

## Effects of micronutrient powder and complementary food blend on growth and micronutrient status of Filipino rural children: a randomised controlled trial

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### ABSTRACT

**Introduction:** This study aimed to evaluate the effects of micronutrient powders (MNP) containing 15 versus nine nutrients, with or without complementary food blend (*BigMo*), on the nutritional status of rural young children in the Philippines. **Methods:** The study was conducted for 6 months among 126 rural children aged 6-17 months in four villages selected by cluster randomisation. Children were randomised into four groups: VitaMix with 15 micronutrients plus Bigas Mongo (*BigMo*) ( $n=31$ ); VitaMix without *BigMo* ( $n=31$ ); Micronutrient Growth Mix (MGM) with nine micronutrients plus *BigMo* ( $n=29$ ); and MGM without *BigMo* ( $n=31$ ). Blood samples were collected at baseline and endline to determine haemoglobin, ferritin, retinol, and zinc concentrations. Intervention compliance, weight, length, and dietary intakes were collected every month. One-way ANOVA was used to compare changes in the mean estimates across groups. McNemar and Pearson's  $\chi^2$  tests were used to compare changes in the proportion estimates within groups and across groups, respectively. **Results:** Both VitaMix and MGM with or without *BigMo* improved haemoglobin concentrations and reduced anaemia ( $Hb < 11g/dL$ ). However, only VitaMix and MGM combined with *BigMo* had effects in reducing moderate anaemia ( $Hb < 10g/dL$ ), compared to groups without *BigMo*. Only MGM+*BigMo* group demonstrated significant reduction in the prevalence of moderate non-iron deficiency anaemia (IDA) ( $Hb < 10g/dL$  and ferritin  $> 12\mu g/L$ ). A significant increase in the length-for-age z-scores was noted in the MGM with and without *BigMo* groups. **Conclusion:** Daily supplementation of MGM with nine micronutrients combined with complementary food blend may have a greater potential than MNP with 15 micronutrients in improving the nutritional status of young children.

**Keywords:** Micronutrient powder, complementary food blend, micronutrient deficiency, anaemia

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## INTRODUCTION

The majority of Filipino young children aged 6-23 months do not meet the minimum acceptable diet, indicating poor dietary diversity and quality, coupled with inadequacy of energy, protein, iron and vitamin A in their diets (FNRI-DOST, 2016). One of the causes identified for the marked increase in undernutrition during the first two years of life was sub-optimal practices of exclusive breastfeeding and complementary feeding (FNRI-DOST, 2015a). In addition, anaemia was highly prevalent, at 39.4% among infants 6-12 months, 24.6% among 1 year old children and 14.0% in 2 years old children (FNRI-DOST, 2015b). Among children 6 months to 5 years, anaemia prevalence was highest in the poorest income group, which commonly resides in rural areas (FNRI-DOST, 2015b).

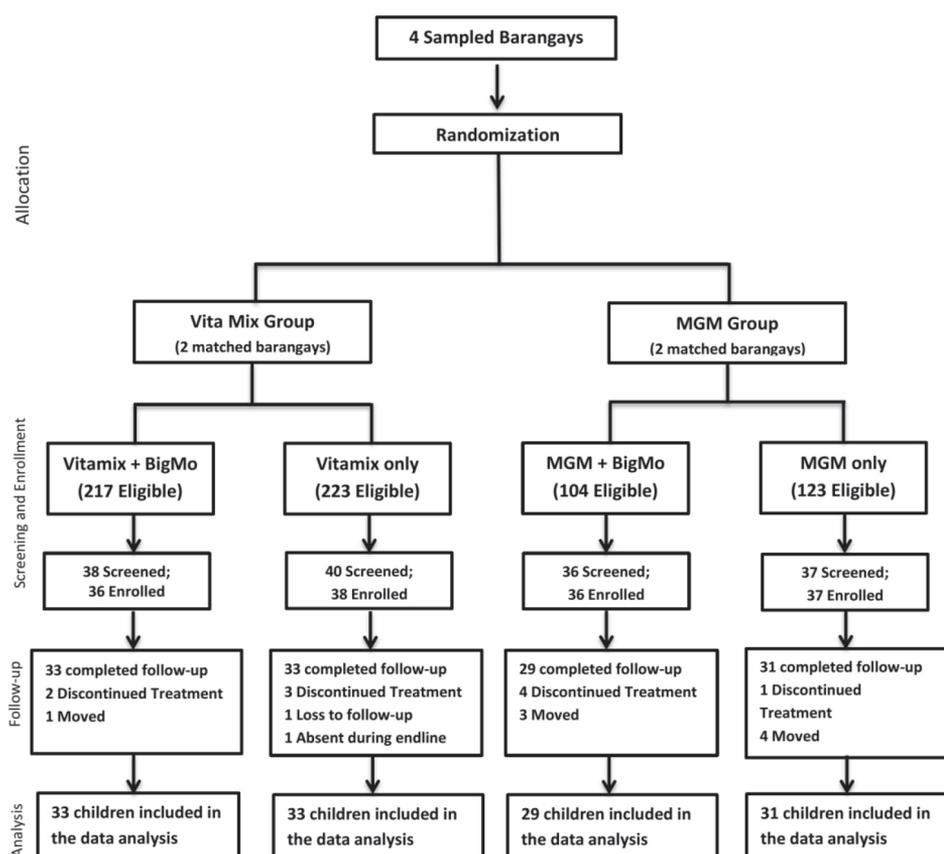
Provision of micronutrients through micronutrient powders (MNP) has been recognised as an effective way to combat infant and childhood micronutrient deficiencies (De-Regil *et al.*, 2011). The World Health Organization (WHO, 2011) highly recommends MNP fortification in countries where anaemia prevalence is 20% or higher among children under 2 years old. Since the Philippines meets this WHO criteria, the Department of Health (DOH) issued Department Memorandum No. 2011-0303 in October 2011 to replace iron syrup with MNP supplementation for all children aged 6-23 months (DOH Philippines, 2011). Despite the implementation of nationwide home fortification using MNP since 2011, there has been limited success in reducing the prevalence of anaemia among children under 2 years old. Hence, anaemia in young children remains a public health concern.

On this basis, plus the knowledge that complementary foods provided to Filipino young children are often low

in energy and protein density, and that increasing micronutrient intake through MNP would not necessarily result in adequate energy and protein intake, this study hypothesised that the combination of MNP along with the complementary food blend known as *BigMo* was more effective in improving dietary quality and adequacy. Children who received the combined supplementation would therefore have better nutritional status than children who only received MNP. This study explored how combined nutrition strategies might effectively combat undernutrition and micronutrient deficiency.

The Philippines, like several other countries, has adopted the use of Vitamix containing 15 micronutrients based on the recommendations of WHO, World Food Program (WFP), and United Nations Children's Funds (UNICEF), as well as experiences from the disaster response to typhoon "Ondoy" and "Pepeng" in 2009. In 2016, the Department of Science and Technology-Food and Nutrition Research Institute (DOST-FNRI) developed Micronutrient Growth Mix (MGM), an MNP containing nine micronutrients aimed at improving the diet quality of young children. The micronutrients added to MGM are considered most problematic among young Filipino children based on the results of national nutrition surveys.

As these two different MNP formulations are currently available in the country, there is a need to evaluate their effects in addressing anaemia and micronutrient deficiency in young children. The findings may provide evidence in determining the appropriate types and levels of micronutrients to optimise MNP supplementation programmes in the Philippines. Thus, this study aimed to evaluate the effects of the two MNP formulations (15 versus nine micronutrients) with or without complementary food blend on the



**Figure 1.** Intervention study participant flow chart

micronutrient status and anthropometric growth of Filipino children aged 6-23 months.

## MATERIALS AND METHODS

### Study area, design and randomisation

The study was conducted in the municipality of Calauan, an agricultural area with a mix of rice fields and upland areas in the southern part of Laguna province in the island of Luzon. The study design used was cluster randomised controlled non-blinded trial study. The village served as the unit of randomisation since it is the main access point for the delivery of health and nutrition services. Four barangays (villages) were randomly selected based

on high prevalence of undernutrition among children aged 0-71 months. Three villages are located on the east of *poblacion* (Dayap, Sto. Tomas and Lamot II) and one barangay (Perez) is located on the west of *poblacion*. These four selected villages have respectively 217, 223, 123 and 104 children aged 6-17 months, providing a total of 667 children. The villages were matched based on their characteristics in terms of population size and location, and further randomised by a statistician into four intervention groups, as shown in Figure 1. Blinding of field staff and mothers involved was not possible in the implementation, but persons responsible for the laboratory and data analysis were blinded to the group assignment.

### Sample size, sampling and subjects

With 90% level of confidence to detect anticipated mean difference in the haemoglobin level of 5.0 g/dL, a design effect of 1.5 and a 10% attrition rate to compensate loss to follow-up, the calculated minimum sample size of children was 144.

Out of the total of 667 children 6-17 months old from the four barangays, 151 were screened at baseline. A final total of 147 children who fulfilled the study's criteria were enrolled. Inclusion criteria were: 1) apparently healthy children between 6-17 months of age at the time of recruitment, who had no feeding problems/inborn/congenital/severe illness, and were not suffering from disease as assessed by a physician; 2) without severe anaemia (Hb < 7 g/dl) and without severe acute malnutrition (weight-for-height z-score < -3SD); 3) already consuming semi or solid food in addition to milk or breastmilk before the beginning of the study; 4) permanent residents in the barangay or municipality for the past 6 months; and 6) mothers who were willing to participate in the study with signed informed consent.

Each intervention group comprised 36-38 children who were selected based on stratified random sampling selection process using the list of eligible children per group. Of the 147 children enrolled to take part in this study, only 126 (85.7%) were able to complete the 6-month intervention period.

### Type of intervention groups

1. *VitaMix and BigMo group*. Children received 12 sachets of VitaMix along with 20 sachets of *BigMo* every month. Mothers/caregivers were advised to add one sachet of MNP into 2-3 tablespoons or approximately 30-45 g of cooked *BigMo*. Giving of MNP along with *BigMo* to the child was done on Mondays, Wednesdays and Fridays. The remaining two

sachets of *BigMo* were given on Tuesdays and Thursdays.

2. *VitaMix alone group*. Children received 12 sachets of VitaMix every month. Mothers/caregivers were advised to add one sachet of MNP on Mondays, Wednesdays and Fridays into a small portion of the child's meal before feeding the child.
3. *MGM and BigMo group*. Children received 30 sachets of MGM in addition to 20 sachets of *BigMo* every month. Mothers/caregivers were advised to add the sachet of MNP into 2-3 tablespoons or approximately 30-45 g of cooked *BigMo* on a daily basis from Monday until Sunday.
4. *MGM alone group*. Children received 30 sachets of MGM every month. Mothers/caregivers were advised to add one sachet of MNP daily into a small portion of the child's meal to ensure the entire consumption of the whole dose of MGM.

### MNP formulations and composition

VitaMix is manufactured by Nutri Foods Corporation, a subsidiary of the Nutrition Center of the Philippines (NCP). The VitaMix formula contained 15 micronutrients including zinc and selenium in a single-dose sachet weighing 1 g/sachet. Each sachet of VitaMix provides 100% of the recommended nutrient intake (RNI) of each micronutrient for a child 6-24 months old, as shown in Table 1. The thrice weekly frequency of VitaMix provided an average of 40% of the RNI of each micronutrient for ages 6-24 months.

On the other hand, the nine nutrients added in the 2 g/sachet of MGM provides lower daily RNI for each nutrient (Table 1), ranging from 12.0-69.0% of the daily recommended amounts for the added micronutrients. These nine micronutrients are inadequately present

**Table 1.** Vitamin and mineral contents of VitaMix and MGM and the corresponding percent contribution of one sachet supplement to the Recommended Nutrient Intake (RNI) for ages 6-24 months

Micronutrients	RNI <sup>†</sup>		VITAMIX (1 g) 15 micronutrients thrice weekly		MGM (2 g) 9 micronutrients daily frequency	
	6-11 months	12-24 months	Amount	% RNI	Amount	% RNI/ day
Calcium (mg)	400	500			60	12
Vitamin A [ $\mu\text{g}(\text{RE})$ ]	400	400	400	100	239	60
Vitamin C (mg)	40	45	45	100	18.8	42
Vitamin D ( $\mu\text{g}$ )	5	5	5	100		
Vitamin E (IU)	4	4	5	100		
Vitamin B <sub>1</sub> (mg)	M: 0.4 F: 0.3	M: 0.5 F: 0.4	0.5	100	0.23	46
Vitamin B <sub>2</sub> (mg)	M: 0.4 F: 0.3	M: 0.5 F: 0.4	0.5	100		
Vitamin B <sub>3</sub> (mg)	5	6	6.0	100		
Vitamin B <sub>6</sub> (mg)	M: 0.2 F: 0.3	0.5	0.5	100		
Vitamin B <sub>12</sub> ( $\mu\text{g}$ )	0.4	M: 0.9 F: 1.0	0.9	100	0.62	69
Folic Acid ( $\mu\text{g}$ )	M: 80 F: 70	150	150	100	55	34
Iron (mg)	M: 10 F: 9	8	10	100	2	28
Zinc (mg)	M: 4.2 F: 3.7	M: 4.1 F: 4.0	4.1	100	2	50
Iodine ( $\mu\text{g}$ )	90	90	90	100	16	17
Copper ( $\mu\text{g}$ )	-	-	0.56	-		
Selenium ( $\mu\text{g}$ )	M: 10 F: 9	M: 17 F: 16	17	100		

<sup>†</sup>Recommended Nutrient Intake based on 2015 Philippine Dietary Reference Intake (PDRI)  
Abbreviation: M, male; F, female

in typical diets in developing countries, thus, it was presumed to be the optimal micronutrient composition to address anaemia.

The complementary food blend Bigas Mongo known as *BigMo* is a processed blend developed by extrusion cooking method and is ready-to-eat by adding hot water intended for infants and pre-school aged children. *BigMo* was first field tested for its effectiveness by the DOST-FNRI in selected Philippine provinces with

high prevalence of underweight children aged 0-5 years, through the programme coined DOST-Pinoy in 2011-2012. The daily portion size of uncooked *BigMo* powder blend (30 g) provides 120 kcal or approximately, or 17.8% and 12.5% of the daily recommendation for calories for children aged 6-11 months and 12-23 months, respectively. For these age groups, the blend also contained 4 g of protein to meet 25.0% and 22.8% respectively of the daily recommendation

for protein. Mothers/caregivers were instructed to prepare the powder blend by adding one sachet or just the amount that the child can consume at a time to one cup of previously boiled water, stirring it well before adding it to the normal diet of the child. This is to ensure that children consume the entire dose of VitaMix and MGM, regardless of whichever group they were assigned to.

### **Data collection**

#### *Household, maternal and child's characteristics at baseline*

Quantitative information at baseline was collected using structured questionnaire to assess the general background information on socio-demographic characteristics of the family including household water and sanitation, maternal health practices (during pregnancy and after giving birth), and the child's characteristics. The questionnaire was pretested among similar respondents before use in the study.

#### *Intervention compliance*

The mean percentage consumption of MNP and *BigMo* over the expected number of sachets to be consumed was determined among children who completed the study. Mothers or caregivers were instructed to fulfil the compliance form daily by recording the feeding schedule, amount consumed by the child, and perceived side effects of the respective intervention.

#### *Anthropometric measurements*

All children were weighed and measured at baseline during recruitment, midline period at 3 months, and after 6 months of receiving intervention. Children were weighed in kilograms (with accuracy of 0.01 kg) using an electronic scale (SECA 874, Hamburg, Germany) without shoes, slippers, or diapers. Recumbent or supine length was measured in

centimetres (with an accuracy of 0.1 cm) using a medical plastic infantometer (SECA 417, Hamburg Germany) without shoes or slippers. Two measurements of weight and recumbent length were taken and recorded. The mean of two measurements was used. The same researchers measured weight and length of the children throughout the 6 months following the same procedure.

#### *Blood samples*

A non-fasting blood sample (1.5 ml) was collected from each child at baseline and endline to determine haemoglobin (Hb), serum ferritin (SF), retinol (vitamin A), zinc and C-reactive protein (CRP) concentrations. Blood samples were collected in the morning only at the field data collection centre through the finger prick method by three registered medical technologists. Blood samples were collected into three separate trace-element-free microtainer tubes (ferritin, retinol and zinc), which were immediately wrapped in dark cloth and placed in a cool box to allow blood to clot. The whole blood sample was centrifuged at 3,000 rpm for 10 min within 2 h of collection using an electric centrifuge (Beckman Allegra model) at the field data collection centre. Serum was aliquoted into plain microtainer tubes using a disposable pipette. The microtainer tubes were stored in the freezer. At the end of data collection, the aliquoted serum was transported to the FNRI laboratory in frozen gel within 2 h and stored at -20°C in a freezer until analysis.

Determination of Hb, SF, retinol and zinc were undertaken at the FNRI laboratory. The FNRI laboratory personnel who performed blood analysis were blinded to the child's group assignment. The Hb level was measured immediately in the field through cyanmethemoglobin method using a portable spectrophotometer (DR2800, Hach Australia). Serum ferritin was

determined by immune-radiometric assay technique (Riakey Ferritin IRMA Kit, 2007) using wizard 2 gamma counter machine (PerkinElmer, IL USA). Serum retinol was measured based on isocratic elution high performance liquid chromatography (HPLC) method using a Hitachi model (China) automated clinical chemistry analyser. Serum zinc was analysed using flame atomic absorption spectrometer (Agilent 240 FS AA). C-reactive protein analysis was carried out using turbidimetry for specific proteins through a chemistry analyser (Cobas Integra 400 Plus). All the biochemical analyses were checked for accuracy using standard reference materials as control for Hb (Liquicheck Hematology™16), SF (Riakey Ferritin IRMA Kit, 2007), retinol (pooled serum), zinc (Seronorm Trace elements L1 and L2), and CRP (PeciControl ClinChem Multi<sub>1</sub> PCC<sub>1</sub>).

In order to account for the effect of inflammation or infection in assessing SF and serum retinol, elevated CRP was used as inflammation biomarker in the study with levels greater than 5 mg/L taken as indicating the presence of infection. Among children with CRP > 5 mg/L, a correction factor of 0.77 was applied for SF, 1.13 for retinol, and 1.20 for zinc based on Thurnham *et al.* method (2015 and 2010).

#### *Dietary assessment*

Dietary data collection was conducted using a 24-h dietary recall method at baseline, every month during the monthly visits and at endline. Calibrated measuring tools (e.g. tablespoon, teaspoon, cups, glass with gradation, matchbox and different sizes of circles) were used to assist the respondents in estimating accurate quantities of foods and beverages consumed by the child. The respondent for the dietary data collection was the person in charge of feeding the child during the previous

day. All solid, semi-solid and liquid food consumed by children were assessed including snacks in between, upon waking up in the morning, at lunch, during afternoon snacks, at dinner and during the night.

#### **Data analysis**

All analyses of data were performed using SPSS version 10.0 for Windows software packages (Chicago, IL, USA). Descriptive statistics (percentages, means, and standard deviation) were calculated to describe the characteristics of the study children, their households and mothers including compliance to the intervention. A *p*-value of 0.10 was considered significant for all tests performed.

Anthropometric z-scores (weight-for-age, length-for-age, and weight-for-length) were computed using the WHO Child Growth Standards software (2006) based on the collected weight and length measurements in order to determine the nutritional status of the children.

Food intakes were converted into weight in grams by trained dietary editors. These food weights were later translated to as purchased values using appropriate conversion factors and were finally transformed into nutrient values through the use of individual dietary evaluation system (IDES) software that includes the updated Philippine food composition table (FNRI-DOST, 2015c). Nutrient-based adequacy was determined by comparing the percentage of consumption to the recommended energy intake (REI) and estimated average requirement (EAR) for specific micronutrients based on the 2015 Philippine Dietary Reference Intakes (FNRI-DOST, 2015d).

The effects of interventions on growth z-scores, Hb, SF, retinol and zinc concentrations were investigated. Significant differences in the baseline, midline (third month), and endline (sixth

month) mean values of growth z-scores across groups; baseline and endline mean values of Hb, SF, retinol and zinc across groups were examined using one-way analysis of variance (ANOVA). Blood samples were only collected at baseline and endline. On the other hand, significant differences in the baseline and endline prevalence of anaemia and micronutrient deficiency across groups were examined based on Pearson's  $\chi^2$  test.

The baseline-endline differences within groups were also calculated. Significant changes in the mean growth z-scores, Hb, SF, retinol and zinc concentrations within groups were reported based on paired t-test, while significant changes in the proportions of these variables were examined based on the McNemar test. If significant difference was detected in the mean estimates across groups at  $p < 0.10$ , pairwise test using Least Square Difference (LSD) was further performed.

### **Ethical approval**

This study was approved by the FNRI Institutional Ethics Review Committee on 16 December 2016. The Informed Consent Form with *Tagalog* translation explained the rationale of the study, the selection process of participants, data collection procedure, the nutrient composition of MNP and *BigMo* blend, the voluntary participation and benefits of participation, possible risks and side effects, right to withdrawal or termination and maintaining subject privacy and confidentiality.

## **RESULTS**

### **Profile of study participants**

A total of 147 children enrolled to take part in this study, but only 126 (85.7%) completed the six-month intervention. Some reasons for not completing were due to dropping out of the intervention

(6.8%), moved residence (5.4%), loss to follow-up (0.7%), and absence during endline assessment (1.4%).

The parental characteristics did not differ significantly between groups in terms of age, educational level, and household average monthly income (Table 2). No significant difference was found in the monthly income and number of households living below the food poverty threshold across intervention groups. Most (87.0%) respondents were from non-food poor families.

Children enrolled in the study did not differ significantly in age, sex, feeding practices, important birth and health characteristics (type of gestation, birth weight, received vitamin A capsule status, type of feeding, and morbidity status) including anthropometric status as shown in Table 2.

### **Compliance to the intervention**

Compliance to the respective MNP supplementation was not significantly different between the VitaMix with and without *BigMo* (78.8% and 85.1%, respectively;  $p > 0.05$ ) and between the MGM with and without *BigMo* (70.3% and 64.7%, respectively;  $p > 0.05$ ). However, children in the VitaMix groups (with and without *BigMo*) had significantly higher percentage consumption relative to the expected amount of intake than those in the MGM groups (with and without). The mean *BigMo* consumption represents 61.3% of the expected intake among those who received the complementary food blend. No significant difference in mean percent consumption of *BigMo* between groups was noted.

### **Effects of intervention on haemoglobin and micronutrient status**

The effects of intervention on changes in the mean concentrations and percentage of deficiency with respect to Hb, SF, retinol, zinc are shown in Table 3. After 6

**Table 2.** Baseline characteristic of study population by intervention group

Characteristics	VITAMIX+BIGMO (n=33)	VITAMIX (n=33)	MGM+BIGMO (n=29)	MGM (n=31)	p*
	Mean ± SD				
Maternal age (years)	29.3±8.6	26.8±6.7	26.5±6.7	28.4±8.3	0.338
Maternal Education					0.574
No education	-	-	-	-	
Elementary education (%)	2.8	8.0	11.1	10.8	
High School education (%)	75.0	65.8	77.8	73.0	
College and above (%)	22.2	26.3	11.1	16.2	
Mothers working outside (%)	30.6	23.7	11.1	18.9	0.085
Household size	6.6±2.3	5.9±2.9	4.9±1.2	5.8±2.4	0.009
Household monthly income					
Mean ±SD (Php)	12,517.14±8,442.45	11,297.37±6,103.72	10,138.71±10,896.74	10,776.93±4,003.50	0.258
Household above threshold† (%)	88.9	86.8	75.0	96.8	0.381
Improved source of water (%)	100.0	94.7	100.0	100.0	0.656
Water-sealed toilet facility (%)	77.8	78.9	80.6	78.4	0.808
Age in months	10.0±2.7	9.3±2.9	10.1±3.2	9.9±2.8	
Age group, months					0.626
6-8	30.6	31.6	33.4	35.2	
9-11	33.3	28.9	33.3	32.4	
12-15	36.1	28.9	33.3	32.4	
Male children (%)	44.4	55.3	44.4	64.9	0.235
Full term babies (%)	97.2	100.0	97.2	97.3	0.316
Birth weight (g)	2,839±435.8	2,987±462.3	2,955±387.7	2,996±431.8	0.338
Received Vitamin A capsule (%)	90.1	96.0	91.0	94.0	0.432
With episode of illness in the past week (%)	61.1	65.8	50.0	51.4	0.449
Breastfed infants (%)	52.8	78.9	72.2	67.7	0.101
Bottle fed infants (%)	41.7	26.4	25.0	35.1	
Consuming complementary foods (%)	98.6	97.3	100	97.3	
Weight (kg)	7.87±1.1	8.27±0.9	8.17±1.4	8.04±1.4	0.568
Length (cm)	70.08±3.35	71.23±3.65	69.89±4.47	70.05±4.26	0.519
Weight-for-age (WAZ)	-0.97 ±1.0	-0.60±0.78	-0.70 ±1.1	-0.70 ±0.98	0.497
Weight-for-length (WLZ)	-0.66±1.04	-0.48±0.87	-0.19 ±1.09	-0.46 ±1.06	0.349

\*Significant difference at &lt;0.05; based on chi-square test (categorical variables) and student t-test (continuous variables)

†Amount in Philippine Peso (Php); above food threshold or non-food poor families are ≥ 4,869.00; food poor families are &lt; 4,869.00

**Table 3.** Intervention effects on mean haemoglobin, micronutrient concentrations, prevalence of anaemia and micronutrient deficiencies among children

Primary Outcomes	VITAMIX +BIGMO (n=33)	VITAMIX only (n=33)	MGM+BIGMO (n=29)	MGM only (n=31)	p
<b>Haemoglobin (Hb, g/dL)<sup>†</sup></b>					
Baseline	10.7±0.8	10.6±0.8	10.4±0.8	10.6±1.0	0.572
Endline	11.3±0.8	11.1±0.7	11.3±0.9	11.2±0.9	0.675
Change	0.6±0.6*	0.5±0.9*	0.9±0.7*	0.6±0.9*	0.205
Adjusted change <sup>†</sup>	0.6±0.6	0.5±0.7	0.8±0.7	0.6±0.7	0.281
<b>Ferritin (µg/dL)<sup>†</sup></b>					
Baseline	26.4±38.9	37.1±65.2	24.6±34.3	33.1±29.1	0.656
Endline	22.5±18.1	25.4±25.0	20.1±24.1	27.1±21.8	0.628
Change	-3.9±28.2	-11.8±67.4	-4.5±3.2	-6.0±34.6	0.899
Adjusted change <sup>†</sup>	-7.3±22.6	-5.6±22.4	-9.7±22.5	-3.3±23.3	0.743
<b>Retinol (µg/dL)<sup>†</sup></b>					
Baseline	26.5±3.6	27.4±4.8	29.4±17.5	26.6±4.9	0.400
Endline	28.1±4.8	27.6±6.1	25.8±4.4	27.7±6.7	0.389
Change	1.6±5.2 <sup>a</sup>	0.2±7.2 <sup>a</sup>	-4.3±7.4 <sup>b</sup>	1.1±6.4 <sup>a</sup>	0.094
Adjusted change <sup>†</sup>	0.6±5.6	-0.1±5.6	-2.0±5.6	-0.1±5.8	0.344
<b>Adjusted zinc (µg/dL)<sup>†</sup></b>					
Baseline	88.6±19.0 <sup>a</sup>	88.4±20.1 <sup>a</sup>	82.3±3.9 <sup>ab</sup>	79.4±13.1 <sup>b</sup>	0.083
Endline	82.2±13.4	83.7±16.9	83.6±17.1	87.1±17.6	0.674
Change	-6.5 ±18.4 <sup>a</sup>	-4.7±3.9 <sup>a</sup>	1.2±16.1 <sup>ab</sup>	7.7±22.8 <sup>ab</sup>	0.025
Adjusted change <sup>†</sup>	-3.5±2.8	-2.0±2.7	-1.6±2.9	3.9±2.9	0.306
<b>Anaemia (Hb &lt;11g/dL), n(%)<sup>‡</sup></b>					
Baseline	17 (51.5)	22 (66.7)	21 (72.4)	18 (58.1)	0.343
Endline	11 (33.3)	16 (48.5)	11 (37.9)	7 (22.6)	0.189
Reduction, % <sup>††</sup>	18.2 <sup>*</sup>	18.2 <sup>**</sup>	34.5 <sup>*</sup>	35.5 <sup>*</sup>	
<b>Moderate anaemia (Hb&lt;10g/dL), n(%)<sup>‡</sup></b>					
Baseline	7 (21.1)	4 (12.1)	8 (27.5)	5 (16.1)	0.453
Endline	1 (3.0)	2 (6.1)	2 (6.9)	3 (9.7)	0.757
Reduction, % <sup>††</sup>	18.1 <sup>*</sup>	6.1	20.7 <sup>*</sup>	6.4	
<b>Moderate non-IDA (Hb&lt;10 g/dL and Ferritin &gt;12 µg/dL), n(%)<sup>‡</sup></b>					
Baseline	3 (9.1)	1 (3.0)	5 (17.2)	2 (6.4)	0.242
Endline	1 (3.0)	0 (0.0)	0 (0.0)	1 (3.2)	0.578
Reduction, % <sup>††</sup>	6.1	3.0	17.2 <sup>**</sup>	3.2	
<b>Low ferritin (&lt; 12µg/dL), n (%)<sup>‡</sup></b>					
Baseline	9 (27.3)	14 (42.4)	13 (44.8)	11 (35.5)	0.469
Endline	8 (24.2)	10 (21.2)	10 (34.5)	7 (22.6)	0.122
Reduction, % <sup>††</sup>	3.0	12.1	10.3	12.9	
<b>Iron Deficiency Anaemia (Hb &lt;11 g/dL and Ferritin &lt; 12µg/dL), n(%)<sup>‡</sup></b>					
Baseline	4 (12.1)	3 (9.1)	3 (10.3)	3 (9.7)	0.980
Endline	0 (0.0)	2 (6.1)	2 (6.9)	2 (6.4)	0.519
Reduction, % <sup>††</sup>	12.1	3.0	3.4	3.3	

Vitamin A deficiency					
(< 20µg/dL), n(%) <sup>§</sup>					
Baseline	0 (0.0)	3 (9.1)	0 (0.0)	1 (3.2)	0.378
Endline	0 (0.0)	3 (9.1)	0 (0.0)	1 (3.2)	0.322
Reduction, % <sup>††</sup>	-	0.0	-	0.0	
Zinc deficiency					
(< 65 µg/dL), n(%) <sup>§</sup>					
Baseline	1 (3.0)	4 (12.1)	4 (13.8)	4 (12.9)	0.455
Endline	4 (12.1) <sup>a</sup>	4 (12.1) <sup>a</sup>	2 (6.9) <sup>b</sup>	1 (3.2) <sup>b</sup>	0.021
Reduction, % <sup>††</sup>	-9.1	0.0	6.9	9.7	

<sup>†</sup>Values are means (±SD); with across groups significant difference at  $p < 0.10$  based on ANOVA. Ferritin, retinol and zinc values adjusted by a correction factor of 0.77, 1.13 and 1.20, respectively to remove the effect of infection (CRP > 5mg/L).

<sup>‡</sup>Values are proportion of children who had anaemia (< 11 g/dL), moderate anaemia (< 10 g/dL), moderate non-IDA (Hb < 10 g/dL and low ferritin > 12 ug/dL) with across groups significant difference at  $p < 0.10$  based on Pearson's  $\chi^2$  test.

<sup>§</sup>Values are proportion of children who had marginal vitamin A (< 20µg/dL) and had low zinc (< 65µg/dL), with across groups significant difference at  $p < 0.10$  based on Pearson's  $\chi^2$  test; within group significant difference at  $p < 0.10$  based on McNemar's test.

<sup>†</sup>Adjusted for age and baseline value.

<sup>††</sup>Values are change in percentage points (PP); within group significant change from first measure to final value using McNemar's chi-square.

<sup>\*</sup>Significant at  $p < 0.05$ ; within treatment change is significant at  $p < 0.05$  using paired t-test.

<sup>\*\*</sup>Significant at  $p < 0.10$ ; across groups significant difference at  $p < 0.10$  based on Pearson's  $\chi^2$  test.

<sup>a,b</sup>Values in the same row with different superscript are significantly different based on Least Square Difference  $p < 0.10$

months, the mean Hb concentration in all intervention groups significantly increased but did not differ significantly between groups. There was insignificant decrease in the mean SF concentrations for all the groups. Similarly, the change in the mean retinol level within group between baseline and endline periods were not statistically significant in all groups. The baseline mean zinc concentrations were similar among three groups, except for the MGM group without *BigMo*, which had significantly lower mean serum zinc at 79.4µg/L. A significant improvement in the mean zinc level among children in the MGM-only group was observed (+7.7±22.8 µg/dL). However, after adjusting for age and baseline zinc values, the differences in the mean change of zinc level between groups were no longer significant.

The prevalence of anaemia was significantly reduced after 6 months by 18.2%, 18.2%, 34.5% and 35.5% in the Vitamix with *BigMo*, Vitamix without *BigMo*, MGM with *BigMo* and MGM without *BigMo*, respectively. Moderate anaemia (Hb < 10 g/dL) was significantly reduced by 18.1% and 20.7% only in the VitaMix with *BigMo* and MGM with *BigMo* groups, respectively. In the Vitamix only and MGM only groups, the reductions between baseline and endline period were not significant. Only the MGM with *BigMo* group demonstrated a significant reduction in the prevalence of moderate non-iron deficiency anaemia (IDA) (Hb < 10 µg/dL and ferritin > 12 ug/dL) by 17.2% between baseline and endline periods.

The prevalence of low storage iron as measured by ferritin level < 12 µg/dL,

corrected by infection based on elevated CRP was not significantly reduced between baseline and endline period in all groups.

Similarly, the prevalence of zinc deficiency did not significantly change between baseline and endline period in all groups. However, MGM with *BigMo* (6.9%) and MGM without *BigMo* (3.2%) demonstrated significantly lower proportions of children with zinc deficiency (<65 µg/dL), compared to the VitaMix with *BigMo* (12.1%) and VitaMix without *BigMo* (12.1%) groups.

### Effects of intervention on nutritional status

The mean weight-for-age z-scores (WAZ) significantly decreased between baseline and midline periods in all groups, while a significant improvement by 0.2 was noted in the MGM without *BigMo* group between midline and endline periods (Table 4). Length-for-age z-scores (LAZ) showed no improvement in the VitaMix groups (with and without *BigMo*). Conversely, a significant increment of 0.3 was noted in the MGM with *BigMo* group between baseline and midline,

**Table 4.** Change in anthropometric z-scores and proportion of children meeting energy and nutrient adequacy during the study period, by intervention groups

Measurements	VITAMIX+ BIGMO (n=33)	VITAMIX ONLY (n=33)	MGM+ BIGMO (n=29)	MGM only (n=31)	p†
Mean WAZ					
Baseline (Month 0)	-0.97±1.0	-0.72±1.0	-0.71±1.1	-0.60±0.8	0.497
Midline (Month 3)	-1.24±1.0	-0.95±1.1	-0.95±1.1	-0.96±0.8	0.469
Endline (Month 6)	-1.13±1.0	-0.91±1.0	-0.90±1.1	-0.72±0.8	0.394
Change in WAZ					
Midline-Baseline difference	-0.3	-0.2	-0.2	-0.4	0.485
p-value	0.003	0.012	0.014	0.000	
Endline-Midline difference	0.0	-0.0	0.1	0.2	0.054
p-value	0.769	0.749	0.520	0.001	
Endline-Baseline difference	-0.3	-0.2	-0.2	-0.1	0.959
p-value	0.110	0.097	0.143	0.167	
Mean LAZ					
Baseline (Month 0)	-0.9±0.9	-0.7±0.9	-1.0±1.2	-0.4±0.8	0.079
Midline (Month 3)	-0.9±0.9	-0.7±1.0	-0.8±1.1 <sup>b</sup>	-0.4±0.9	0.232
Endline (Month 6)	-1.0±1.0 <sup>a</sup>	-0.7±1.0 <sup>a</sup>	-0.9±0.9 <sup>a</sup>	-0.2±1.0 <sup>b</sup>	<0.001
Change in LAZ					
Midline-Baseline difference	-0.1	0.0	0.3	0.0	0.135
p-value	0.738	0.998	0.010	0.980	
Endline-Midline difference	-0.0 <sup>a</sup>	-0.1 <sup>a</sup>	-0.1 <sup>a</sup>	0.2 <sup>b</sup>	<0.001
p-value	0.838	0.375	0.051	0.020	
Endline-Baseline difference	-0.1 <sup>a</sup>	-0.1 <sup>a</sup>	0.1 <sup>a</sup>	0.2 <sup>b</sup>	0.004
p-value	0.663	0.510	0.250	0.020	
Mean WLZ					

Baseline(Month 0)	-0.7±1.0	-0.5±1.1	-0.2±1.1	-0.5±0.9	0.350
Midline (Month 3)	-1.1±1.0	-0.8±1.1	-0.8±1.1	-1.0±0.8	0.457
Endline (Month 6)	-0.9±0.8	-0.8±0.9	-0.6±1.1	-1.0±0.8	0.454
Change in WLZ					
Midline-Baseline difference	-0.4	-0.3	-0.6	-0.5	0.216
<i>p</i> -value	< 0.001	< 0.001	0.000	0.025	
Endline-Midline difference	0.2	0.0	0.2	0.0	0.352
<i>p</i> -value	0.040	0.852	0.163	0.854	
Endline-Baseline difference	-0.3	-0.3	-0.4	-0.5	0.499
<i>p</i> -value	0.039	0.030	0.004	< 0.001	
% Meeting the REI/EAR <sup>‡</sup>					<i>P</i> <sup>§</sup>
Energy (kcal)					
Baseline (Month 0)	10.5 (0.6-20.5)	10.0 (0.5-19.5)	11.1 (0.6-21.6)	11.6 (8.1-35.2)	0.305
Intervention (Month 1-6)	27.1 (4.4-29.9)	25.4 (3.8-27.0)	24.3 (2.4-26.2)	26.2 (4.1-28.4)	0.990
Difference	16.6*	15.4*	13.2*	14.6*	0.707
<i>p</i> -value	0.041	0.047	0.045	0.055	
Protein (g)					
Baseline (Month 0)	25.3 (39.1-71.4)	27.5 (13.4-41.6)	19.4 (6.2-32.7)	35.1 (19.4-50.7)	0.115
Intervention (Month 1-6)	49.4 (34.5-68.4)	48.7 (32.7-64.7)	48.6 (31.6-65.5)	70.3 (55.2-85.3)	0.182
Difference	24.1* <sup>a</sup>	21.2* <sup>a</sup>	29.1* <sup>b</sup>	35.1* <sup>b</sup>	0.070
<i>p</i> -value	0.050	0.052	0.005	0.002	
Iron (mg)					
Baseline (Month 0)	26.3 (12.0-40.6)	17.5 (5.5-29.5)	16.7 (4.2-29.1)	35.1 (19.4-50.9)	0.143
Intervention (Month 1-6)	65.7 (49.6-81.8) <sup>a</sup>	84.6 (73.1-96.2) <sup>a</sup>	42.9 (26.1-59.6) <sup>b</sup>	62.2 (46.2-78.1) <sup>a</sup>	0.003
Difference	39.4* <sup>a</sup>	67.1* <sup>a</sup>	26.2* <sup>b</sup>	27.0* <sup>b</sup>	0.030
<i>p</i> -value	<0.001	<0.001	0.008	0.020	
Vitamin A (mcg RE)					
Baseline (Month 0)	42.1 (26.1-58.1)	25.0 (11.3-38.7)	25.0 (10.5-39.5)	35.1 (19.4-50.9)	0.116
Intervention (Month 1-6)	97.1 (91.5-103) <sup>a</sup>	100.0 <sup>a</sup>	71.4 (56.1-86.7) <sup>b</sup>	91.9 (82.9-100.8) <sup>a</sup>	<0.001
Difference	55.0*	75.0*	46.4*	56.8*	0.239
<i>p</i> -value	<0.001	<0.001	<0.001	<0.001	

<sup>†</sup>Values are based on ANOVA, with significant difference across groups at *p*-value <0.10.

<sup>‡</sup>Values are estimated proportion, % (95% CI) of children meeting the energy and nutrient intakes based on age-specific recommended energy intake (REI) and estimated average requirement (EAR), respectively.

<sup>§</sup>Values are based on Pearson's  $\chi^2$  test, with significant difference at *p*-value <0.10.

\*Change is significant within intervention group at *p*-value <0.10 in independent t-test.

<sup>a,b</sup>Values in the same row with different superscript are significantly different based on Least Square Difference *p*<0.10

as well as in the MGM without *BigMo* (by 0.2) between midline and endline periods. The increase in length-for-age was significantly greater in the MGM-only group than in the remaining three groups. On the other hand, the weight-for-length z-scores (WLZ) significantly decreased between baseline and midline, as well as between baseline and endline periods in all groups, with the decreases similar across groups.

### **Effects of intervention on children's dietary intake**

The proportion of children meeting the recommended energy intake significantly increased from 10.5% to 27.1% in VitaMix with *BigMo*, from 10.0% to 25.4% in VitaMix without *BigMo*, from 11.1% to 24.3% in MGM with *BigMo* and from 11.6% to 26.2% in MGM without *BigMo* over the six-month study period. However, majority of children in VitaMix with *BigMo* (72.9%), VitaMix without *BigMo* (74.6%), MGM with *BigMo* (75.7%) and MGM without *BigMo* (73.8%) had inadequate intake in energy, with no significant differences noted between groups (Table 4).

Significant increase in the proportion of children meeting the protein requirement was also observed over the 6 months intervention in VitaMix with *BigMo* (25.3% to 49.4%), VitaMix without *BigMo* (27.5% to 48.7%), MGM with *BigMo* (19.5% to 48.6%), and MGM without *BigMo* (35.1% to 70.3%). However, a significantly greater number of children met the age-specific protein requirement in the MGM group (with: 29.1% and without *BigMo*: 35.1%) than in the VitaMix group (with: 24.1% and without *BigMo*: 21.1%).

Overall, adding MNP to the complementary food of children 6-23 months of age significantly increased intake of vitamin A and iron during the whole study period in all groups as shown in Table 4. But the increase in

the proportion of children meeting iron requirement between baseline and during the intervention period was significantly higher in the VitaMix with (39.4%) and without *BigMo* (67.1%) than in the MGM with (26.2%) and without *BigMo* (27.0%). It was also noted that during intervention period, there was significantly higher proportion of children meeting the Vitamin A requirement in VitaMix with (55.0%) and without *BigMo* (75.0%) than in the MGM with (46.4%) and without *BigMo* (56.8%). However, no significant difference was noted in the increase in proportion of children meeting vitamin A requirement across groups.

### **DISCUSSION**

Analysis on the compliance of the supplementation showed that VitaMix groups (with and without *BigMo*) had significantly greater compliance than MGM groups (with and without *BigMo*). Significantly higher mean consumption of the supplements in the VitaMix groups than in the MGM groups might be attributed to the generally less frequent supplementation in the VitaMix groups at only thrice a week compared to the daily supplementation of MNP in the MGM group (with and without *BigMo*), which explains the lower compliance rate in the daily MNP supplementation. These findings are consistent with the study by Kounnavong *et al.* (2011) in Lao PDR where children under twice-weekly supplementation yielded a higher compliance rate than those in the daily MNP supplementation. Likewise, highest adherence was observed in trials wherein children received MNP on an intermittent basis (Ip *et al.*, 2009), which may be explained by mothers or caregivers perceiving the intermittent supplementation (e.g. 2-3 times weekly) as causing less mental pressure and anxiety among mothers or caregivers.

However, both types of MNP (VitaMix and MGM) showed a similar effect in increasing Hb levels among the study children 6-23 months of age. This finding is consistent with the Cochrane review of trials on home fortification with MNP containing at least iron, zinc, and vitamin A in children under 2 years old (De-Regil *et al.*, 2011; Jack *et al.*, 2012; Suchdev *et al.*, 2012; Kounnavong *et al.*, 2011; Adu-Afarwuah *et al.*, 2008; Mennon *et al.*, 2007). This result can be attributed to the following reasons. First, both formulations contain several nutrients, including B<sub>12</sub>, folic acid, vitamin A, zinc, and vitamin C, which, together with iron, enhance Hb synthesis, iron transport, or absorption in young children. Our results agree with research conducted in Mexico (Rosado *et al.*, 2010), which concluded that micronutrient supplementation with smaller doses of iron is as effective as larger doses to increase Hb level and to reduce anaemia among children 6-42 months old. Second, giving VitaMix intermittently (thrice a week) and daily supplementation with MGM but with lower dose of iron per sachet resulted in similar increases in Hb concentrations, consistent with the findings in the cluster randomised trial conducted by Ip *et al.* (2009) among children aged 6-24 months. Third, all intervention groups received infant and young child feeding education and promotion activities through home visits and mothers' classes to encourage MNP compliance and adoption of appropriate feeding practices. However, only VitaMix and MGM along with *BigMo* blend were effective in reducing moderate anaemia, compared to VitaMix and MGM use without complementary food blend, indicating that MNP usage was insufficient unless supported by adequate food intake.

With regards to SF levels, both MNP formulations, with or without *BigMo* failed to significantly improve ferritin concentration among young children

in the study area within 6 months of supplementation. The high proportion of anaemia incidence (baseline: 62.0%, endline: 37.8%) among the study children could not be attributed to iron deficiency anaemia based on low Hb and low SF levels (baseline: 10.3%, endline: 4.0%), suggesting that other nutritional and non-nutritional factors were the underlying causes of anaemia, such as infection, presence of genetic Hb disorders, or other micronutrient deficiencies such as vitamin B<sub>12</sub> and folate. The result of this study is consistent with the results of the meta-analysis study of Salam *et al.* (2013) on the effectiveness of MNP among children in reducing anaemia and improving Hb level but not on SF deficiency.

The retinol level of vitamin A deficiency prevalence was the same over the intervention period of 6 months, indicating that MNP supplementation likely contributed to the maintenance of normal levels of stored retinol. The very low prevalence of vitamin A deficiency among the study children at baseline and at endline periods may be attributed to the bi-annual, high-dose vitamin A supplementation (VAS) targeting children 9 months old and above employed by the national *Garantisadong Pambata* programme of the DOH Philippines, coupled with regular MNP supplementation. A small and insignificant effect of MNP on serum zinc and reduction of zinc deficiency were noted in the MGM group (with and without *BigMo*), while no effect was observed in the VitaMix group (with and without *BigMo*). This finding was more likely attributable to the finding of a significantly greater increase in the percentage of children meeting the recommended protein intake were recorded in the MGM group (with and without *BigMo*) than in the VitaMix group (with and without *BigMo*), highlighting the importance of protein-rich foods

not only in improving dietary diversity but also in improving micronutrient status such as zinc. The enhancing effect of animal protein on dietary zinc absorption has been reported for beef, pork, chicken, and fish (Tontisirin, Nantel & Bhattacharjee, 2002).

The study showed that daily supplementation of low iron-MGM with and without *BigMo* blend was more effective in improving linear growth than VitaMix with 100% RNI for most nutrients. The significant improvement in the Z- scores for length-for-age may be related to the greater increase in the percentage of children meeting the protein recommendation in the MGM group and meeting the minimum acceptable diet, including the small but insignificant improvement in zinc intake, in the MGM with *BigMo* group relative to the VitaMix group. This underscores that increased intakes of food from animal sources containing high-quality protein and zinc are beneficial to child growth.

Furthermore, the result of this study showed that when MNP supplements were added to complementary food significantly improved the children's intake of micronutrients, thereby, contributing to children meeting their age-specific requirements for micronutrients. Nonetheless, the majority of children's intake remained inadequate in energy and protein, which resembles the national estimates in the Philippines. Unfortunately, adequate micronutrient intake alone, without sufficient macronutrient intake, cannot optimize children's health and growth.

While combining MNP with *BigMo* blend was hypothesised to be effective in improving the dietary adequacy of children, our results did not show that children who received *BigMo* had higher energy intake than children who did not receive, in both the VitaMix and MGM groups. The lack of significant difference in energy intake could be mainly due

to the low mean consumption (61.3%) of *BigMo* by the children. Only 37.0% of children who received *BigMo* showed 80.0% compliance, indicating that the product was not well accepted. Similar findings were reported by three efficacy studies (Owino *et al.*, 2007; Hossain, Wahed & Ahmed, 2005; Mamiro *et al.*, 2004), whereby complementary food supplementation (fortified or unfortified) aimed at increasing energy intake showed no significant increase in all intervention groups.

## CONCLUSION AND RECOMMENDATIONS

After evaluating the effects of MNP containing 15 versus 9 nutrients, with or without complementary food blend on the nutritional status of rural young children for 6 months, it can be concluded from this study that daily supplementation of MNP containing less than 100% of the RNI combined with complementary food blend and education may have a greater potential effect in addressing anaemia, zinc deficiency, and improving linear growth of young children than MNP containing 100% of the RNI. Aside from supplementation, appropriate education strategies such as home visits or mothers' classes within the behavioural change perspective should be put in place. This is to ensure that requirements for additional energy and micronutrient intakes from complementary foods, specifically the consumption of protein rich foods such as meat, fish, poultry, and eggs as sources of high-quality protein and micronutrients, alongside breastfeeding promotion be delivered among mothers and caregivers of young children.

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#### Authors' contributions

GEA, carried out the field work, conceived the manuscript, drafted and revised the manuscript; BCVC, conceived the manuscript; TMTM, drafted and revised the manuscript; PMM, conceived the manuscript; RAC, conceived the manuscript; TNA, analysed and interpreted the data; all authors read and approved the manuscript.

#### Conflict of interest

The authors declare that they have no competing interests.

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