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## Effect of the Provision of Small-Quantity Lipid-Based Nutrient Supplements on Gross Motor Developmental Milestones in Indonesian Infants

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**Abstract:** The first of 1000 days of life have been considered critical time for child growth and development. The purpose of this study was to compare the achievement of gross motor development and early social and language milestones among infants who received SQ-LNS (small-quantity lipid-based nutrient supplements), biscuits, or no intervention. A 6-month, non-randomized, controlled trial was performed among 220 infants who received 20 g of LNS (n = 70) or a 30 g of biscuit (n = 79) or who were controls with no intervention (n = 53). The percentage of children able to perform hand and knees crawling was significantly higher in the LNS group (100%) than in the control group (94.8%) after 3 months of the intervention. After 6 months of the intervention, the percentage of children able to walk alone was significantly higher in the LNS group (55.7%) than in the control group (37.7%) and the biscuit group (36.7%). Compared with children in the control group, the odds ratio (95% CI) of walking alone in the LNS group was 2.03 greater and significantly different (OR 2.03; 95% CI 1.03; 4.30, p = 0.040). There was no significance difference in the percentage of children able to say a single comprehensible word and to wave goodbye among the study groups. There was no significant difference in the percentage of children able to drink from a cup among three study groups (control group 69.8%, LNS group 82.9%, biscuit group 73.4%, p>0.05). The percentage of children able to eat alone in the control group (81.1%) was lower and significantly different compared to the LNS group (98.6%) and the biscuit group (98.7%). Small-quantity lipid-based nutrient supplements for six months had positive effects on the achievement of selected gross motor development skills during childhood in rural Indonesia.

**Key words:** Lipid-based nutrient supplement, biscuit, motor development milestones

### INTRODUCTION

Early childhood is the most rapid period of development in human life. Children's motor development milestones are essential aspects of development and indicators of normal growth and development. Development of cognitive, motor and socio-emotional skills during infancy affects childhood development, academic achievement, adult productivity and earning potential (Victora *et al.*, 2008). The first 1000 days of life have been considered a critical time for child growth and development. Cognitive, motor and socio-emotional development during infancy affects later childhood development, as well as academic achievement, adult productivity and earning potential (Grantham-McGregor *et al.*, 2007; Victora *et al.*, 2008).

Under nutrition, especially stunting and iron deficiency anemia, among children less than two years old is a major problem in Indonesia. Basic Health Research 2013 concluded that the prevalence of stunting was 37.2% among children under five years old (MOH, 2013). A preliminary survey in Bangkalan district, Indonesia, showed that almost 4 out of 10 children 6 to 23 months of age were stunted (LAZ<-2 SD) and 5 of 10 children had iron deficiency anemia (Muslihah, 2014).

The WHO Multicentre Growth Reference Study (2006) has developed six gross motor developmental milestones (sitting without support, standing with assistance, hands and knees crawling, walking with assistance, standing alone, walking alone) in children up to age 18 months old. Some studies have provided food supplementation to improve children's nutritional status and development, demonstrating benefits in motor development, mental development, cognitive ability and adult economic productivity (Walker *et al.*, 2005; Hoddinot *et al.*, 2008). Other studies of food supplementation have indicated that the effects on child development are inconsistent. Provisional food supplementation with *Nutributter*, *Sprinkle*, or *Nutritab* in Ghana showed positive effects on the achievement of motor development (Adu-Afarwah *et al.*, 2007). Another study in rural Malawi, providing LNS and corn and soybean for 12 months showed no significant differences in the mean age of achievement of gross motor development (Mangani *et al.*, 2013). In addition, a study providing fortified milk with multiple micronutrients also showed no significant differences in the achievement of motor and mental development, compared with the control group (Dhingra *et al.*, 2004).

Currently, complementary feeding interventional approaches have consisted of fortified complementary food with multiple micronutrient powder (MNP) or lipid-based nutrient supplements (LNS). In Indonesia, the provision biscuit 'MP-ASI' is used in supplementary feeding programs for children younger than five years old. LNS in a small quantity of 20 g per day is a food supplement with peanut paste containing protein, essential fatty acids and 22 micronutrients. Lipid-based nutrient supplements (LNS), which can be added to complementary food at the time of consumption, are designed to prevent Under nutrition and to promote healthy growth and development (Arimond *et al.*, 2013). Research is needed to assess the impact of the provision of fortified complementary food with multiple micronutrients using peanut paste, like LNS, on achieving motor development and it could provide additional information to benefit and promote optimal growth and to prevent Under nutrition.

The purpose of the study was to compare the achievement of gross motor development and early social and language milestones among infants receiving SQ-LNS, biscuits, or no intervention.

## MATERIALS AND METHODS

**Study design and participants:** The study was conducted in 50 villages from eight sub-districts in Bangkalan District, Madura Island, East Java Province, Indonesia, between October 2014 and August 2015. A community-based, non-randomized, controlled intervention was selected for the study design. Potentially age-eligible children were identified by infant cohort data from midwives.

The inclusion criteria included infants 6 months of age who had consumed complementary food, resided in the study area and had the signed informed consent of at least one guardian. The exclusion criteria were severe stunting (LAZ < -3 SD), severe anemia (Hb < 5.0 g/dl), acute infectious disease (i.e., TBC), presence of edema, history of peanut allergy and concurrent participation in another clinical trial.

**Intervention and follow-up:** The study compared the effects of three intervention schemes with small-quantity lipid-based nutrient supplements (SQ-LNS), biscuits and a control or no intervention group. Infants in the control group were not provided with any complementary food supplements during the study period, but they received delayed supplementation with biscuits for one month of consumption. In the LNS group, infants received SQ-LNS 20 g per day in 1 sachet (118 kcal) for six months. LNS were provided by Nutriset SAS (Malaunay, France). In the other treatment group, the infants received biscuits in 3 pieces per day (30 grams with 135 kcal) for six months. The biscuit was donated by the Ministry of Health,

Indonesia and was developed for a national supplementary feeding program. The energy and nutrient contents of a daily ration of LNS and biscuits are reported in Table 1.

During the intervention period, infants could receive vitamin A supplementation and vaccination. All of the mothers were encouraged to continue breast feeding on demand and to feed their infants with the usual complementary food. LNS and biscuits were delivered by a field team to the home every month for the 6 month intervention period. The field team distributed 30 sachets of LNS or 8 packages of biscuits (96 pieces) per infant and collected information on the use and possible complaints or adverse events.

**Measurement of outcome variables:** The outcome variables in the study were the proportion of children who achieved selected motor development (walking with assistance, standing alone and walking alone), two early social milestones (drinking from a cup and eating by themselves) and two early language milestones (saying single comprehensible words and waving goodbye). The child's, maternal and household characteristics were collected at baseline using a structured questionnaire.

Information on the measurements of the weight and length of the body, dietary intake and gross motor development were collected at baseline and at 3 months and 6 months after the intervention. Nutrition knowledge was assessed using a questionnaire with 10 questions on breast feeding and complementary feeding. Validity analysis, using product moment testing and 10 questions, showed significant correlations ( $p < 0.01$ ) and reliability of the instrument to assess nutritional knowledge (Cronbach's  $\alpha = 0.222$ ). Household category based on food security status was assessed using nine questions on the household's food access, developed by the FANTA project.

Gross motor development corresponded to the assessment in the WHO Multicentre Growth Reference Study (MGRS), (WHO MGRS, 2006): sitting without support, standing with assistance, hands and knees crawling, walking with assistance, standing alone, walking alone, based on mother's reports and field team's observations. In addition, the study examined two early social milestones (drinking from a cup and eating by themselves) and two early language milestones (saying single comprehensible words and waving goodbye), selected from Denver Development Screening Test II (Frankenburg *et al.*, 1992).

Anthropometric measurements of the infants included weight and length, performed at the baseline, mid-point and end of the study by trained field staff. Infants were weighed using an electronic infant weighing scale and weights were recorded to the nearest 10 g. Length was measured to nearest 5 mm using a length board (SECA 210). Anthropometric indices were calculated using the

SPSS macro for the WHO Child Growth Standards (WHO 2006). Hemoglobin concentrations were measured using a Hemocue portable photometer (Hemocue, Angholm, Sweden) by trained field staff. Capillary blood samples were obtained by a finger prick using an aseptic technique. Underweight was defined as  $<-2$  standard deviations (SD) of weight for age, wasting was defined as  $<-2$  standard deviations (SD) of weight for length and stunting was defined as  $<-2$  standard deviations (SD) of length for age. Anemia was defined as a hemoglobin concentration less than 11 g/dl.

**Data management and statistical analysis:** The completeness, accuracy and consistency of the data were multilevel checked by the self-enumerators, other field staff and by field supervisors for data quality. Statistical analysis was performed using IBM® SPSS®, version 20.0 (IBM Corp., NY, USA) For continuous and categorical outcomes, means or proportions of three groups were compared with ANOVA and Pearson's Chi-square test or Fisher's test, respectively. Values of  $p < 0.05$  were considered to be significant for all tests.

The study was approved by the Ethical Committee of Faculty of Public Health, University of Diponogoro (UNDIP), Indonesia. At least one parent for all children participating in the study provided written informed consent prior to enrollment in the study.

## RESULTS

The study was conducted between October, 2014 and August, 2015. A total of 324 infants were identified as age eligible from the birth cohort and 269 of them were enrolled. Participants in the study came from 50 villages in 8 sub-districts and they were divided into the LNS (97 infants), Biscuit (99 infants) and Control groups (73 infants). A total of 67 infants (24.9%) dropped out of the study. Reasons for dropping out were: migration to other areas temporarily ( $n = 43$ ), not receiving supplementation for more than 3 months ( $n = 18$ ), refusal to continue participating in the study due to the child not liking the supplement or vomiting ( $n = 4$ ), mother being busy ( $n = 1$ ) and the child having severe illness requiring hospitalization ( $n = 1$ ). The dropout rate among the study groups was not statistically significantly different: 27.4, 27.8 and 20.2% for the control, SQ-LNS and Biscuit groups, respectively. Potential biases associated with loss to follow-up were assessed. There were no significant differences in any background characteristic (child, maternal and household) between the 67 infant dropouts and the 202 infants who completed the study (data not shown). The flow of participants is shown in Fig. 1.

Table 2 shows that there were no significant differences in the proportion of means from selected children's, maternal and household characteristics among the three study groups ( $p > 0.05$ ).

At enrollment, the infants had a mean age of  $6.01 \pm 0.67$  months old and most of the infants still consumed breast milk (79.7%). The mean mother's age was  $27.84 \pm 5.76$  years old. Most of the mothers had low education levels or had gone to primary school (68.8%) and did not have occupations (84.7%). The percentage of households of participants with food insecurity was 61.9%.

The mothers reported that adherence to LNS was 62.9% and 59.5% at the 3 month and 6 month follow-ups. The proportions of infants in the high adherence category ( $\geq 70\%$ ) were 54.3% and 41.4%, while adherence as recommended (7 sachets per week) was 34.3% and 18.6% over the 3 month and 6 month intervention. There was no significance difference in the proportion of adherence to LNS and the high adherence category at 3 and 6 months of the intervention ( $p > 0.05$ ); however, the proportion of adherence as recommended was significantly different at 3 and 6 months of the intervention ( $p = 0.030$ ). The proportion of adherence to the biscuits after 6 months of the intervention was 91.0% with the high adherence category and as recommended (21 pieces of biscuit per week), the proportion of adherence was 91.1%.

**Gross motor development milestones:** After three months of the intervention, the percentages of children who achieved hands and knees crawling were significantly different among the study groups ( $p = 0.000$ ). The percentage of children able to hand and knees crawl was significantly higher in the LNS group (100%) than in the Control group (94.8%,  $p = 0.11$ ); however, it was not significantly different than in the Biscuit group (98.6%,  $p = 0.650$ ). There were no children who had delayed achievement of hand and knees crawling development (based on the child's age at achieving motor development and age reference according to the 99th percentile WHO MGRS (2006) for hand and knees crawling age 5.2 to 13.5 months).

The percentages of children who achieved selected gross motor development milestones after six months of the intervention are presented in Fig. 2. At the end of study, there was no significant difference in the percentage of children able to walk with assistance and stand alone among the study groups ( $p > 0.05$ ), although the percentage for the LNS group (100 and 72.9%) was higher than in the 00Biscuit (93.7 and 58.2%) and Control groups (92.5 and 69.8%).

The percentage of children able to walk alone was significantly higher in the LNS group (55.7%) than in the Control group (37.7%) ( $p = 0.049$ ) and the Biscuit group (36.7%) ( $p = 0.021$ ). Compared with children in the Control group, the odds ratio (95% CI) of walking alone after six months of the intervention in the LNS group were 2.03 greater and significantly different (OR 2.03; 95% CI 1.03; 4.30,  $p = 0.040$ ). There were no children with delayed achievement of walking alone in the LNS group,

Table 1: Energy and nutrient contents of daily servings of S-LNS and biscuits and percentages of RDA

		SQ-LNS <sup>1</sup>		Biscuit <sup>2</sup>		RDA for child
Nutrient	Unit	Total	% RDA	Total	% RDA	7-11 months old <sup>3</sup>
Daily serving <sup>4</sup>	g	20	30			
Energy	kcal	118	16.3	135	18.6	725
Protein <sup>ii</sup>	g	2.6	14.4	2.4	13.3	18
Lipids	g	9.9	27.5	5.0	13.9	36
Linoleic acid, LA	g	2.8	63.6	0.42	9.5	4.4
α-linolenic acid, ALA	g	0.58	116	0	0	0.5
Vitamin A <sup>i</sup>	μg	400	100	105	26.3	400
Vitamin B1 <sup>i</sup>	mg	0.5	125	0.12	30	0.4
Vitamin B2 <sup>i</sup>	mg	0.5	125	0.12	30	0.4
Vitamin B3 <sup>i</sup>	mg	6.0	150	1.5	37.5	4.0
Vitamin B5 <sup>i</sup>	mg	2.0	111.1	0	0	1.8
Vitamin B6 <sup>i</sup>	mg	0.5	166.7	0.12	40	0.3
Vitamin B12 <sup>i</sup>	μg	0.9	180	0.21	42	0.5
Folic acid <sup>i</sup>	μg	150	187.5	18	22.5	80
Vitamin C <sup>i</sup>	mg	30	60	0	0	50
Vitamin D <sup>i</sup>	μg	10	200	1.5	30	5
Vitamin E <sup>i</sup>	mg	6	120	1.5	30	5
Vitamin K <sup>i</sup>	μg	30	600	3	60	5
Calcium <sup>i</sup>	mg	280	112	60	24	250
Copper <sup>i</sup>	mg	0.34	154.5	0	0	0.22
Iodine <sup>i</sup>	μg	90	75	21	17.5	120
Iron <sup>i</sup>	mg	6	85.7	1.8	25.7	7
Magnesium <sup>ii</sup>	mg	40	72.7	0	0	55
Manganese <sup>i</sup>	mg	1.2	200	0	0	0.6
Phosphorus <sup>ii</sup>	mg	190	76	45	18	250
Potassium <sup>ii</sup>	mg	200	28.6	0	700	
Selenium <sup>i</sup>	μg	20	200	3.9	39	10
Zinc <sup>ii</sup>	mg	8	266.7	0.9	30	3

<sup>1</sup>Analysis LNS Infant 20 g (Nutraset); <sup>2</sup>nutrient content of biscuit 'Biscuit MP ASI' (MOH, 2007); <sup>3</sup>RDA Indonesia (MOH, 2013); <sup>4</sup>Serving portion is 1 sachet per day for LNS and 3 pieces per day for biscuits; <sup>i</sup>Nutrient type 1 (calcium, iron, copper, selenium, manganese, iodine and vitamins A, B, C, D, E and K); <sup>ii</sup>Nutrient type II (protein, magnesium, phosphorus, potassium, zinc)

Table 2: Baseline characteristics of participants by study group

Variable	Control	SQ-LNS	Biscuit	p-value
Total participants	53	70	79	
<b>Child characteristics</b>				
Sex, % male (n)	62.3 (33)	55.7 (39)	54.4 (43)	0.374
Age, month	6.04±0.66	6.07 ± 0.67	5.93 ± 0.68	0.651
Still breast feeding, % (n)	77.4 (41)	72.9 (51)	87.3 (69)	0.08
Underweight (WAZ<-2SD), % (n)	5.7 (3)	14.3 (10)	17.7 (14)	0.131
Stunting (LAZ<-2SD), % (n)	0	4.3 (3)	6.3 (5)	0.196
Wasting (WLZ<-2SD), % (n)	7.8 (4)	11.4 (8)	13.9 (11)	0.569
Anemia, Hb<10 g/dl, % (n)	65.6 (21)	72.3 (34)	71.4 (50)	0.790
<b>Maternal characteristics</b>				
Mother's age, years	27.92±5.96	27.73±6.32	27.88±5.15	0.981
Mother with low education level, % (n)	73.6 (39)	65.7 (46)	68.4 (54)	0.704
Mother with no occupation, % (n)	75.5 (40)	88.6 (62)	87.3 (69)	0.643
Mother with low nutrition education, % (n)	45.3 (24)	47.1 (33)	40.5 (32)	0.702
<b>Household characteristics</b>				
Household with food insecurity, % (n)	58.5 (31)	54.3 (38)	70.9 (56)	0.096
Household with food low dietary diversity, % (n)	3.8 (2)	4.3 (3)	1.3 (1)	0.513

Values are expressed as the mean±SD or % (n); SQ-LNS (small-quantity lipid-based nutrient supplement); mother with low education level (primary school), mother's nutrition knowledge was assessed using a questionnaire that analyzed validity and reliability from 10 questions on breast feeding and complementary feeding. Households with food insecurity were assessed using nine questions developed by the FANTA project; low dietary diversity (household member consumed 1 to 3 food groups over the past 24 h preceding the interview)

while in the Control and Biscuit groups, the percentage of children with delayed achievement of walking were 3.8 and 5.1%, respectively (based on the child's age at achieving

motor development and age reference at the 99th percentile WHO MGRS (2006) for walking alone age 8.2 to 17.6 months).

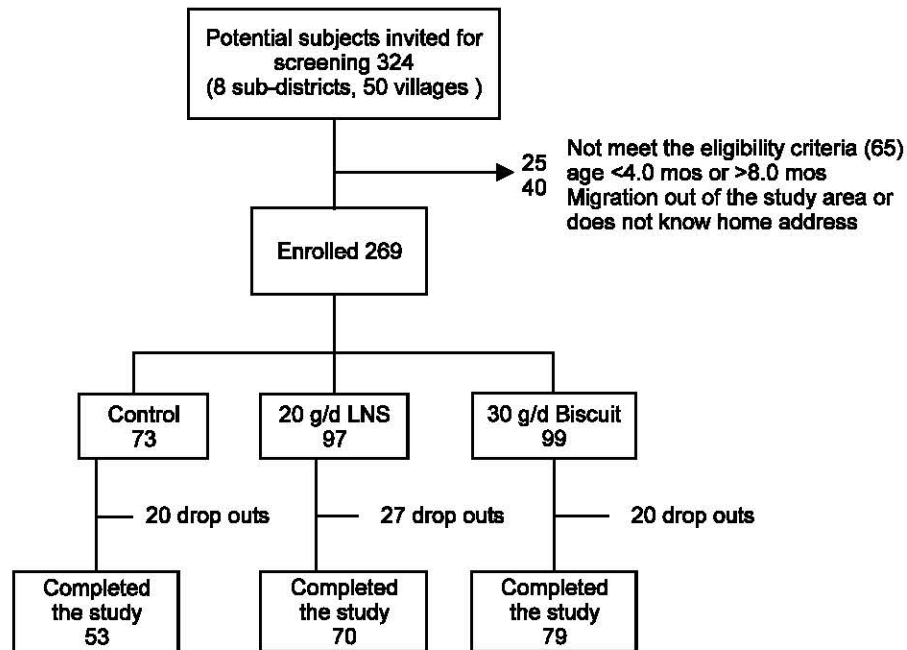


Fig. 1: Flow diagram of participants

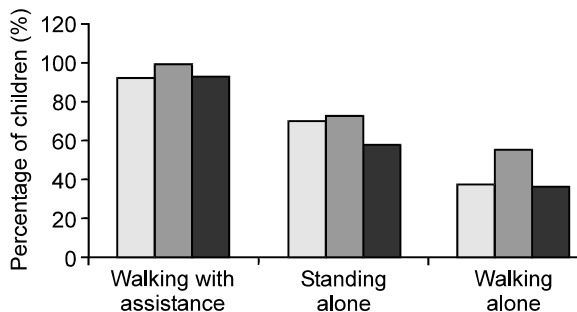


Fig. 2: Percentage of children achieving walking with assistance, standing alone and walking alone milestones after 6 months of intervention by study groups

#### Early language and social development milestones:

Early language development milestones during early childhood were measured using the ability to say single comprehensible words and to wave goodbye. Early social development milestones were measured using the ability to drink from a cup and eating by oneself. The percentages of children who achieved selected early language and social development milestones after six months of the intervention are presented in Fig. 3.

At the end of the study, there was no significant difference in the percentages of children able say single comprehensible words among the study groups (Control group 98.1%, LNS group 98.6%, Biscuit group 100%,  $p > 0.05$ ). All of the children in LNS group were reported by their mothers to have the ability to wave goodbye (100%) and there was no significant difference with the control

group (98.1%) ( $p > 0.05$ ). The percentage of children able to wave goodbye in the LNS group was significantly different compared to the Biscuit group (91.1%) ( $p = 0.011$ ).

There was a significant difference in the percentage of children able to drink from a cup among the three study groups (Control group 69.8%, LNS group 82.9%, Biscuit group 73.4%,  $p > 0.05$ ). The percentage of children able to eat by themselves in the Control group (81.1%) was lower and there were significant differences compared to the LNS (98.6%) and Biscuit groups (98.7%) ( $p = 0.000$ ).

#### Relationship of anthropometric indicators and child developments:

The correlations of changes in anthropometric indicators and the achievement of gross motor development and language and social development milestones are presented in Table 3. The data concluded that there was validity of the relationship between a child's nutritional status and development. Weight gain over six months had a positive and significant correlation with the achievement of gross motor development milestones and the ability to stand independently ( $p = 0.043$ ).

20100 Motor development milestones for the ability to walk independently had a positive and significant correlation with weight gain ( $p = 0.011$ ) and weight-for-age z-score ( $p = 0.016$ ). There was no significant correlation between changes in anthropometric indicators and hemoglobin regarding early language abilities (saying single comprehensible and words and waving goodbye). Early social development based on drinking from a cup had a positive and significant correlation with increased

Table 3: Relationship of changes in anthropometric indicators and hemoglobin levels in the achievement of early motor skills

Variable	Changes in anthropometric indicators and hemoglobin levels				
	Body weight	Body length	WAZ	LAZ	Hb
<b>Gross motor skills</b>					
Standing alone	0.051 (0.472)	0.145 (0.043)*	0.078 (0.271)	0.100 (0.163)	0.061 (0.709)
Walking alone	0.178 (0.011)*	0.069 (0.339)	0.170 (0.016)*	0.031 (0.666)	-0.009 (0.957)
<b>Early language skills</b>					
Saying single comprehensible words	-0.016 (0.139)	-0.106 (0.139)	-0.019 (0.790)	0.050 (0.488)	-0.080 (0.624)
Waving goodbye	0.095 (0.180)	0.087 (0.224)	0.089 (0.210)	0.050 (0.486)	n/a
<b>Early social skills</b>					
Drinking from a cup	0.088 (0.221)	0.048 (0.499)	0.032 (0.651)	0.017 (0.815)	0.362 (0.022)*
Eating by themselves	0.163 (0.023)*	0.153 (0.030)*	0.093 (0.190)	0.032 (0.659)	-0.049 (0.763)

Data: Pearson correlation (p-value); \*Significant correlation ( $p < 0.05$ ), WAZ (weight-for-age z-score), WLZ (weight-for-age z-score), LAZ (length-for-age z-score)

hemoglobin level during three-month intervention ( $p = 0.22$ ), while the ability to eat by oneself had a positive and significant correlation with weight gain ( $p = 0.023$ ) and length gain ( $p = 0.030$ ) over the 6 month intervention.

## DISCUSSION

This study was conducted to assess the effects of the daily provision of SQ-LNS (small-quantity lipid-based nutrient supplements) on infants' gross motor development milestone attainments. The purpose of this study was to assess and compare the achievement of gross motor development and early social and language milestones among infants receiving SQ-LNS and biscuits. Intervention with SQ-LNS over a three month period showed that a significantly higher percentage of children were able to hand and knee crawl than in the Control group. Assessment of developmental milestones at the end of the study after 6 months of the intervention also concluded that the percentage of children able to walk alone was significantly higher in the LNS group than in Control and Biscuit groups. Children in the LNS group had a 2.03 greater and significantly different OR (OR 2.03; 95% CI 1.03; 4.30,  $p = 0.040$ ) than the Control group. There was a significant difference in the percentage of children able to drink from a cup among the three study groups (Control group 69.8%, LNS group 82.9%, Biscuit group 73.4%,  $p > 0.05$ ). The percentage of children able to eat alone in the Control group (81.1%) was lower and significantly different than in the LNS (98.6%) and Biscuit groups (98.7%).

The findings of this study also support the evidence base from previous studies that complementary food supplementation based on peanuts and containing extra energy, essential protein and fatty acids and fortified with 12 vitamins and 10 minerals could promote the achievement of motor development milestones in early childhood. Research in Ghana providing LNS for 6 months had showed that the percentage of children able to walk independently was higher and significantly different, compared to the Control group (Adu-Afarwah *et al.*, 2007).

Other research has concluded that there was no effect of the provision of fortified food on the achievement of motor development milestones. An intervention with LNS and corn and soybeans for 12 months did not result in significant difference in the achievement of gross motor development or early social development at 18 months old (Phuka *et al.*, 2012). Intervention with milk-LNS also did not result in significant difference in the mean age at standing alone or walking alone (Mangani *et al.*, 2014). In Indonesia, infants who received food with 280 kcal and 12 mg of Fe every day indicated the achievement of walking at an earlier age than children who received only

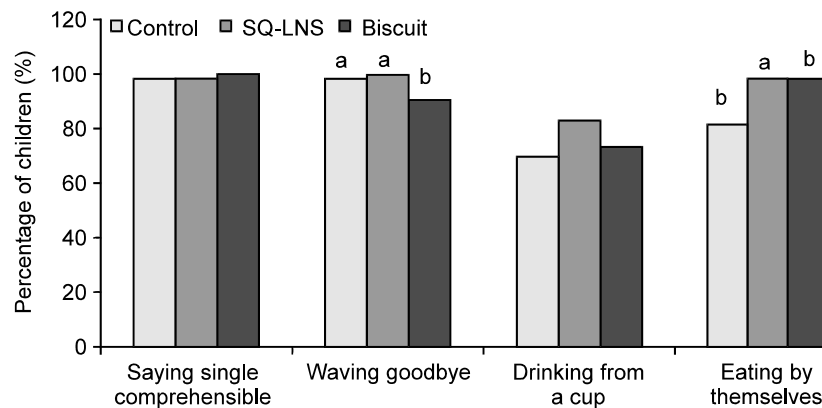


Fig. 3: Percentage of children achieving early language and social development milestones after 6 months of the intervention by study group

250 kcal or 50 kcal and 12 mg of Fe (Jahari *et al.*, 2000). Another study also found that an intervention with complementary food purly in Jakarta for 3 months resulted in fine and gross motor scores greater than in children receiving commercial complementary food (Astuti, 2009). Small-quantity lipid-based nutrient supplements used for months have an impact on the achievement of selected gross motor developments in rural Indonesian children.

Some strengths of the study were the characteristics of the participants and those who dropped out during the six month intervention period were similar, which minimized the potential for selection bias. The delivery of complementary food supplement with LNS or biscuits by field workers every month ensured that the product was received by the beneficiaries of the study. Field worker assessed compliance with LNS and biscuits every month and could support the mothers in regularly giving LNS or biscuits to children and discussions could occur to resolve any adverse events due to consumption of LNS or biscuits. Trained enumerators with nutrition backgrounds and educations performed the measurement of anthropometric data, interviews using structured questionnaires and recall of dietetic history, ensuring they were conducted by competent people. All of the processes of measurement of length, weight and hemoglobin concentrations used standardized guidelines. Multilevel checks of the questionnaire were performed to assure the quality of the data.

The limitations of the study were that allocation of participants to the study was not randomized; there was no blinding of group allocation and no masking mothers or field workers to who received LNS or biscuits, which might have influenced the anthropometric measurements and the assessment of development milestones. Hawthorne's effect, due to monthly home visits in the LNS and Biscuit groups, might have influenced the amount of attention paid to dietary intake and caring for children, thus impacting the children's nutritional status.

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