cost-effectiveness. Compared to BP-100, the local alternatives are cheaper, which is an important factor in resource-limited settings such as the current economic crisis in Sri Lanka (World Bank, 2022). This could lead to substantial savings for healthcare systems and other stakeholders involved in nutritional interventions. In addition, when the RUTF is available at a low cost, the programmes using it can cover a larger number of malnourished children.

Since Sri Lanka has more MAM children, a similar type of locally produced ready-to-use-supplementary food (RUSF) can be prepared in the similar manner to treat MAM children. This shift towards local production can foster sustainability and self-reliance within communities. It will also reduce dependence on imported therapeutic foods.

The findings of this study have significant implications for policy and practices in the field of malnutrition treatment. Policymakers and programme implementers should explore how to foster production of local RUTFs and incorporate it into their nutritional intervention strategies. The cost savings and high acceptability observed suggest that these products could enhance the efficiency and effectiveness of malnutrition programmes.

While this study provides valuable insights, it has limitations that should be addressed in future research. The acceptability was conducted mainly among MAM and normal children. Further testing should be done in children suffering from SAM, the target user for the product. While one type of RUTF was the first thing consumed in one school and the second type in the other school, all children consumed the BP 100 last and they may have been tiring of eating these unusual foods by then. Future studies should explore the effectiveness of using locally produced RUTFs in different settings. Additionally, research into the supply chain and processes of local RUTFs can identify potential areas for improvement to ensure consistent quality and viability in collaboration with the private sector. The sample size was not large or varied enough to cover all possible combinations of the variables involved, leading to potential issues with generalizability.

CONCLUSION

In conclusion, the locally produced RUTF tested in this study offers a well-accepted, cost-effective, and safe alternative to BP-100. Ethnicity was an important factor in determining the acceptability of RUTF. This study's findings reveal that well-accepted locally produced RUTF can be developed in countries with limited resources. Its production on an adequately large scale would help to enhance the local

economy, empowering the food industry towards the common goal of implementing nutritional interventions to reach more malnourished children and improve outcomes in a sustainable manner. It is recommended to conduct effectiveness trials in collaboration with the food industry through public-private partnerships.

AUTHOR CONTRIBUTIONS

RJ conceptualisation of the study conducted data analysis, interpretating the results, and wrote the first draft of the manuscript. BS and YA helped to design the study, formulation of RUTF, data collection, and editing; All authors contributed and agreed to the final version of the manuscript.

CONFLICT OF INTEREST

None declared

PATIENTS AND PUBLIC INVOLVEMENTS

Patients and/or the public were not involved in the design, or reporting, or dissemination plans of this research.

ETHICS APPROVAL

The study protocol was approved by the Lady Ridgeway Children's hospital Ethical Review committee (Approval Number LRH/DA/29/2022).

INFORMED CONSENT STATEMENT

Informed written consent was obtained from mothers/guardians of children involved in the study.

DATA AVAILABILITY STATEMENT

The data presented in this study are available upon request from the corresponding authors.

ACKNOWLEDGEMENTS

The authors thank the participating children and their mothers, the preschool staff at Lasallian community, and the local health officials for their cooperation and support in this study. The authors would like to acknowledge the staff of the Department of Nutrition at MRI for data collection that helped make this work possible; the UNICEF and WFP staff who supported our work from the beginning; and the Steering committee members of the Ministry of Health for their valuable input.

FUNDING

This research was supported by UNICEF, Colombo under the annual funding for the ministry of health.

Submitted: August 8, 2024; Accepted: September 24, 2024; Published: September 30, 2024.

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