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Original Article

Effects of Formula-100 therapeutic milk and *Bregas Nutriroll* ready-to-use therapeutic food on Indonesian children with severe acute malnutrition: A randomized controlled trial study

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Abstract

Severe acute malnutrition (SAM) is a global health concern that affects children and leads to delayed growth. The aim of this study was to compare the impact of F100 milk and *Bregas Nutriroll*, a local ready-to-use therapeutic food (RUTF), on SAM children. An unmasked, non-blinded, two-group, and simple randomized controlled trial was conducted. Indonesian children aged 12–59 months with SAM were randomly assigned to receive either F100 milk or *Bregas Nutriroll*. After eight weeks, the increase in the mean weight gain in both groups was assessed. The *Bregas Nutriroll* group (n=19) had a mean weight gain of 1.07±0.09 kg, while the F100 group (n=17) had a mean weight gain of 1.05±0.11 kg. The *Bregas Nutriroll* group had a slightly higher gain of mid-upper arm circumference (MUAC) than the F100 group (0.62±0.34 cm vs 0.50±0.37 cm). The gain of children's height of the *Bregas Nutriroll* group was 0.96±0.42 cm, while the F100 group was shorter at a mean of 0.81±0.44 cm. Statistically significant differences (p<0.001) in nutritional status were observed based on weight, MUAC, and height/length after F100 and *Bregas Nutriroll* interventions. The intervention with F100 increased hemoglobin (Hb) levels of 0.71±1.25 mg/dL, while the *Bregas Nutriroll* intervention led to an increase of 0.11±1.39 mg/dL. In conclusion, our study showed that community-based treatment with F100 milk or *Bregas Nutriroll* resulted in nutritional status in children with SAM. These findings suggested that both treatments could be effective in treating SAM in improving nutritional status and child health outcomes.

Keywords: Nutritional status, severe acute malnutrition, stunting, *Bregas Nutriroll*, F100 milk

Introduction

Children under five with malnutrition are a significant health concern that affects millions of individuals worldwide [1]. This concern is a pressing issue that must be addressed on a global scale. Approximately 60 million children are affected by severe acute malnutrition (SAM) worldwide [2]. SAM is defined as a state in which a child's exceptionally low body weight in relation to height falls below the -3 standard deviation (SD) threshold of the median growth benchmark established by the World Health Organization (WHO) or a mid-upper arm

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circumference (MUAC) of less than 11.5 cm [3]. SAM is the ailment most frequently encountered in maternal and pediatric healthcare facilities. It is a matter of great concern that a significant proportion of children under the age of five years old lose their lives because of SAM and are required to be hospitalized in numerous developing nations, with a mortality rate of 25–30% [4].

Acute malnutrition is a multifaceted condition affected by various factors, such as reduced food intake, heightened nutritional requirements, impaired nutrient absorption, substantial nutrient depletion, and concurrent medical ailments [5]. It greatly elevates the likelihood of fatal and debilitating outcomes from typical childhood conditions, thereby impeding optimal physical and mental development, and affecting long-term health in adulthood [6]. SAM in children is typically identified by the presence of bilateral pitting edema caused by malnutrition or severe wasting in children between 6 and 59 months of age [7].

Community-based management of acute malnutrition (CMAM) suggested two methods for addressing children under five with SAM [8-10]. Those who demonstrate appetite and lack medical complications will undergo outpatient treatment, while those who fail the appetite test due to having one or more medical complications are admitted to the therapeutic feeding center (TFC) [11]. The TFC treatment process is divided into three phases: stabilization, transition, and rehabilitation. During the stabilization phase, the main objective is to stabilize the child's condition by administering F-75, a low-protein and low-energy formula, while addressing any concurrent medical issues. In the transitional and rehabilitation phases, therapeutic food is gradually transitioned to ready-to-use therapeutic food (RUTF) or F100, which promotes weight recovery and supports optimal catch-up growth. RUTF's nutritional profile is comparable to that of F100, a therapeutic diet utilized in medical facilities, with the exception of its iron content [12]. Alternative RUTFs that are more affordable than standard RUTFs are being developed [13], one of which is the *Bregas Nutriroll* from local food ingredients in Indonesia. *Bregas Nutriroll* is a fully developed RUTF that comes in the form of wafer rolls filled with paste developed by an Indonesian company [14]. This product has been formulated to meet the strict nutritional standards set by WHO [14].

Bregas Nutriroll and F100 are therapeutic foods rich in energy, protein, and micronutrients. The *Bregas Nutriroll* is a wafer roll-filled peanut paste, whereas the F100 is a milk formula. Regarding nutrient content, *Bregas Nutriroll* provides a nutritional intake equivalent to F100 for SAM children, supplemented with an additional Fe of 36 mg/100 gram [14]. The nutrition-to-energy ratios of both therapeutic diets are the same; however, *Bregas Nutriroll* has an energy density five times greater than F100 [8]. Enhancing the energy density of the *Bregas Nutriroll* by incorporating peanut butter into a portion of the powdered skim milk utilized in the F100 recipe is an effective strategy.

In the previous study, children fed with RUTF demonstrated better average weight gain as well as faster recovery durations, according to a pilot study carried out in India [15] and a randomized controlled trial (RCT) in Senegal [16]. Conversely, a study conducted in India found that F100 promoted faster recovery times than RUTF [17]. Due to these inconsistent findings, the aim of this study was to compare the effects of *Bregas Nutriroll* as a representative of RUTF and F100 milk feeding on the nutritional status of children under five years old who suffer from SAM.

Methods

Study design and setting

A randomized controlled clinical trial was conducted to determine whether the provision of *Bregas Nutriroll* improved the nutritional status of children aged below five years with SAM. The population of the study was selected among children living in the South Timor Tengah district, East Nusa Tenggara Province, who were 12–59 months old and had SAM without complications. The clinical trial was conducted from June 2023 to October 2023.

Established inclusion and exclusion criteria were used in the recruitment process of the participants, ensuring a balanced allocation (1:1) between the two intervention groups. The inclusion criteria were: (a) clinically healthy children; (b) children with adequate appetite; (c) children under five years old meeting the WHO criteria for SAM as identified by either a weight-for-height Z-score (WHZ) of <-3 SD or a MUAC of 11.5 cm; and (e) had a decent appetite. Children

exhibiting symptoms such as high fever, difficulty in breathing, persistent vomiting, edema, lethargy, apathy, unconsciousness, or seizures were ineligible for participation in the study and were referred to a stabilization center (TFC) for appropriate treatment. Those diagnosed with recent episodes of watery diarrhea, accompanied by symptoms such as eyelid retraction, decreased tear production, cold extremities, lethargy, low blood sugar, high fever, an eating disorder, or severe lower respiratory tract infection associated with SAM were excluded from the study. Additionally, children were screened for anemia, and those with severe anemia were excluded from trials involving the administration of RUTF, as recommended in the guideline [8].

Sample and sampling method

Using Lemeshow formula [18], with α of 0.05 and a SD from the previous study of 2.4 g/kg/day [19], a minimal sample of 32 participants (16 in each group) was required. To anticipate the dropouts, an additional 20% was added. Therefore, the total sample size was 20 participants in each group.

Participant screening

Children aged 12–59 months with SAM were identified in communities through a house-to-house survey. All children under five years who fulfilled the criteria of the outpatient treatment program for SAM were referred for assessment by a qualified nutritionist and doctor to confirm the SAM status. After consenting to enroll their children in the study, the children were assessed for any complications and associated illnesses.

Children who met the inclusion criteria from the screening process were gathered at the village office or an Integrated Health Post (*Posyandu*) to undergo an appetite test. The appetite test was conducted by providing one pack of *Bregas Nutriroll*, which contained seven pieces of wafer rolls and an adequate amount of drinking water. Children under five who can finish one pack of *Bregas Nutriroll* within 30 minutes were considered to have good appetite. For children within the F100 milk group, the appetite test was carried out simultaneously with a demonstration of the preparation of F100, according to the guidelines of the Indonesian Ministry of Health on the management of SAM [20]. Children who could finish 250 mL of F100 milk within 30 minutes were categorized as having a good appetite test. A comprehensive evaluation encompassing a detailed medical history and physical examination was then performed to assess participant eligibility.

Baseline assessment

Following the enrollment, the children diagnosed with uncomplicated SAM underwent comprehensive baseline assessments. Sociodemographic data and anthropometric measurements were collected, including MUAC and blood samples. Age information was primarily retrieved from antenatal records documented in the Maternal and Child Health Book (*Buku KIA/Kesehatan Ibu dan Anak*). For children who were born at home, parent reports were used to obtain age data. A trained nutritionist performed all weight and MUAC measurements using standardized procedures and calibrated equipment. To ensure accuracy, duplicate measurements were taken, and in cases of disparity between readings, additional measurements were conducted until a precise value was obtained.

Children's body weight was evaluated and documented using a national standardized Gea Medical digital weighing scale, with measurements rounded to the nearest 10 g, either when unclothed or dressed in light clothing. Before each measurement, the scale was adjusted to zero. In cases where infants or children were unable to stand, the measurement was conducted with the assistance of the mother. The MUAC was measured at the midpoint between the tendon and acromion processes using color-coded MUAC tape, and readings were rounded to the nearest 0.1 cm. The child's arm was carefully measured, with the upper arm bent and exposed, extending from the shoulder to the lower arm placed transversely on the stomach, while the child looked ahead. The tip of the children's elbow bone and the top of their shoulder were identified, and the distance between these points was halved to determine the midpoint. The MUAC tape was then comfortably applied around the arm at this midpoint, ensuring it was neither too tight nor too loose. MUAC measurements serve as an indicator for evaluating and categorizing the nutritional status of children.

Intervention

All children who fulfilled the inclusion criteria were enrolled in the study for a duration of eight weeks, with a 1:1 allocation ratio between the F100 and *Bregas Nutriroll* groups. F100 milk was prepared by trained nutritionists following the guidelines for the management of malnutrition in toddlers in outpatient care [20]. F100 is administered according to the body weight of the toddler and modified based on the calculated daily intake deficiency. Toddlers weighing 5–6.9 kg were given 500 mL/day, and those weighing 7–9 kg were given 500–750 mL/day.

Bregas Nutriroll was produced by Java Indo Sejahtera Mandiri Company, Depok, Indonesia. The product complies with the WHO standard (**Table 1**). Children weighing 5 and 6.9 kg received two packs per day, those weighing 7 and 9.9 kg received three packs, and those weighing 10 kg or more received four packs. Each pack of *Bregas Nutriroll* has 100 grams [14].

Parents within the F100 and *Bregas Nutriroll* groups were instructed by trained nutritionists on the importance of providing their children with F100 milk or *Bregas Nutriroll* as appropriate. They were instructed to feed their children with the provided packages for a period of 8 weeks. Parents were supplied with F100 or *Bregas Nutriroll* for a 7-day administration period. On the eighth day, the mothers or the caregivers were requested to return to the assigned facility to collect the next week's package.

Table 1. Nutrient content of each package of *Bregas Nutriroll and* F100 milk [14,21]

Nutrients	Unit	F100	*Bregas Nutriroll*	WHO requirement
Total calories	Kcal	101.17	534.47	520.00–550.00
Total fat	g	5.97	31.59	26.72–35.63
Moisture content	%	-	2.05	≤2.50
Protein	g	3.09	13.53	13.36–16.03
Vitamin A	mg	-	0.57	0.8–1.1
Vitamin C	mg	-	5.17	≤50
Vitamin D	µg	-	9.53	15–20
Vitamin E	mg	-	23.97	≤20
Vitamin K	mg	-	14.96	15–30
Vitamin B1	mg	-	0.65	≤0.5
Vitamin B3	mg	-	0.39	≤5
Vitamin B5	mg	-	0.27	≤3
Vitamin B6	mg	-	4.33	≤0.6
Vitamin B9	mcg	-	295.67	≤200
Vitamin B12	mcg	-	2.76	≤1.6
Vitamin B7	mcg	-	92.3	≤60
Vitamin B2	mg	-	1.33	≤1.6
Selenium	mcg	-	11.83	20–40
Copper	mg	-	0.68	1.4–1.8
Zinc	mg	4.12*	7.51	11–14
Iron	mg	0.085	6.14	10–14
Magnesium	mg	8.74*	36.32	80–140
Phosphor	mg	-	218.28	300–600
Calcium	mg	-	179.61	300–600
Potassium	mg	-	599.93	1100–1400
Iodine	mcg	-	40.63	70–140
Omega 3	Kcal/100 kcal	-	6.63	3–10
Omega 6	Kcal/100 kcal	-	0.45	0.3–2.5

* The estimated value after converting 500 mL [22] to 100 mL (100 g)

Laboratory methods

The hemoglobin concentration of each individual was measured at the site through a finger-prick blood sample utilizing a portable hemoglobinometer device (HemoCue 301+, Ängelholm, Sweden), which has been endorsed by the WHO for field survey [23]. Approximately 10 µL of blood was drawn into the HemoCue301+ microcuvette using capillary, after which the absorbance of whole blood at the Hb/HbO_2 isosbestic point was immediately measured using two wavelengths (506 and 880 nm). The hemoglobin level was subsequently calculated and reported in accordance with the WHO guideline [23].

Follow up assessments

Monitoring was conducted every seven days for 56 days (eight weeks). Parents and guardians were asked to bring the children to the village office for anthropometric measurements, which included weight, height, and MUAC. After taking measurements, they were given packages of *Bregas Nutriroll* or F100 milk for the next seven days. If the children were unable to come, trained nutritionists visited them at home.

Statistical analysis

Data skewness and data normality were assessed. A paired Student t-test was employed to compare outcome measures within the treatment group before and after treatment, while an independent Student's t-test was used to compare outcome measures between the F100 and *Bregas Nutriroll* groups. Analysis of Variance (ANOVA) was used to test the differences in weight variables among the intervention groups. All statistical tests were performed with a 95% confidence interval (CI) and a significance level of $p<0.05$ was considered statistically significant. The analyses were conducted SPSS version 26 (IBM, New York, USA).

Results

Of the 60 children initially examined from Electronic Community-Based Nutrition Recording and Reporting System (known as EPPGBM), 50 were diagnosed with severe acute malnutrition (SAM) and met the inclusion and exclusion criteria for the study. Among these 50 children with SAM, seven did not pass the appetite test, two refused to participate, and one did not attend the initial measurement. Consequently, 40 children were eligible and underwent the appetite test.

These 40 children were then randomized into two groups: the *Bregas Nutriroll* group (20 subjects) and the F100 group (20 subjects). During the 8-week study period, one subject in the Bregas Nutriroll group and three subjects in the F100 group dropped out. Therefore, the final analysis included 19 subjects in the *Bregas Nutriroll* group and 17 subjects in the F100 group (**Figure 1**).

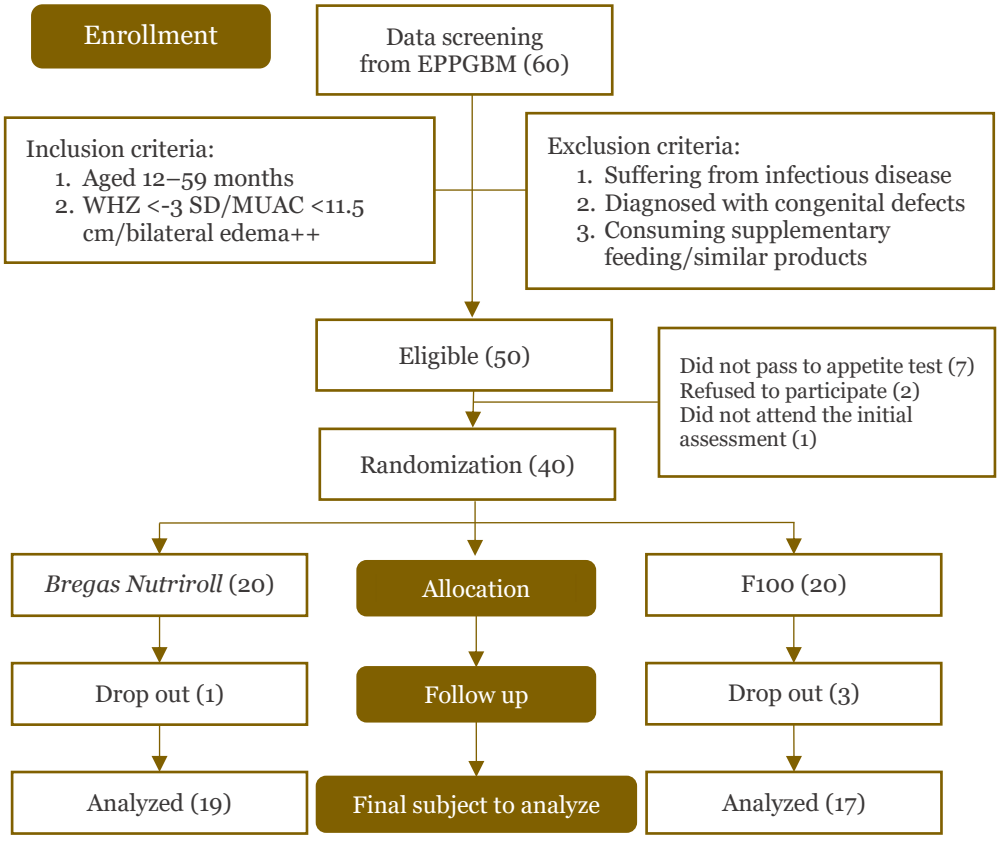

Figure 1. Flowchart diagram of participant recruitment.

Characteristics of the SAM children included in the study

The sociodemographic and baseline characteristics of patients are outlined in **Table 1**. The mean age of the F100 group was 31.7±14.3 years and 19.7±7.2 years for the *Bregas Nutriroll* group. A higher percentage of males was present in both groups, with the F100 group having 58.8% and *Bregas Nutriroll* group having 36.8% males. Immunization completion rates were higher in the Bregas group (94.7%) than in the F100 group (76.5%). A birth interval of less than three years was more common in the F100 group (41.2%) than in the *Bregas Nutriroll* group (31.6%). Interestingly, household income and food expenditure were significantly higher in the *Bregas Nutriroll* group, with an income of IDR 1.259.473±16.333 per month and food expenditure of IDR 1.111.157±69.571 per month, compared to IDR 538.235±50.482 and IDR 544117±32.000, respectively, in the F100 group.

A greater proportion of individuals in the *Bregas Nutriroll* group initiated early initiation of breastfeeding (EIB) and continued with exclusive breastfeeding for six months (EBF) compared to the F100 group (**Table 2**). Specifically, the EIB rate was 42.1% and 76.5% in the *Bregas Nutriroll* and F100 groups, respectively. Similarly, the EBF rate was 68.4% and 82.4% in the *Bregas Nutriroll* and F100 groups, respectively. In terms of family size, the table shows that a larger percentage of subjects in the *Bregas Nutriroll* group came from small families (less than four members) compared to the F100 group. Specifically, 73.7% of the subjects in the *Bregas Nutriroll* group came from small families, compared to 58.8% in the F100 group.

The information of the mothers' education level also provided in **Table 2**. The data explained that a higher percentage of mothers in the *Bregas Nutriroll* group had a higher level of education than those in the F100 group. Specifically, 52.6% of mothers in the *Bregas Nutriroll* group had a higher level of education compared to 23.5% in the F100 group. The sociodemographic data and characteristics of subjects in the two groups were not different (p>0.05).

Table 2. Sociodemographic and baseline characteristics of the subjects

Characteristics	All subjects (n=36)	F100 (n=17)	*Bregas Nutriroll* (n=19)	*p*-value
Age at recruitment, mean±SD	25.4±12.5	31.7±14.3	19.7±7.2	0.051*
Male, n (%)	17 (47.2)	10 (58.8)	7 (36.8)	0.067*
Female, n (%)	19 (52.8)	7 (41.2)	12 (63.2)	
Birth weight in g, mean±SD	2905±348	2900±339	2.910±364	0.100*
Birth length in cm, mean±SD	48.14±1.07	47.82±1.3	48.47±0.6	0.053*
Immunization status, n (%)				0.064*
Complete, n (%)	31 (86.1)	13 (76.5)	18 (94.7)	
Incomplete, n (%)	5 (13.9)	4 (23.5)	1 (5.3)	
EIB, n (%)	21 (58.3)	13 (76.5)	8 (42.1)	0.673*
EBF 6 m, n (%)	27 (0.75)	14 (82.4)	13 (68.4)	0.745*
Birth interval, n (%)				
<3 years		7 (41.2)	6 (31.6)	0.445*
>3 years		10 (58.8)	13 (68.4)	
Household income (IDR) in month, mean±SD	928.611±12.676	538.235±50.482	1.259.473±16.333	0.647*
Food expenditure (IDR) in month, mean±SD	844.444±61.768	544.117±32.000	1.111.157±69.571	0.369*
Family size, n (%)				0.232*
Small	7 (19.4)	4 (23.5)	3 (15.8)	
Large	29 (90.6)	13 (76.5)	16 (84.2)	
Mother education, n (%)				0.522*
Low	22 (61.1)	13 (76.5)	9 (47.4)	
High	14 (38.9)	4 (23.5)	10 (52.6)	
MUAC in cm, mean±SD	12.07±0.60	12.26±0.54	11.91± 0.62	0.078*
Weight in kg, mean±SD	7.73±1.41	8.32±1.60	7.22±1.02	0.052*
Length in cm, mean±SD	78.50±7.91	81.64±9.15	75.70±5.45	0.208*
WHZ in SD, mean±SD	-3.25±0.20	-3.30±0.23	-3.21±0.18	0.812*

EIB: early initiation of breastfeeding; EBF: exclusive breastfeeding for six months; MUAC: mid-upper arm circumference; WHZ: weight-for-height Z-score

* The p-value >0.05, indicating that the sociodemographic data and characteristics of the subjects in the two groups were homogeneous

Our data indicated that the nutritional status pre-treatment between groups including MUAC, weight, length/height, and Z-scores for weight-for-height (WHZ), were not different or homogenous (**Table 2**).

Weight gain

A comparative analysis of the mean weight gain that was measured in kg within the two groups subjected to different treatments, *Bregas Nutriroll* and F100, is presented in **Table 3**. The data were collected at various intervals: enrollment, week 2, week 4, week 6, and week 8. In the F100 group, there was a consistent increase in mean weight from 8.32 kg at enrollment to 9.39 kg by week 8. Similarly, the *Bregas Nutriroll* group exhibited an increase from 7.22 kg to 8.27 kg over the same period. However, it is notable that, at every measurement interval, the F100 group had a higher mean weight than the *Bregas Nutriroll* group.

Table 3. Mean weight gain (kg)

Variables	F100 (n=17)	*Bregas Nutriroll* (n=19)	*p*-value [a]
Admission	8.32±1.60	7.22±1.02	0.052
2 weeks	8.71±1.65	7.48±0.99	0.013*
4 weeks	8.94±1.67	7.74±1.04	0.018*
6 weeks	9.17±1.63	7.98±1.09	0.017*
8 weeks	9.39±1.69	8.27±1.13	0.029*

[a] Analyzed using ANOVA test
* Statistically significant at $p<0.05$

Comparison of nutritional status outcome of SAM children under five within group

A detailed comparison between the nutritional status of children with SAM upon admission and discharge, focusing on two distinct groups, the F100 and *Bregas Nutriroll*, is provided in **Table 4**. In the F100 group, 17 children were observed, while in the *Bregas Nutriroll* group 19 were under observation. Key variables include weight, length, MUAC, and weight-for-height Z-score (WHZ) were meticulously recorded to evaluate the effectiveness of the interventions.

Table 4. Comparison between nutritional indicator outcomes of children with severe acute malnutrition within group

Variables	Groups		*p*-value [2]
	F100	*Bregas Nutriroll*	
Weight (kg)			
Baseline	8.32±1.60	7.22±1.02	0.052
Endline	9.39±1.69	8.27±1.13	0.029
p-value [1]	<0.001	<0.001	
Δ	1.05±0.39	1.07± 0.39	0.859
Height/length (cm)			
Baseline	81.64±9.15	75.70±5.45	0.208
Endline	82.45±9.09	76.66±5.46	0.031
p-value [1]	<0.001	<0.001	
Δ	0.81±0.44	0.96±0.42	0.198
MUAC (cm)			
Baseline	12.26±0.54	11.91± 0.62	0.078
Endline	12.76±0.51	12.52±0.44	0.115
p-value [1]	<0.001	<0.001	
Δ	0.50±0.37	0.62±0.34	0.337
WHZ (SD)			
Baseline	-3.86±0.48	-3.49±0.55	0.812
Endline	-1.97±0.60	-1.84±0.66	0.522
p-value [1]	<0.001	<0.001	
Δ	1.32±0.57	1.37±0.57	0.787
Hemoglobin (Hb) (mg/dL)			
Baseline	10.78±1.37	11.20±1.12	0.322
Endline	11.49±1.04	11.31±0.45	0.487
p-value [1]	0.032*	0.349	
Δ	0.71±1.25	0.11±1.39	0.026

Δ: the difference between baseline and endline
[1] Paired sample t-test for baseline and endline
[2] Independent t-test between groups

The F100 group showed significant improvements in all measured variables upon discharge. The mean weight increased from 8.32±1.60 kg to 9.39±1.69 kg (Δ 1.05±0.39 kg); length from 81.64±9.15 cm to 82.45±9.09 cm (Δ 0.81±0.44 cm); MUAC from 12.26±0.54 cm to 12.76±0.51 cm (Δ 0.50±0.37 cm); and WHZ improved drastically from -3.86±0.48 SD to -1.97±0.60 SD indicating a positive shift towards better nutritional health. On the other hand, improvements in the *Bregas Nutriroll* group also exhibited notable progress in all key variables post-treatment: weight increased from an initial mean of 7.22±1.02 kg to a healthier mean of 8.27±1.13 kg (Δ 1.07±0.39 cm); length saw an increase from an average of 75.70±5.45 cm to 76.66±5.46 cm (Δ 0.96±0.42 cm); MUAC improved from 11.91±0.62 cm at admission to 12.52±0.44 cm (Δ 0.62±0.34 cm) at discharge; and WHZ showed significant improvement moving up from -3.49±0.55 SD initially to -1.84±0.66 SD post-treatment. The results showed that the implemented interventions were successful in enhancing the nutritional condition of the children in both the test and control groups.

At baseline, the average Hb level in the F100 group was 10.78±1.37 mg/dL, while in the *Bregas Nutriroll* group, it was 11.20±1.12 mg/dL (p=0.322). At the endline, the average Hb level in the F100 group increased to 11.49±1.04 mg/dL, whereas in the *Bregas Nutriroll* group, it slightly increased to 11.31±0.45 mg/dL (p=0.069). The difference in Hb level increase (Δ) between the two groups was significant (p=0.026), with the F100 group showing a significant increase in Hb levels (p=0.032) compared to the non-significant increase in the *Bregas Nutriroll* group (p=0.487).

The recovery rates represented the effectiveness of an intervention in improving the nutritional status of children under five with severe acute malnutrition (SAM) after a two-month intervention, based on weight-for-height Z-score (WHZ). In the F100 group, children who received the F100 intervention exhibited a recovery rate of 94.2%, with 47.1% reaching moderate acute malnutrition (MAM) and 47.1% achieving normal nutritional status. In comparison, the *Bregas Nutriroll* group showed a slightly higher recovery rate of 94.7%, with 26.3% reaching MAM and 68.4% achieving normal nutritional status (**Table 5**).

Additionally, a reduction in the prevalence of anemia within the F100 group, decreasing from 41.2% at baseline to 23.5% after an eight-week administration of F100 milk, is indicated in **Table 5**. A comparable trend was observed in the *Bregas Nutriroll* group, where the prevalence of anemia decreased from 26.3% at baseline to 5.3% following an eight-week administration of *Bregas Nutriroll* RUTF.

Table 5. Recovery rate of children with severe acute malnutrition after intervention

Variables	F100 (n=17)			*Bregas Nutriroll* (n=19)		
	Baseline	Endline	Recovery rate	Baseline	Endline	Recovery rate
WHZ (%)						
SAM	17 (100)	1 (5.9)	94.2	19 (100)	1 (5.3)	94.7
MAM	0	8 (47.1)		0	5 (26.3)	
Normal	0	8 (47.1)		0	13 (68.4)	
Hb status (%)						
Anemia	7 (41.2)	4 (23.5)		5 (26.3)	1 (5.3)	
Normal	10 (58.8)	13 (76.5)		14 (73.7)	18 (94.7)	

Discussion

Malnutrition has a significant and ongoing impact on the social, medical, economic, and developmental aspects of individuals, families, communities, and nations. This randomized controlled trial aimed to evaluate the impact of F100 and *Bregas Nutriroll* interventions on the nutritional status of children with SAM aged between 12 and 59 months. In the present study, we found that both F100 and *Bregas Nutriroll* could increase the weight, height, and MUAC of children with SAM.

This study revealed that the F100 intervention was able to increase the mean weight of SAM children from 8.32 kg at admission to 9.39 kg at the end of the study. Our findings align with those of previous studies in Northwest Ethiopia [24], Sudan [25], Pakistan [26,27], and Malawi [28]. There was an increase in weight of at least 1.06 kg for eight weeks in the F100 interventions group. Our findings are consistent with research conducted in India, which demonstrated that

the administration of F100 milk intervention could increase SAM children's weight by 6.75 g/kg/day [29]. Another similar study in Senegal and Indian hospitals showed that average weight gains in F100 groups were 10.1 g/kg/day and 5.41 g/kg/day, respectively [15,16]. F100 milk, also known as Formula 100, is a specialized milk variant tailored to address severe malnutrition in children. This high-energy, high-protein formula is specifically formulated for use during the recovery phase of malnutrition treatment following the restoration of appetite [30]. F100 provides 100 kcal and 2.9 grams of protein per 100 mL, making it well-suited for meeting the nutritional needs of children with SAM as they regain their health [20].

Currently, the WHO and UNICEF endorse the use of RUTFs for managing SAM in children who are uncomplicated at home. A study has shown that it is effective in improving weight gain and promoting functional recovery of SAM children who are affected. [31]. Our study found that *Bregas Nutriroll* significantly increased the weight gain in SAM children from 7.22 kg to 8.27 kg, indicating that the increase rate was 38 g/kg/day, which is in line with findings of trials in Tanzania [32], Malawi [33], Cambodia [34] and Vietnam [35]. This rate is higher than the 4.0 g/kg/day set by the WHO [36]. The results also align with previous investigations conducted in Ethiopia [37], Ghana [38], India [39], and Pakistan [9], where children attained their appropriate weight following treatment with RUTF. A systematic review revealed that modified RUTF significantly enhanced the daily rate of weight [40,41], height [42,43], and MUAC [44] in children under five with SAM. The RUTF could fill the nutritional gap for children under five [45] since RUTF is developed to have the same nutritional profile as F100 therapeutic formula milk. One of the advantages is that RUTF can be prepared locally without the need for prior preparation or cooking and a minimal risk of contamination [46,47].

The *Bregas Nutriroll* group exhibited a higher recovery rate compared to the F100 group

Recovery from SAM in children is defined by the absence of pitting edema, WHZ score exceeding -2 SD, and MUAC measurement surpassing 11.5 cm [19,48-52]. The findings of this study illustrated the improvements in the mean weight, MUAC, and height/length of the children treated either with the F100 or *Bregas Nutriroll* groups, as well as in other growth indicators. These improvements are in line with a study from Indonesia, which found that the improvement in nutritional status between the RUTF and F100 groups was not significantly different [22].

This study also found recovery rates of SAM were 68.4% and 47.1% in the *Bregas Nutriroll* and F100 groups, respectively (**Table 5**). The recovery rate was measured by the percentage of SAM children who achieved normal body weight (WHZ more than -2 SD) after receiving intervention for eight weeks. The recovery rate of the *Bregas Nutriroll* group was higher than the F100 group. Giving F100 milk to SAM children can ideally provide a chance of getting out of malnutrition of more than 60% [53]. Children who were given RUTF demonstrated more rapid rates of weight gain and had a 51% higher probability of achieving recovery (as defined by a WHZ ≥-2) [54]. These findings are almost in accordance with studies on the effectiveness of RUTF in Odisha, Indonesia and Malawi [29,55-56]. A systematic review study also proved that administering RUTF in its standard form and its modifications can increase the recovery rate by 70–100% [57]. RUTF successfully supplied the necessary metabolites derived from plasma amino acids to aid in the recovery of malnutrition caused by SAM [58].

This study also showed that the administration of F100 and *Bregas Nutriroll* increased the length of children with SAM. Other studies have also demonstrated the same results. A study in Odisha resulted in local RUTF was able to increase the WHZ score of SAM children up to 1 SD below the median, while F100 milk was only able to increase it to 0.56 SD [29]. Furthermore, a study in Burkina Faso also found that RUTF intervention with 1-2 packs/day for six weeks in SAM children was able to increase body length by 26.46 mm [59]. Studies on healthy children aged 13 months showed an average growth increase of approximately 16.8 mm/six-week [60]. Children with SAM who experience rapid recovery have a better chance of achieving normal growth and developmental milestones, such as healthy children. Improving early nutrition is an opportunity to reduce morbidity and mortality as well as improve child development [61].

Another study found that Hb levels increased in the F100 group but did not have a significant effect after administering *Bregas Nutriroll*. These findings align with previous research on SMS

RUTF, which showed no statistically significant difference in the proportion of anemic children (with hemoglobin levels of 11.0 g/dL) discharged after recovery [62]. Historically, there has been concern that iron may cause children with SAM to develop non-detoxifying free radicals [63]. The potential impact of *Bregas Nutriroll* on iron levels presents an intriguing area for further research. Although the administration of RUTF was able to increase Hb levels, it did not produce a statistically significant effect [64]. Several factors might contribute to this outcome, such as interactions with other micronutrient supplements, the presence of phytates in the formula, or the high fiber content, which may inhibit iron absorption and its utilization in the body. Additionally, the iron dose provided may be insufficient to meet the elevated iron requirements associated with weight gain.

Limitations

This study has several limitations. Firstly, the number of participants available for the analyses was small. Second, the study lacked blinding, which was challenging given the distinct nature of the two interventions being compared. Third, the relatively short duration prevented the assessment of whether children could sustain their weight recovery and developmental progress for long-term benefits. Ultimately, financial constraints prohibited laboratory tests to evaluate micronutrient deficiency and recovery during the pre- and post-examination phases.

Conclusion

In summary, this study concluded that F100 milk and *Bregas Nutriroll* are beneficial for improving the nutritional status of children under five with severe acute malnutrition (SAM) as long as they are administered promptly and according to WHO guidelines. Implementing locally produced RUTF (*Bregras Nutriroll*) administration in CMAM are feasible, effective, well-received, and adequately supported is essential for achieving population-level improvements, especially among vulnerable subgroups (children with SAM aged 12–59 months without medical complication).

Ethics approval

The Advanced Study Research Board at Health Polytechnics of Kupang approved this study (reference Number: LB.02.03/1/0147/2023). Written informed consent was obtained from the parents or guardians of the children who participated in the study.

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Competing interests

The authors declare no conflicts of interest.

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Underlying data

Derived data supporting the findings of this study are available from the corresponding author on request.

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