

# Effectiveness of a reduced dose of ready-to-use therapeutic food (RUTF) in the treatment of severely wasted children under 5 years in routine practice : a randomized controlled trial, DRC



Julien NTAONGO ALENDI<sup>1</sup>, Cécile SALPETEUR<sup>2</sup>, Steve BOTOMBA<sup>4</sup>, Victor NIKIEMA<sup>2</sup>, Jean Baptiste MAYAVANGA<sup>5</sup>, Benjamin GUESDON<sup>2</sup>, Alemayehu Argaw ALEMAYEHU<sup>3</sup>, Marie PETRY<sup>2</sup>, Uwimana SEBINWA<sup>2</sup>, Aimée MUPUALA<sup>6</sup>, Florence MIABI<sup>7</sup>, Didier BOMPANGUE<sup>1</sup>, Samuel MAMPUNZA<sup>7</sup>, Marie-Claire MUYER<sup>4</sup>

1. Ecology & Infectious Disease Control Service, Faculty of Medicine, University of Kinshasa, DRC ;
2. Research, Analyses and Learning Service, Expertise and Advocacy Department, Action Against Hunger, France;
3. Department of Food Technology, Safety and Health, University of Gent, Belgium.
4. Nutrition Department, School of Public Health, University of Kinshasa, DRC ;
5. National Nutrition Programme, Ministry of Public Health, Hygiene and Prevention, DRC ;
6. Paediatrics Department, University Clinics, University of Kinshasa, DRC ;
7. Paedopsychiatric Unit, Neuro-psycho-pathological Centre, University of Kinshasa, DRC,

## What is at stake?

The proposed reduced RUTF dosage was proven effective in 2019 in ideal conditions in Burkina Faso with the MANGO trial. Savings represented 16.8% or \$15 per child treated. More children could hence benefit of a treatment in particular in humanitarian crises, when the number of children suffering of SAM increases. But such a reduced dose strategy remains to be demonstrated effective in a context of food insecurity and when delivered in routine practice.

Table 1: dosage of RUTF per child weight category

DOSAGE	Number of sachets of RUTF (92g) per week		
	Standard dose	Reduced dose	
Child's Weight (kg)	Admission to Discharge	Admission and Week 1	Week 2 to Discharge
3.0-3.4	9	9	7
3.5-4.9	11	11	7
5.0-6.9	14	14	7
7.0-9.9	21	21	14
10.0-14.9	28	28	14

## Main objective

To evaluate in routine practice and in a context of food insecurity the effectiveness of a reduced dose of RUTF in the management of children aged 6 to 59 months and suffering of SAM, in terms of weight gain velocity (g/kg/d).

## Methods

**Type of study** : Non-inferiority randomized controlled trial

**Population** : children without medical complications aged 6-59 months, suffering from SAM defined as: WHZ<3 zscore and/or MUAC < 115 mm and/or bilateral pitting oedema.

**Randomization**: individual

**Study area** : 14 health areas, Bonzola and Nzaba Health Zones, Mbuji-Mayi town, Kasai Oriental province, DRC

**Sample size** : 1000 children, 500 (reduced dose) and 500 (standard dose)

**Intervention** : SAM treatment per national protocol, similar in both groups except for RUTF dosage – see table 1

**Data analyses** : using WHO anthro package in Stata v17, discarding WHO outliers, comparative analyses and tests, regression models, correlation between children features and outcomes, interaction tests for exploring the effects of reduced RUTF dose in subgroups.

**Registration**: <https://doi.org/10.1186/ISRCTN15258669>

Table 2: Weight gain velocity per group, in *intention-to-treat* or *per-protocol* analyses, and after 2 weeks (when reduction starts)

Outcome	Reduced RUTF		Standard RUTF		Unadjusted model		Adjusted model	
	n	mean ± SD	n	mean ± SD	Difference (95% CI)	p-value	Difference (95% CI)	p-value
<b>ADMISSION TO DISCHARGE</b>								
Weight gain velocity (g/kg/d)								
<i>Intention-to-treat (all children)</i>	478	4.91 ± 2.39	468	5.14 ± 2.24	-0.23 (-0.49; 0.04)	0,09	-0.11 (-0.33; 0.12)	0,34
<i>Per-Protocol (best care received)</i>	293	4.84 ± 2.38	320	5.12 ± 2.29	-0.28 (-0.61; 0.04)	0,09	-0.07 (-0.34; 0.20)	0,62
Recovered	315	5.30 ± 2.24	320	5.52 ± 2.13	-0.23 (-0.52; 0.07)	0,13	-0.03 (-0.25; 0.18)	0,78
Defaulted	11	2.68 ± 2.97	8	2.91 ± 2.62	-0.23 (-2.66; 2.21)	0,85	-2.40 (-4.33; -0.46)	0,02*
<b>MUAC gain velocity (mm/wk)</b>								
<i>Intention-to-treat (all children)</i>	478	2.22 ± 0.94	468	2.37 ± 0.89	-0.14 (-0.25; -0.04)	0,01*	-0.07 (-0.16; 0.01)	0,09
<i>Per-Protocol (best care received)</i>	293	2.20 ± 0.98	320	2.38 ± 0.84	-0.17 (-0.30; -0.04)	0,01*	-0.10 (-0.21; 0.01)	0,08
<b>AFTER TWO WEEKS</b>								
Weight gain velocity (g/kg/d)								
<i>Intention-to-treat (all children)</i>	455	4.28 ± 2.10	440	4.52 ± 2.22	-0.21 (-0.46; 0.03)	0,08	-0.12 (-0.35; 0.11)	0,29
<i>Per-Protocol (best care received)</i>	274	4.24 ± 1.97	298	4.55 ± 2.22	-0.32 (-0.60; -0.04)	0,03*	-0.14 (-0.42; 0.13)	0,31
<b>MUAC gain velocity (mm/w)</b>								
<i>Intention-to-treat (all children)</i>	455	2.12 ± 1.07	440	2.31 ± 1.01	-0.17 (-0.29; -0.05)	0,01*	-0.12 (-0.23; -0.01)	0,03*
<i>Per-Protocol (best care received)</i>	274	2.14 ± 1.13	298	2.36 ± 0.96	-0.20 (-0.35; -0.05)	0,01*	-0.13 (-0.28; 0.01)	0,08

## Conclusions

- The strategy of a reduced dose of RUTF from the 3rd week of treatment is non-inferior in terms of weight gain velocity, compared with the standard dose, in the management of children with SAM and no medical complications, and this in a context of moderate and severe food insecurity.
- The fact that caregivers who gave the RUTF were not blinded to the dosage was a limit in the sense that children under reduced dose may have benefited from increased attention. Community health workers and nurses received incentives for their work.
- Only 7% of children presented with oedema in our study hence our results are not sufficiently powered to demonstrate effectiveness of a reduced RUTF dose for these children.
- The sharing of RUTF is widespread within families, and due to low access to drinkable water 1 sachet is given in exchange for water, as highlighted in our sociological report available on the project webpage <https://www.actioncontrelafaim.org/projet-eframas>.

## Thanks to the support from donors



This study would not have been possible without the trust of the children and their families, the engagement of congolese authorities, the support of communities, the quality work of the nurses and community volunteers, and the dedication of ACF's teams to facilitate operational research. Please find here the expression of our gratitude !

Copyright © 2024 Cecile Salpeteur, [csalpeteur@actioncontrelafaim.org](mailto:csalpeteur@actioncontrelafaim.org)



## Key takeaways

- The present clinical trial confirms the effectiveness of a reduced dose of RUTF during treatment of children with SAM in a humanitarian emergency context and delivered in routine practice.
- Once scaled up, this strategy could increase the coverage of programs addressing wasting in a country like the DRC, with savings in treatment costs.
- Promoting children's growth and development by improving post-treatment follow-up is a complementary strategy that remains to be demonstrated.

## Results

From August to November 2021, 968 children were admitted to the study with mean age of 29 months, 54% male, and mean weight of 7.9 kg. Of these, 7% had nutritional oedema, and 97% of the children's households were moderately or severely food insecure.

Table 3: Programmatic results in both groups

Outcome	Reduced RUTF		Standard RUTF		Difference (95% CI)	p-value
	n	median [IQR]	n	median [IQR]		
Length of stay, days	490	42 [35-54]	478	43 [35-56]	-0.4 (-2.2; 1.5)	0,70
<b>Subgroup analysis by</b>						
WHZ at admission	490		478			0,74
<-3	241	49 [35-56]	236	49 [35-56]	-0.6 (-3.2; 2.0)	0,66
≥-3	226	42 [35-49]	230	43 [35-51]	0.1 (-2.6; 2.7)	0,97
		% (n)		% (n)		
Recovery	490	64.3 (315)	478	66.9 (320)	-2.8 (-8.6; 3.0)	0,34
Default	490	0.6 (3)	478	0.0 (.)	0.0 (.; .)	na
Death	490	0.0 (.)	478	0.2 (1)	na	na
False discharge	490	29.8 (146)	478	27.0 (129)	3.0 (-2.6; 8.6)	0,29
Non responder	490	0.6 (3)	478	0.2 (1)	na	na
<b>Referral criteria met</b>						
Weight loss	490	2.9 (14)	478	2.1 (10)	0.9 (-1.3; 3.0)	0,43
Stagnant weight	490	20.6 (101)	478	19.7 (94)	1.2 (-3.8; 6.2)	0,63
<b>Medical complication</b>	490	0.6 (3)	478	0.4 (2)	0.3 (-2.1; 2.7)	0,79
Relapse as SAM over 3 months	245	2.9 (7)	250	2.4 (6)	0.5 (-2.4; 3.3)	0,75
Lost-to-follow up	490	5.1 (25)	478	5.6 (27)	-0.7 (-3.7; 2.4)	0,67

- Non inferiority is demonstrated on weight gain velocity.
- Recovery rates and other key outcomes were similar in reduced dose group to those in standard group and not significantly different after adjustment.
- Length of stay is not different between the 2 groups.
- Relapse rate as SAM over 3 months of follow-up among children discharged recovered is low and similar in both groups.

Figure 1: Non inferiority graph of weight gain velocity

