

## Effectiveness Of MASO31 In the Prevention of Malnutrition: Randomized Controlled Nutrition Trials in Children 12-20 Months in The Kapolowe Health Zone, Haut-Katanga, DR Congo, 2022

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### Abstract

*Inadequate complementary feeding is one of the main causes of malnutrition in the world. Approximately 51.5 million children under 5 years of age worldwide were emaciated of which 6.9 million died due to acute malnutrition whose 12.6% of deaths with more than one-third related to inadequate complementary feeding in 2016. The objective of this study was to assess the effectiveness of the MASO31 recipe in increasing the weight-for-height anthropometric index in the prevention of acute malnutrition.*

*We conducted Randomized Controlled Nutrition Trials to evaluate the efficacy of MASO31 in the prevention of malnutrition. The control was the « MASO30 » consisting of supplementary food given by the mothers locally. Allocation of the « MASO31 » into 2 groups was simply randomized using the double-blind method.*

*The randomized controlled nutrition trials show an improvement in weight and anthropometric index of weight-for-age, weight-for-height, and height-for-age in both intervention and control groups. Both MASO31 and MASO30 improved the growth of children. However, MASO31 significantly improved weight ( $F=1.653$ ;  $p=0.005$ ) and weight-for-height index ( $F=2.939$ ;  $p=0.000$ ) compared to MASO30*

*The local MASO31 recipe was effective in improving the weight-for-height anthropometric index. Its use in supplementary feeding will be a sustainable solution in the prevention of malnutrition in some provinces of DR Congo that produce locally the ingredients that compose it.*

**Keywords:** MASO31, clinical, trials, prevention, malnutrition, health zone, Kapolowe, Haut-Katanga, DR Congo.

### Introduction

Maternal and child nutrition during the first 1000 days of life, from conception to the child's second birthday, is an issue that has been identified as a priority program for UNICEF to guide its strategies between 2020 and 2030. The aim was to provide optimal breastfeeding (OBA), including exclusive breastfeeding (EBF) for the first six months of birth followed by continuous breastfeeding (CBF) with complementary feeding (CF) from 6 months to two years or beyond, in both development and humanitarian contexts [1].

During this first 1000-day period, the child may be affected by acute malnutrition, which can lead to mortality (due to decreased immunity) or stunting if the child consumes insufficient amounts of poor-quality foods for a long time, even if the child had received optimal breastfeeding [2-4]. In their global strategy, WHO and the United Nations Children's Fund (UNICEF) recommend the use of locally produced foods as complementary foods for infants and young children to ensure optimal complementary feeding for their

optimal growth, development and well-being [5-7]. Despite the WHO recommendations on infant and young child feeding (IYCF) on the one hand and several improvements in child health on the other, malnutrition is still a major public health concern.

In 2020, the triple burden of malnutrition is still a major concern, especially in low- and middle-income countries (LMICs). In LMICs, about 200 million children are affected by stunting or wasting, and almost twice as many children are deficient in vitamins and other essential micronutrients. Overweight and obesity are increasing in the poorest households at the same time. Together, undernutrition (stunting and wasting), widespread micronutrient deficiencies, and high prevalence of overweight, and obesity constitute the triple burden of malnutrition on children worldwide [1].

Globally, 149.2 million children under five are stunted, 45.4 million are wasted and 38.9 million are overweight. Over 40% of all men and women (2.2 billion people) are now overweight or obese. Some countries are making encouraging progress. For example, of the 194 countries assessed, 105 are on track to meet the target for child overweight and more than a quarter are on track to meet the targets for stunting and wasting. However, anaemia levels have stagnated or even worsened in 161 countries [8].

In 2016, acute malnutrition affected almost 51.5 million children under 5 years of age worldwide and was a cause attributed to 12.6% of 6.9 million deaths, with more than a third linked to inadequate complementary feeding. Nineteen million of these 51.5 million children were severely affected and at higher risk of mortality, the vast majority in sub-Saharan African countries [9].

Inadequate complementary feeding (CF) and worrying childcare practices remain a challenge in many households, particularly in low-income countries [10].

At the same time, food insecurity as an underlying cause of malnutrition was reported in approximately 80 million households in 2015 and 108 million households in 2016 [11].

The Democratic Republic of Congo (DRC) is one of the 34 countries in the world with the highest prevalence of malnutrition. Almost one in two children under 5 years is stunted [12]. Approximately 600,000 children under five die each year as a result of malnutrition. Nearly 35528 children under 5 years of age suffering from severe acute malnutrition were under treatment, including 2401 in the Intensive Therapeutic Nutritional Unit (ITNU) and 33127 in the Ambulatory Therapeutic Nutritional Unit (ATNU) in October 2019 [13].

In the DRC 857,000 children under the age of 5 are emaciated, of whom 26%, or 21,900 children, are in a severe form, and 468,000 pregnant and breastfeeding women are in a state of acute malnutrition [14].

It has been estimated that nearly 900,000 children under five and more than 400,000 pregnant and lactating women are likely to be acutely malnourished until August 2022 for the 70 health zones analyzed by the technical working group out of a total of 519 health zones. These estimates include more than 200,000 severely malnourished children requiring urgent care. This precarious nutritional situation is the result of a combination of several factors, mainly, poor feeding quality due to poor child feeding practices (ANJE), acute food insecurity, high prevalence of childhood diseases (malaria and diarrhea) and measles and cholera outbreaks, poor hygiene conditions (inaccessibility to adequate sanitation facilities), very low coverage of access to drinking water, and the negative effects of the security situation which leads to massive population displacement [14].

According to WHO recommendations, by the 6th month of life, breast milk becomes quantitatively insufficient to meet the nutritional needs of children. In the Pacific Region of Asia, 9 studies had shown early initiation of complementary foods compared to the WHO recommendations [15]. On the South Indian coast, 68% of mothers who initiated complementary feeding at 6 months of age gave an inadequate and nutrient-poor amount [2]. Africa is not immune to the nutritional problems associated with complementary feeding. In Ethiopia, about 60% of children were introduced to CFs at 6 months of age. And the mean prevalence of introducing complementary foods at the recommended age of 6 months was associated ( $p < 0.007$ ) with the high level of education of the children's mothers [16].

In DRC, the Demographic and Health Survey (DHS) and the Multiple Indicators Cluster Survey (MICS) 2018 showed that the prevalence of chronic malnutrition was 43% and 42% respectively, and that national indicators of complementary feeding practices were below the 80% coverage recommended by [12, 17, 18].

Intervention studies to determine the impact of timing and local complementary food types on the nutritional status of children aged 6-23 months were recommended by the COCHRANE review. It also added the combination of education with the provision of accessible complementary foods for children in food insecure countries [19].

However, a study on the effectiveness of the local MASO31 recipe in preventing malnutrition in Upper Katanga and DRC was needed.

### Research question

The demographic health surveys [17] and the multiple indicators cluster surveys [12] carried out in the Democratic Republic of Congo show that malnutrition in all its forms is still a permanent public health problem. And the infant and young child feeding indicators are far from reaching the 80% coverage target set by the World Health Organisation [18], despite the many training sessions and interventions carried out by the National Nutrition Programme (PRONANUT) in DR Congo every year for decades. Several authors have highlighted complementary feeding as one of

the main causes that potentially impact on nutritional status [20, 10, 21] worldwide and in Africa. However, studies on measures of association and impact between complementary feeding and nutritional status of children aged 6-23 months in Upper Katanga and DRC are needed.

« What is the effectiveness of the local recipe « MASO31 » in preventing malnutrition (on the gain of anthropometric index)?

### Objectives of the study

The overall objective of this study was to assess the effectiveness of the MASO31 recipe and its ability to increase the weight-for-height anthropometric index in the prevention of acute malnutrition and, in turn, to contribute to the reduction of malnutrition and mortality among children under 2 years of age in the health zone of Kapolowe, Haut-Katanga in the DRC, by highlighting an appropriate locally produced complementary food (CF) that is geographically, culturally, financially accessible and non-binding. In this way, we will have indirectly contributed to the achievement of MDG 2 « Zero Hunger, Food Security and Nutrition with Sustainable Agriculture » in DRC.

Specifically, the study proposed to 1° Evaluate the mean of weight-for-height, weight-for-age, and height-for-age anthropometric index in children aged 6-23 months before and after intervention in the intervention and comparison groups; 2°. Compare the paired means of the anthropometric index weight-for-height, weight-for-age, and height-for-age within each group (intervention and control); 3°. Compare the actual difference in the means of the gains in the anthropometric index weight-for-height, weight-for-age and height-for-age in the intervention to that of control groups of children.

### Methods

#### Study site

The randomized controlled nutrition trials were conducted in the Kapolowe Health Zone located in the Province of Haut Katanga (in the former District of Likasi) where the prevalence of chronic malnutrition is 40% [12].

#### Study population

The target population was children aged 6-23 months residing in the Kapolowe health zone.

The source population was children aged 12-20 months residing in the Kapolowe health zone.

#### Sampling

To conduct the randomized nutrition trials, we calculated the sample size using both the P-S Power and sample size calculation software version 3.1.2. and the sample size calculation formula  $n = 2 (Z\alpha + Z [1-\beta])^2 \times SD^2 / d^2$ ,  $\alpha=0.01$ ,  $Z\alpha=2.58$ ,  $\beta=0.10$ ,  $Z (1-\beta) =1.28$ ;  $SD=1z$ -score (in each participant group),  $d$  (effect size)  $=0.55z$ -score to arrive at the same result. D'où,  $n=2(2.58+1.28)^2 \times (1)^2 / (0.55)^2=99$ . The sample size  $N$  that takes into account the attrition rate of  $R=10\%$  was  $NR=n/(1-R) =99 / (1-0.90) =110$  intervention and 110 control [22,23]. Using the P-S Power and sample size calculation software version 3.1.2. the minimum sample size was 214 mother-child pairs of which 107 were in the

intervention group and 107 in the control group. Therefore, we adopted the larger size to increase the reliability of the results and to control type I get II errors.

#### Type of study

We conducted Randomized Controlled Nutrition Trials (RCTs) to evaluate the efficacy of « MASO31 » in preventing malnutrition. The control was « MASO30 » constituted by complementary foods (CF) given by the mothers locally. The allocation of « MASO31 » into 2 groups was simply randomized using the double-blind method. The mixing of MASO31, its packaging, and the packaging of MASO30 were carried out in a remote area (in Lubumbashi) by a team of trained mothers under the supervision of the MASO31 nutritionists.

#### Design and description of MASO31 (intervention)

Here is the composition of the ingredients of the MASO31 evaluated in local measures for the mixture consider any standard measure

3 measures of maize flour (e.g., 3kg)

1 Measure of soya flour (e.g., 1kg)

½ measure of sugar (e.g., 0.5kg)

½ measure of palm oil (e.g., 0.5 kg)

1/10 measure of cooking salt (e.g., 0.100 kg).

To the total mixture:

Add powdered sprouted and dried corn to 1% (e.g., 0.010 kg) to improve the vitamin and digestive enzyme content (sprouted corn) and Add caterpillar powder at 1% (e.g., 0.010 kg) concentration to improve protein, calcium, and phosphorus content.

#### Acceptability of MASO31

In our experience in the Kifungo health area, Kalemie health zone in Tanganyika province, we conducted an unpublished pilot study on the acceptability of MASO31 that found that 98% of children whose mothers were members of infant and young child feeding support groups agreed to consume MASO31. This is because MASO31 improved flour is a blend of locally produced foods that are available, geographically and financially accessible, affordable and not a constraint in terms of culinary preparation. Also, in our study conducted in the province of LUALABA, both the acceptability of MASO31 and the availability of its ingredients were demonstrated [18].

#### Randomisation of MASO31.

The principal investigator assigned a « 1 » label to the package containing MASO31 and a « 2 » label to the package containing MASO30, without the knowledge of the entire team of mothers and supervising nutritionists. Upon entry into the study, according to the above entry criteria, the children were given tokens numbered 1 to 220 according to their order of entry into the study. Recipes « 1 » and « 2 » were given randomly to children who received the « odd » and « even » numbered tokens respectively. The mothers were scheduled daily for the preparation of the porridge and the wet ration distributors the form of already cooked porridge did not know who was given the intervention and who was given the control recipe. At the same time, these mothers were responsible for cooking the recipe marked

« 1 » or « 2 » according to the odd or even numbers of the tokens their children received at intake and were assigned to the health areas where their children were randomly assigned respectively. Children aged 12-20 months who participated in the study received 200g of MASO31 or MASO30 as a porridge per day prepared in three doses (3 different preparations, at 7:00 am, 1:00 pm, and 6 :00 pm). Children with odd-numbered tokens were referred to the Lupidi health area I preparing the numbered ration 1, while those with even-numbered tokens were referred to the Lupidi health area II preparing the numbered ration 2. The analyzing statistician did not know the codes (intervention and control).

**Data collection techniques.**

Before, during, and at the end of the study, we collected data by:

- Anthropometry of children for measurements of weight, height, arm circumference and oedema check,
- Interviewing mothers to collect socio-economic characteristics and feeding practices of their children using the 24-hour diet recall method,
- Medical examinations to identify sick children and refer them to health facilities.

**Ethical considerations**

**Results**

1°We received the authorization and approval of the UNILU ethics committee in order to guarantee respect for the individual, benevolence and the fair & honest distribution of the risks and benefits of the study, 2°We obtained permission from the DRC health authorities in Haut Katanga and the visa of the National Nutrition Programme, 3°The investigators read and signed the free consent form to participate in the study and to respect the ethical conditions. The mothers of children participating in the study also freely signed a free consent form or consented verbally for those who could not write, 4° Participation was free. After free consent, mothers were interviewed about their complementary feeding practices and the nutritional status of the children 6-23 months was assessed, 5°When the mother selected by the survey was less than 18 years old, the child’s grandmother obtained informed information and freely signed a form (or agreed verbally if she could not write) before interviewing the mother and assessing the child’s nutritional status, 5°The « MASO31 » intervention and the « MASO30 » placebo to which the children were subjected consisted of local food mixtures commonly consumed in the population without any risk, 6°The participants in this study were the first beneficiaries of the efficacy of this recipe in case the results confirmed it.

**Table 1:** Results by participant group before and after intervention.

	Intervention Group (IG)		Control Group (CG)		Intergroup difference	
<b>Before Intervention</b>						
N	110		115			
Average weight in kg (±SD)	9,100	2,500	9,000	1,700	0,100	0,800
Average WHZ index (±SD)	-0,900	1,500	-0,900	1,300	0,300	0,200
Average WAZ index (±SD)	-1,481	1,400	-1,800	1,100	0,300	0,300
Average HAZ index (±SD)	-1,600	1,800	-2,200	1,800	0,600	0,000
Lost to view	9		4			
<b>After Intervention</b>						
N	101		111			
Average weight in kg (±D)	13,300	2,500	12,100	1,800	1,200	0,700
Average WHZ index (± SD)	3,200	1,300	1,800	1,300	1,400	-0,500
Average WAZ index (± SD)	1,400	1,000	0,300	1,000	1,100	0,000
Average HAZ index (±SD)	-2,000	1,900	-2,000	1,800	0,000	0,100
<b>Intra-group difference</b>						
Average weight in kg (±SD)	4,198	-0,019	3,097	0,652		
Average WHZ index (±SD)	4,108	1,216	2,726	0,892		
Average WAZ index (±SD)	2,881	0,825	2,126	0,688		
Average HAZ index (±SD)	-0,321	0,924	0,228	0,801		
<b>Difference of Differences</b>						
Average weight in kg (± SD)					1,101	-0,112
Average WHZ index (±SD)					1,382	-0,119
Average WAZ index (±SD)					0,755	-0,218
Average HAZ index (±SD)					-0,550	0,074

SD: standard deviation; WHZ: weight for height z-score; WAZ: weight for age z-score; HAZ: height for age z-score; kg: kilogramme

This table 1 shows the number of participants in the two groups before and after the intervention, the difference in mean weights, and anthropometric indices in the two groups before and after the intervention.

**Table 2:** Results of the difference-in-means test for paired data in the intervention and control groups.

Nutritional parameter	Difference in paired means	Standard deviation	CI of the difference at 95%.		t	p
			Lower	Upper		
<b>INTERVENTION GROUP (IG)</b>						
weight After Intervention - weight before Intervention	4,198	-0,019	4,062	4,334	61,4	,000
Index WHZ after Intervention - Index WHZ before Intervention	4,108	1,216	3,868	4,348	33,9	,000
Index WAZ after Intervention - Index WHZ before Intervention	2,881	0,825	2,718	3,044	35,1	,000
Index HAZ after Intervention - index T before Intervention	-0,321	0,924	-0,504	-0,139	-3,5	,001
<b>IN THE CONTROL GROUP (CG)</b>						
Weight in kg after Intervention - Weight in kg before Intervention	3,097	0,652	2,975	3,220	50,0	,000
Index WHZ after Intervention - index WHZ before Intervention	2,726	0,893	2,558	2,894	32,2	,000
Index WAZ after Intervention - index WAZ before Intervention	2,127	0,688	1,997	2,256	32,6	,000
Index HAZ after Intervention - index HAZ before Intervention	0,229	0,802	0,078	0,380	3,01	,003

CI: confidence interval; t: t-test of independent comparison of paired means

The table 2 shows us that in both groups (intervention and control) the difference in anthropometric indices after and before intervention was statistically significant. In other

words, there was a significant gain in all anthropometric indices at the end of the intervention in both study groups, considering the t-test value and the p-value.

**Table 3:** Comparison of the differences in the means of the intervention and control groups.

DIFFERENT INDICATORS	The difference in paired means	Standard deviation	The difference in Differences Paired Means	t	ddl	p-value	F	p-value
<b>Weight in kg</b>								
In the IG	4,2	0,700	1,1	9,86	210	0,000	1,653	0,005
In the CG	3,1	0,900						
<b>Index WHZ</b>								
dans le GI	4,1	1,200	1,0	7,318	158	0,000	2,939	0,000
dans le GT	3,1	0,700						
<b>Index WAZ</b>								
In the IG	2,900	0,800	0,800	7,76	210	0,000	1,306	0,085
In the CG	2,100	0,700						
<b>Index HAZ</b>								
In the IG	-0,300	0,900	-0,500	-4,3	210	0,000	1,266	0,113
In the CG	0,200	0,800						

F: two-t-tests of independent comparison of the difference of the paired means differences

Our Table 3 shows a statistically significant difference between the intervention and control groups for the weight (F=1.653; p=0.005) and weight-for-height index (F=2.939; p=0.000). The MASO31 intervention was therefore more effective than the MASO30 control in significantly increasing weight and weight-for-height index.

However, there was no statistically significant difference between the intervention and control groups for the indicators underweight (F=1.306; p=0.085) and height-for-age index (F=1.266; p=0.113). The MASO31 intervention was therefore not more effective than the MASO30 control

in significantly increasing the weight-for-age index and the height-for-age index.

### Discussion of results

Our randomized controlled nutrition trials show improvements in weight and anthropometric indices P/A, P/T, and T/A in both the intervention and control groups. Both MASO31 and MASO30 improved children's growth. However, MASO31 significantly improved weight (F=1.653; p=0.005) and weight-for-height index (F=2.939; p=0.000) compared to MASO30. These results corroborate those found in Indonesia in a quasi-experimental study where all anthropometric indices P/A, P/T, T/A, and BMI/A were

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improved by a local recipe used as a complementary food in children aged 6 to 36 months [24]. However, a study in Myanmar showed that the supplementary diet based on locally produced foods was deficient in some essential nutrients including niacin, folate, thiamine, iron, zinc, calcium, and vitamin B6, as recommended by WHO, and that these local recipes should be fortified [25]. This explains the statistically significant difference in the improvement in weight and weight-for-height (W/H) anthropometric index by MASO31 which was fortified using a local food of animal origin (caterpillars) compared to MASO30 which was not fortified (the usual local mixture of mothers in Kapolowe). Caterpillars are rich in protein and are therefore rich in niacin, folate, thiamine, iron, zinc, calcium, and vitamin B6 [26,27] to allow for the validity of the efficacy of the MASO31.

## Conclusion

As the local MASO31 recipe is effective in improving anthropometric P/T and P/A indices, its use in supplementary feeding will be a sustainable solution in the prevention of malnutrition in some provinces of DR Congo that produce the ingredients locally. And other local recipes could be identified by region and enriched locally with the same aim of preventing malnutrition in a sustainable way.

**Conflict of interest:** None

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