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Oral Nutrition Supplements: Regulation and Distribution in Indonesia – a Study in a Private Hospital in Surabaya

Oral Nutrition Supplements: Regulasi dan Distribusi di Indonesia - Studi di Rumah Sakit Swasta di Surabaya

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ABSTRACT

Background: Oral Nutrition Supplements (ONS) in the Minister of Health Regulation No. 29 year 2019 which was made as the guidance of nutritional management for children with nutritional problems, especially growth failure (still prevalent) and became one of Indonesia governments' goal for MDG's achievement.
Objectives: To describe the regulations and distributions of ONS as a strategy to reach the optimal catch-up growth in children under 5 years-old in private hospital in Surabaya based on the Minister of Health Regulation No. 29 year 2019. Also to determine the effect of ONS on insulin-like growth factor-1 (IGF-1) as a growth marker and lymphocytes as immune cells involved in immune response.
Methods: A quasi-experiment with pre-post design involving children aged 12-60 months old. The subjects received 400 ml of ONS (~400 kcal/day with estimated nutritional requirement of 1000 kcal/day) under the provision of the pediatrician as an adjuvant to cover their nutrients deficits.
Results: ONS intervention along with dietary counselling for nutritional therapy and medication improved the children's growths parameters, including body weight (from 10.38±2.28kg at day-0 to 11.27±2.38 at day-90, p-value=0.000) and body length/height significantly (from 82.94±9.58cm to 85.75±8.93 at day-90, p-value=0.000). ONS also improved IGF-1 in children with growth failure.
Conclusions: ONS intervention was proved to improve the IGF-1 levels, but not with the number of lymphocyte cells. The regulation of ONS must be under professional provision as it has the effect to increase body weight rapidly and must be stopped when the children receive the prescription reached their catch-up growth.

INTRODUCTION

Oral Nutrition Supplements (ONS), referred to in Indonesia as *Pangan Olahan untuk Keperluan Medis Khusus* (PKMK), are defined under the Minister of Health Regulation No. 29 of 2019. This regulation provides guidance for the nutritional management of children with specific health and nutritional challenges. PKMK targets children at risk of growth faltering, underweight, wasting, preterm birth, very low birth weight, cow's milk protein allergy, or inborn errors of metabolism[1]. The production and regulation of PKMK, also known as Ready-to-Use Therapeutic Food (RUTF), are governed by the CODEX ALIMENTARIUS COMMISSION (CX/NFSDU 16/38/9), a joint initiative of the World Health Organization (WHO) and the Food and Agriculture Organization (FAO). According to this standard, RUTF refers to high-energy, fortified, ready-to-eat foods designed for children aged six months or older diagnosed with severe acute malnutrition. These foods must meet specific criteria, such as being soft, crushable, and easy to consume without preparation[2].

Before the release of CODEX ALIMENTARIUS COMMISSION standard CX/NFSDU 16/38/9, the WHO and FAO introduced CODEX STAN 72-1981, which governs the standards for infant formula and formulas for special medical purposes production[3]. Ten years later, in 1991, WHO and FAO issued CODEX STAN 180-1991, which regulates the labeling and claims of Food for Special Medical Purposes (FSMP)[4]. This term is comparable to PKMK in Indonesia, although the usage of these specialized foods differs. The European Parliament, through Regulation (EU) No. 609/2013, specifies that such formulas must be formulated to meet the specific nutritional needs of the intended population. These

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products must also comply with labeling requirements, including the designation "foodstuffs for particular nutritional uses" and the indication of their specific nutritional purpose[5].

Under the Minister of Health Regulation No. 29 of 2019, PKMK is defined as processed food specifically designed and formulated for the medical and dietary management of children with certain health conditions, including failure to thrive and undernutrition (underweight, wasting, and stunting). These two common childhood nutritional disorders must be diagnosed by physicians at public health centers using anthropometric measurements, following the WHO Child Growth Standards (2006)[1]. Failure to thrive, now called growth faltering, describes children who do not achieve the expected weight, length, or body mass index (BMI) for their age[6]. Previously, failure to thrive was defined as a child's weight-for-age falling below the 5th percentile on CDC (Centers for Disease Control and Prevention) growth charts, typically caused by inadequate nutritional intake[7]. However, when this older definition was applied, opportunities for optimal catch-up growth were often missed. ONS are recommended to meet the nutritional needs of children at risk of undernutrition and to support timely intervention for optimal growth[8].

Undernutrition, particularly stunting, is one form of growth faltering and a major problem in Indonesia, with prevalence rates higher than in other ASEAN countries[9]. Stunting is a length-for-age or height-for-age measurement below −2 SD of the World Health Organization Child Growth Standards median[10]. Research shows that dietary recommendations focused on animal protein intake alone are insufficient to meet the nutritional needs of children with special conditions like stunting, as they require higher energy intake to support catch-up growth[11]. While Indonesian researchers are still exploring "local food"[12,13] for stunting therapy[14,15], such interventions are most appropriate for children without signs of growth faltering. However, children experiencing weight faltering need more intensive support, and it would be unethical for healthcare providers to withhold appropriate nutritional interventions. These children require high-quality protein and energy to promote catch-up growth and support cognitive development[16–18]. The use of Oral Nutrition Supplements (ONS) has been shown to enhance dietary intake and improve the nutritional status of children struggling to meet their needs through regular food alone[11,19–21]. To address the stunting crisis, the President of Indonesia issued Presidential Regulation No. 72 of 2021. Thus, the use of ONS is a logical strategy to reduce stunting in Indonesia.

Several studies have shown that the use of ONS in nutrition interventions for malnourished children (mild or moderate) resulted in significantly greater weight gain (0.423 kg, [95% confidence interval: 0.234–0.613], p-value<0.001) and height gain (0.417 cm, [0.059–0.776], p-value=0.022) compared to control treatments (usual diet, placebo, or dietary counseling alone)[11]. Not only in children but daily intake of S-ONS in adults with a history of poor nutritional status also improved quality of life and general health scores (p-value=0.005)[22]. This study aims to describe the regulation and distribution of ONS as part of strategies to achieve optimal catch-up growth in children under five years old at a private hospital in Surabaya, following Minister of Health Regulation No. 29 of 2019. This analysis is supported by evidence from the literature on the effects of ONS on insulin-like growth factor-1 (IGF-1), a marker of growth, and on lymphocytes, immune cells involved in the body's immune response.

METHODS

Study Design

A quasi-experimental pre-post design study was conducted involving children aged 12 to 60 months, who received 400 ml of ONS (equivalent to 400 kcal) as an adjuvant due to inadequate nutritional intake resulting from the secondary effects of Urinary Tract Infections (UTI) and Tuberculosis (TB). A pediatrician confirmed the diagnoses using urine cultures, chest X-rays, and Mantoux tests. Most participants presented with feeding difficulties and stagnant weight gain as their primary complaints. The study was carried out between October 2021 and July 2022. Inclusion criteria required children with feeding difficulties due to UTI or TB, aged 12 to 60 months, with stagnant weight gain or declining growth trajectories, and without any of the following conditions: congenital heart disease, chronic illness, congenital abnormalities, hormonal disorders, Cow's Milk Protein Allergy (CMPA), or lactose intolerance.

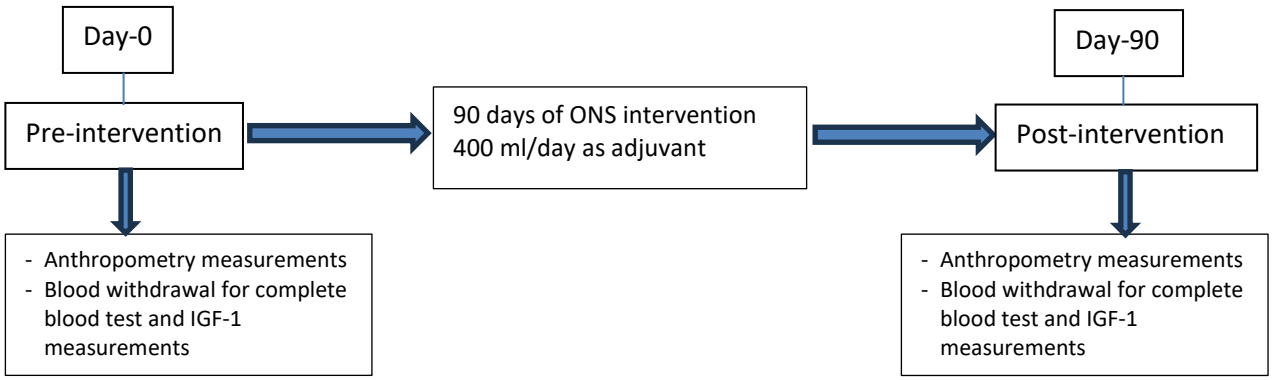

Figure 1. A pre-post design

A pediatrician diagnosed growth failure using the WHO Child Growth Standards. The subjects' parents received Dietary Counseling (DC), medication, and a prescription for ONS as part of the medical and

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nutritional intervention. The ONS dosage was set at 400 kcal/day, divided into four servings per day, with an energy density of 1 kcal per ml. Each 15-day supply consisted of four 400 g boxes. The pediatrician from the Pediatric Outpatient Installation prescribed the ONS, which had to be redeemed at the pharmacy. On day 15, parents were required to bring their child for growth monitoring and to obtain the next 15-day ONS prescription. Follow-up visits were scheduled on days 30 and 60 to monitor growth parameters, evaluate potential adverse reactions, and refill the ONS prescription. Parents received eight 400 g boxes per month until the 90th day. The pediatrician monitored the effectiveness of ONS through biweekly follow-ups, during which parents reported on body weight progress, compliance, and any adverse effects. If no adverse effects were reported and the child's compliance was satisfactory (consuming more than 75% of the prescribed ONS), the intervention was continued until catch-up growth was achieved. Success was measured using Weight-for-Age Z-score (WAZ), Length/Height-for-Age Z-score (LAZ/HAZ), and Weight-for-Length or Weight-for-Height Z-score (WLZ/WHZ), with target values exceeding -2.00 Standard Deviation (SD) according to WHO Child Growth Standards.

The growth parameters including body weight (measured using Seca Robusta 813, Seca, Germany) and body length/ height (measured using Seca infantometer 416 or Seca stadiometer 213, Seca, Germany). The measurements were enrolled by two trained nurses in the hospital under the supervision of the pediatrician (researchers) at the day of 0, 15, 30, 60 and 90th for growth monitoring (WAZ, LAZ/HAZ, WFL/WFH), which were assessed using WHO Anthro (the value in interval). For IGF-1 investigation, the researchers needed to draw blood samples which were conducted by the laboratory employer in the hospitals. The blood was withdrawn of 5 ml on the day of 0 (before the intervention or after the parents were agree to join the study by signing inform consent and informed for consent). Human IGF-1 serum was examined using ELISA KIT BT LAB (Bioassay Laboratory Technology) F0103 Hu.

Ethical Clearance

This study was reviewed and declared to be ethically appropriate by the Health Research Ethics Committee of Universitas Airlangga, School of Medicine with approval number of 293/EC/KEPK/FKUA/2023 on October 26th, 2023. This demonstrates our commitment to maintaining high ethical standards in every step of the research. All research procedures are conducted in compliance with applicable ethical principles, including the protection of research subjects.

Statistical Analysis

The statistical analysis conducted in this study include test of normality (Kolmogorov Smirnov) and paired sample T-test or Wilcoxon sign rank. The test used depends on the normality test result (the samples were normal if the p-value or significancy was >0.05). All the analysis were conducted using SPSS ver. 21 (IBM, US).

RESULTS AND DISCUSSIONS

It should be known to all the citizens that ONS must be prescribed by a pediatrician in a short-term event, just to treat the growth faltering in children, and when the children had been reached their catch-up growth, the ONS must be stopped, because ONS can lead to a dramatic rise in weight and height[23]. A long-term used only allowed for 48-week[24]. So the use of ONS must be through a clinical screening first done by a General Practitioner (GP)[25], in Indonesia, must be done in the primary healthcare services[1].

Soderstrom et al. (2020) describe ONS as a sip feeding containing a mix of macronutrients (protein, carbohydrate and fat) and micronutrients (vitamins, minerals and trace elements). ONS is one of Foods for Special Medical Purposes (FSMPs) type, with a strict regulation under the Foods for Specific Groups Regulation 609/2013 and the Food Information for Consumers Regulation 1169/2011 in British. ONS was specialized formulated for the purpose as the dietary management for them whom unable to meet their nutritional needs through diet alone, and should be used under a medical supervision, so the person who can be prescribed should be the special community[26].

Health service facilities are required to document all cases of nutritional problems in children related to illness. These records must be reported to the Minister of Health through the district/city and provincial regional health services. Reports are submitted in stages, with a copy sent to the Directorate General of Public Health, and must be submitted monthly[1]. When discussing ONS, cost considerations are crucial, as ONS is more expensive than other types of formula. However, the long-term benefits of ONS far outweigh its cost, as the expense of treating malnutrition is significantly higher than preventing it. Studies indicate that the use of ONS for prevention can reduce healthcare expenditures by £172.2–£229.2 million due to lower healthcare costs associated with malnutrition[26].

The implementation of ONS prescriptions in Surabaya aligns with Surabaya Mayor Regulation No. 5 of 2019, which ensures that children diagnosed with failure to thrive by a pediatrician and holding a Surabaya ID card are closely monitored. Upon hospital discharge, the pediatrician is required to prescribe ONS and refer the child to primary care services. Primary care facilities then provide a two-week supply of ONS for monitoring purposes based on the pediatrician's prescription[27].

Indonesian law states that only pediatricians in hospitals, based on primary care referrals, have the authority to prescribe ONS. Patients receiving ONS must remain under the supervision of a pediatrician. The prescribed ONS must have a minimum energy density of 0.9 kcal/mL and can only be administered orally or enterally, not parenterally. The provision of PKMK (Processed Food for Special Medical Purposes) can be implemented through central or regional government programs in accordance with statutory regulations[1].

Table 1 summarizes the characteristics of the study participants. A total of 75 subjects were invited to participate after obtaining parental permission. Informed consent was obtained by having parents sign the necessary forms provided by the researchers. The participants' mean age was 25.09±10.99 months (range:

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10–51 months), male/female number was 7/8, with stagnant body weight reported as the primary complaint in 68% of the cases. The average age at the onset of complaints was 15.32±11.02 months, and the caloric deficit averaged 434.78±137.55 kcal.

Table 1. Frequency distribution of subject characteristics (children aged 12-60 months) in a private hospital in Surabaya, Indonesia during October 2021-July 2022

Characteristics	*x ± SD*
Age (months-old)	25.09±10.99
Gender	
Male	35
Female	40
Complains	
Feeding Problems and Stagnant Body Weight	24
Stagnant Body Weight	51
Age of Complains were Identified (months-old)	15.32±11.02
Duration of Complains (month)	9.95±8.55
Gestational Age (weeks)	37.94±3.03
Birth Weight (kg)	2.94±0.58
Birth Length (cm)	48.70±3.12
Calorie Requirements (kcal)	1,081.07±164.62
Calorie Deficits (kcal)	434.78±137.55

Children with, or at risk of, impaired growth require additional nutritional support and are often prescribed ONS[28]. Several intervention strategies to manage malnutrition in children include behavioral interventions, oral nutritional support, enteral nutrition, and appetite stimulants. For infants under 2 years old with suboptimal growth (weight-for-length dropping by more than one percentile band and/or no weight gain) and at risk of malnutrition, nutritional counseling, behavior management, and ONS are recommended interventions[29].

Based on the results in Table 2, there was a significant difference (p-value<0.05) in the weight and height of children before and after receiving ONS (p-value =0.000). These findings align with a study by Hubbard et al., (2020) which showed significant improvements in growth parameters, with weight (p-value=0.007) and height (p-value=0.006) both increasing in intervention groups. These results suggest that specialized pediatric ONS with a low volume and high energy density (2.4 kcal/ml) can effectively improve nutritional intake, growth, and appetite in children requiring oral nutritional support[28].

Table 2 summarizes the results of growth parameters, lymphocyte levels, and IGF-1 before and after the intervention. The 90-day ONS intervention improved children's body weight, increasing from 10.38 ± 2.28 kg at day 0 to 11.27±2.38 kg at day 90 (p-value=0.000). Similarly, body length/height showed positive growth, increasing by 2.81 cm (from 82.94±9.58 cm to 85.75±8.93 cm) over the same period (p-value=0.000). Regarding immunity markers, lymphocyte levels decreased after the intervention, from 5.66±1.99 to 5.17±1.5 x 10^3/mm^3 (p-value=0.026), indicating a potential stabilization of immune function. Additionally, IGF-1 levels significantly increased (p-value=0.014) following the ONS intervention, reflecting improvements in growth-related hormone activity.

Table 2. The change of IGF-1, lymphocyte, body weight, and body length/height in children at a private hospital in Surabaya, Indonesia after intervention during October 2021-July 2022

Variables	*Mean±SD*		*Change*	*p-value*[1]
	Pre	**Post**		
Body Weight (kg)	10.38±2.28	11.27±2.38	0.89	0.000
Body Length/Height (cm)	82.94±9.58	85.75±8.93	2.81	0.000
IGF-1 (ng/ml)	12.45±10.24	14.6±10.42	2.15	0.014
Lymphocyte (mm^3)	5.66±1.99	5.17±1.5	-0.49	0.026

[1]Paired sample T-test

The z-scores from the 2018 Riset Kesehatan Dasar (RISKESDAS) dataset were used to assess children's nutritional status, evaluating age, weight, and height through three anthropometric measures: Weight-for-Age (W/A), Height-for-Age (H/A), and Weight-for-Height (W/H). These measures were standardized into z-scores based on the WHO anthropometric standards for children, enabling a comprehensive evaluation of growth and nutritional status for children under five years old[30]. In line with these findings, research Zhang et al., (2021) showed that children receiving ONS in an intervention group experienced greater gains in weight (0.423 kg [95% confidence interval 0.234, 0.613], p-value<0.001) and height (0.417 cm [0.059, 0.776], p-value=0.022) compared to control groups[11]. Notably, weight gain can be observed within as little as 7–10 days. For children with mild to moderate malnutrition, ONS use results in significantly better growth outcomes compared to control interventions such as regular diet, placebo, or diet counseling (DC) alone. Furthermore, combining ONS with DC is more effective in promoting catch-up growth than

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DC alone, underscoring the importance of oral nutritional support in pediatric nutritional interventions[31].

Undernutrition, defined as growth parameters below -2.00 SD, is often associated with deficiencies in key nutrients, particularly iron and zinc, which impair immune functions such as leukocyte trafficking and effector activity. Protein malnutrition can also halt cell cycle progression, causing an arrest at the hematopoietic progenitor cells' G0/G1 phase[32]. Additionally, micronutrients serve as cofactors and protect against DNA damage[33]. Nutritional interventions involving micronutrients have demonstrated improvements in lymphocyte parameters, however, interventions using probiotics and soy-based protein showed no effect on lymphocyte counts[34]. Other studies found no significant difference between intervention and control groups in T-lymphocyte proliferative responsiveness[35]. However, in contrast to these findings, our study observed a decrease in lymphocyte levels following the ONS intervention. This decline may be attributed to viral infections, which can cause lymphopenia (a reduction in lymphocyte counts)[36]. Notably, the data collection period for this study coincided with the peak of the COVID-19 outbreak in Indonesia, likely influencing the immune profiles of participants.

There was a significant difference in IGF-1 levels in children before and after giving ONS, mean that ONS along with medication and dietary counselling had a positive effect toward IGF-1 level. These result are in accordance with previous research conducted by Soliman et al. (2021) where there was an increase in IGF-1 levels in young teenagers (5-14 years) with a significant result (p-value=0.02)[37]. In this study, it was stated that over 1 year the use of ONS increased more in the cONS group (1.5 kcal/ml) compared to the sONS group (1 kcal/ml). The use of ONS to increase caloric and protein intake significantly increased weight gain/day (WGD) and BMI-SDS which was associated with increased IGF1-SDS[23].

Nutrition is a major factor in regulating IGF-1 secretion. If the intake of calorie increased, there would be an increase in IGF-1 secretion, resulting in changes in IGF-1 levels. Both protein and energy balance participate in the regulation of hepatic synthesis with energy regulating IGF-1 gene transcription and protein functioning primarily to regulate mRNA stability and translation[23]. In line with this findings, a research by Pereira et al., (2022) found that there was a significant increment in biomarkers (IGF-1, etc) in response to ONS supplementation in elderly people living in communities who were malnourished with sarcopenia, found an increase of 46.96±77.08^{c} in the ONS group and 38.39±66.14^{c} in the control group[38]. Different results were shown in research by Davison et al., (2020) which showed that the use of ONS in the form of colostrum supplementation (20 g/day) for 12 weeks did not have a significant relationship with IGF-1 levels. This is because enzymes were greater than the absorption of IGF-1 from the colostrum[39].

However this study is imperfect, as this study did not investigate the effectiveness of ONS+DC to the cognitive development and intelligence quotient (IQ), the effect in the infection itself, such as proinflammatory and anti-inflammatory response, and the intervention in older children (>60 months-old). This study highlighted the role of cow's milk protein as the source of protein, in which has been used for several "modified nutritional intervention" such as F-100 and RUTF, and it counted as 50% of all the energy coverage. By adding the cow's milk protein, it improves the protein quality within the formulas and reduced anti-protein content such as phytates. Cow's protein also improves flavor. The role of cow's milk protein also had small amounts of IGF-1 and type II minerals that stimulates the growth[38]. ONS was designed for children with increased energy requirements but limited in volume, with poor feeding or appetite loss due to the disease, as it was nutrient dense with complete nutrients without affecting fullness[27]. So, it is rationale to use ONS for nutritional intervention in stunted children as they had increased nutritional requirements for catch up growth, as the usage has been protected by the law.

CONCLUSIONS

ONS is a special food for medical purposes given to children with growth faltering or had a risk to have growth faltering, which can only be prescribed by a pediatrician. The purpose for diet management for children who are unable to meet their nutritional needs through diet alone. The uses must be under medical supervision and not advisable to give for a long-term uses, as it has the potential to increase weight rapidly. So, ONS must be given for a certain time in accordance with Minister of Health Regulation Number 29 of 2019. ONS intervention was proved to improve the IGF-1 levels after the intervention, but not with the number of lymphocyte cells.

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CONFLICT OF INTEREST AND FUNDING DISCLOSURE

All authors declare no conflict of interest and no funding was provided on behalf this study.

AUTHOR CONTRIBUTIONS

LA: conceptualization, formal analysis, writing-original draft, writing-review & editing; NAW: conceptualization, formal analysis, methodology, supervision, resources; YN: data curation, software, validation; EA: conceptualization, methodology, writing-original draft, writing-review; AZA: resources, writing–original draft, writing–review and editing; EH: validation, writing–original draft.

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