



**EFFICACY OF MICRONUTRIENTS POWDER SUPPLEMENTATION ON
GROWTH AND IRON STATUS OF ORANG ASLI CHILDREN IN
SELANGOR, MALAYSIA**

By

NUR DAYANA SHAARI

**Thesis Submitted to the School of Graduate Studies, Universiti Putra Malaysia,
in Fulfilment of the Requirements for the Degree of Doctor of Philosophy**

March 2022

FPSK (p) 2022 53

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Abstract of thesis presented to the Senate of Universiti Putra Malaysia in fulfilment of the requirement for the degree of Doctor of Philosophy

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Chairman : Professor Zalilah Mohd Shariff, PhD
Faculty : Medicine and Health Sciences

In Malaysia, the prevalence of undernutrition and anaemia in Orang Asli (OA) children under five are relatively higher than the general population, even though many strategies have been implemented. The effect of micronutrients powder (MNP) has been indicated as a recuperative, but not a preventive strategy of child undernutrition. MNP was developed and formulated by World Health Organisation (WHO) and produced by DSM Nutritional Products in Selangor. To date, MNP is not commercially available in market. This study aimed to determine the effect of MNP (containing 15 micronutrients) on growth, iron status and dietary intakes as a prevention of underweight, stunting, wasting and anaemia among OA children with normal nutritional status (normal in weight-for-age/ WAZ, length-for-age/ LAZ, weight-for-length/ WLZ and haemoglobin level) at baseline. In phase one, a feasibility study was conducted among 25 OA children aged 6-31 months in Negeri Sembilan to determine the MNP compliance, acceptance, preference, and adverse effect. The children received three MNP sachets weekly for 5 weeks. In phase two, a cluster randomised controlled trial was conducted with 98 children aged 6-24 months from OA villages in Selangor. The children were assigned randomly into two groups: 49 children in intervention group received three MNP sachets weekly for 12 months plus health and nutrition advice, while 49 children in control group received health and nutrition advice. Growth (weight, length, WAZ, LAZ, WLZ) and iron status (haemoglobin) were the primary outcomes, while dietary intake (energy, nutrients, food group) was the secondary outcomes. Analysis for the feasibility study was based on descriptive statistics, whereas ANCOVA using General Linear Model (GLM) for repeated measures was performed in the trial (per protocol analysis). The findings of the feasibility study showed a high compliance, no adverse effect and no changes in foods mixed with MNP. During the trial, 43 and 44 children remained in intervention and control group, respectively. For the trial, the results were presented in 3 models. Model A controlled for age and gender, Model B controlled for age, gender and proportion of children meeting iron recommendation at baseline, and Model C controlled for age, gender, proportion of children meeting iron recommendation and %

energy from protein at baseline. The results revealed length and LAZ were significantly different between groups (in Model A and B, but none in Model C). Other indicators such as weight, WAZ, WLZ, haemoglobin and dietary intakes were not significantly different. The rate of stunting in control group was significantly five times higher than intervention group at month 12. In conclusion, the feasibility study revealed that MNP was feasible for a randomised controlled trial among OA children in Selangor. The randomised controlled trial in Selangor confirmed that MNP given three times weekly for 12 months and provided with health and nutrition advice can improve length, LAZ and prevent stunting among OA children but no impact on weight and haemoglobin. However, future studies with diverse sub-tribes of OA would provide more information on the effect of MNP on growth, iron status and dietary intake of children.

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai memenuhi keperluan untuk ijazah Doktor Falsafah

**KEBERKESANAN SUPLEMEN SERBUK MIKRONUTRIEN TERHADAP
STATUS TUMBESARAN DAN ZAT BESI DALAM KALANGAN KANAK-
KANAK ORANG ASLI DI SELANGOR, MALAYSIA**

Oleh

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Prevalens kekurangan zat makanan dan anemia dalam kalangan kanak-kanak Orang Asli (OA) berusia bawah 5 tahun adalah lebih tinggi dari populasi umum di Malaysia walaupun pelbagai strategi telah dilaksanakan. Kesan suplemen serbuk mikronutrien (MNP) telah banyak ditunjukkan sebagai strategi penyembuhan kepada kekurangan zat makanan kalangan kanak-kanak, dan bukan sebagai strategi pencegahan. MNP telah dibentuk dan diformulasikan oleh Pertubuhan Kesihatan Sedunia (WHO) dan dikeluarkan oleh DSM Nutritional Products di Selangor. Hingga kini MNP tiada di pasaran bagi tujuan komersial. Kajian ini bertujuan untuk menentukan kesan MNP (mengandungi 15 mikronutrien) terhadap status tumbesaran, zat besi dan pengambilan diet sebagai pencegahan kepada kekurangan berat badan, terbantut, susut dan anemia dalam kalangan kanak-kanak OA yang mempunyai status pemakanan (berat-untuk-umur/ WAZ, panjang-untuk-umur/ LAZ, berat-untuk-panjang/ WLZ dan paras hemoglobin) yang normal di awal kajian. Dalam fasa pertama, kajian kebolehlaksanaan telah dijalankan melibatkan 25 orang kanak-kanak OA berumur 6-31 bulan di Negeri Sembilan, dan ia bertujuan untuk menentukan kepatuhan, penerimaan, pilihan, dan kesan buruk MNP. Kanak-kanak tersebut telah menerima tiga bungkusan MNP setiap minggu dalam tempoh lima minggu. Dalam fasa kedua, ujian kluster rawak terkawal telah dijalankan melibatkan seramai 98 orang kanak-kanak berusia 6-24 bulan daripada perkampungan OA di Selangor. Kanak-kanak tersebut telah diasingkan secara rawak kepada dua kumpulan: 49 orang kanak-kanak dalam kumpulan intervensi menerima tiga bungkusan MNP setiap minggu dalam tempoh 12 bulan serta nasihat kesihatan dan pemakanan, manakala 49 orang kanak-kanak dalam kumpulan kawalan menerima nasihat kesihatan dan pemakanan. Status tumbesaran (berat, panjang, WAZ, LAZ, WLZ), dan status zat besi (hemoglobin) adalah kesan utama yang dikaji, manakala pengambilan diet (tenaga, nutrien, kumpulan makanan) adalah kesan kedua yang dikaji. Analisa bagi kajian kebolehlaksanaan adalah berdasarkan statistik deskriptif, manakala ANCOVA menggunakan General Linear Model (GLM) untuk ukuran berulang telah dijalankan untuk ujian kluster rawak terkawal (analisa per protokol). Hasil kajian

kebolehlaksanaan menunjukkan tinggi kepatuhan, tiada kesan sampingan dan tiada perubahan dalam makanan yang dicampurkan dengan MNP. Semasa ujian kluster rawak terkawal dijalankan, seramai 43 dan 44 orang kanak-kanak masing-masing kekal dalam kumpulan intervensi dan kawalan. Bagi ujian kluster rawak terkawal, keputusan telah disampaikan dalam tiga model. Model A mengawal umur dan jantina, Model B mengawal umur, jantina dan proporsi kanak-kanak yang memenuhi saranan pengambilan zat besi di awal kajian, dan Model C mengawal umur, jantina, proporsi kanak-kanak yang memenuhi saranan pengambilan zat besi dan peratusan tenaga daripada protein di awal kajian. Keputusan menunjukkan panjang dan LAZ adalah berbeza secara signifikan antara kumpulan (bagi Model A dan B, tetapi tidak bagi Model C). Indikator lain seperti berat, WAZ, WLZ, hemoglobin dan pengambilan diet adalah tidak berbeza secara signifikan. Kadar terbantut dalam kumpulan kawalan adalah lima kali lebih tinggi daripada kumpulan intervensi secara signifikan pada bulan ke-12. Tiada kesan MNP didapati terhadap status zat besi, dan pengambilan makanan. Kesimpulannya, kajian kebolehlaksanaan telah menunjukkan bahawa MNP adalah boleh dilaksanakan bagi ujian kluster rawak terkawal dalam kalangan kanak-kanak OA di Selangor. Ujian kluster rawak terkawal telah mengesahkan MNP yang diberi sebanyak tiga kali seminggu dalam tempoh 12 bulan bersama nasihat kesihatan dan pemakanan dapat meningkatkan panjang, LAZ dan mencegah masalah terbantut dalam kalangan kanak-kanak OA, namun tiada kesan terhadap berat dan haemoglobin. Walaubagaimanapun, kajian yang melibatkan OA dengan kepelbagaian etnik pada masa akan datang dapat memberikan hasil kajian yang lebih jelas dan memberi lebih maklumat mengenai kesan MNP terhadap status tumbesaran, zat besi dan pengambilan diet kanak-kanak.

ACKNOWLEDGEMENTS

First and foremost, all praise to Allah SWT for the strengths and His blessing in completing this work.

My highest appreciation is given to my supervisor Professor Dr. Zalilah Mohd Shariff for her consistent coaching, expertise, valuable suggestion and tremendous support throughout the period of the study. I would like to thank Associate Prof. Dr. Loh Su Peng and Associate Prof. Dr. Gan Wan Ying as members of my supervisory committee for the guidance, views, and comments at various stages of the study.

My appreciation also to my beloved parents Allahyarham Haji Shaari Yusoff, Hajah Roslina Tan and siblings for the prayer, advice, and support during my study. My special thanks to my lovely soulmate Mohd Solehan Haji Ahmad Shah and to my adorable children Syahadah, Sofi, Sakinah and Yusuf for the love, funds, sacrifice, support and patience. Ummi love you forever till Jannah.

Last but not least, thanks to all my friends Rozalina, Sulhariza, Dr Liyana, Dr Heng Yaw, Dr Baizura, my helpful enumerators and many more for the prayers and supports throughout my journey. Without all of you, I would not have had such a positive and fulfilling experience.

“May Allah blessed all of you with the best rewards, ameen”

This thesis was submitted to the Senate of Universiti Putra Malaysia and has been accepted as fulfillment of the requirement for the degree of Doctor of Philosophy. The members of the Supervisory Committee were as follows:

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LIST OF ABBREVIATIONS

ANOVA	Analysis of Variance
ANCOVA	Analysis of Covariance
AOR	Adjusted Odd Ratio
BMR	Basal Metabolic Rate
CG	Control group
cm	Centimeter
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CI	Confidence Interval
d/ L	Deciliter
EI	Energy intake
EPU	Economic Planning Unit
FAO	Food and Agriculture Organization of the United States
FPSK	Fakulti Perubatan dan Sains Kesihatan
g	Gram
GLM	General Linear Model
HAZ	Height-for-age z score
Hb	Haemoglobin
IASG	United Nations Inter-Agency Support Group
ICC	Intraclass Correlation Coefficient
IG	Intervention group
IWGIA	International Work Group for Indigenous Affairs
IYCF	Infant and Young Child Feeding

JAKOA	Jabatan Kemajuan Orang Asli
JKEUPM	Jabatan Etika Penyelidikan Melibatkan Manusia Universiti Putra Malaysia
Kcal	Kilocalorie
kg	Kilogram
LAZ	Length-for-age z score
L	Liter
Mg	Milligram
MNP	Micronutrients Powder
MOH	Ministry of Health
NCCFN	National Coordinating Committee on Food and Nutrition
NHMS	National Health and Morbidity Survey
OA	Orang Asli
PhD	Philosophy of Doctorate
RCT	Randomised controlled trial
RDA	Recommended Dietary Allowance
RE	Retinol Equivalent
RNI	Recommended Nutrient Intake
SD	Standard deviation
SPSS	Statistical Package for Social Sciences
STH	Soil-Transmitted Helminths
UNICEF	United Nations Children's Fund
WAZ	Weight-for-age z score
WFP	World Food Program
WHO	World Health Organization

WLZ Weight-for-length z score

µg Microgram



CHAPTER 1

INTRODUCTION

1.1 Background

Nutrition has a major impact on early child growth and development. Child undernutrition is largely attributed to inadequate nutrition and infectious diseases. Undernutrition is a condition resulting when a person's diet does not provide adequate nutrients for growth and maintenance or when a person is not able to adequately utilise the food consumed due to illness (UNICEF, 2009). During early childhood, undernutrition defined as underweight, stunting, wasting or micronutrient deficiencies, could have short term adverse effects on child cognitive and motor development, resistance to infections, morbidity and mortality, and long-term socio-economic and health consequences such as academic performance, economic productivity and risk of chronic diseases (Black et al., 2013; Victora et al., 2008).

Globally, it is estimated that 21.3% children under five are affected by stunting and 6.9% wasting (WHO, 2020). While low estimates of underweight, stunting and wasting are observed in developed countries such as Northern America (0.4%, 3.2% and 0.0%, respectively) and Australia (0.2%, 2.1% and 0.0%, respectively) (WHO, 2021), estimates of stunting and wasting in Asia are at 54% and 69%, respectively (WHO, 2020). It was reported that underweight, stunting and wasting in children under five are prevalent in developing countries such as Indonesia (17.7%, 31.8% and 10.2%, respectively), followed by Malaysia (14.1%, 20.9% and 9.7%, respectively) and Thailand (7.7%, 12.3% and 7.7%, respectively) (WHO, 2021).

Micronutrient deficiency is a common disorder in undernourished children especially from low-income population (Shenton *et al.*, 2020). Iron deficiency is one of the most common micronutrient deficiencies in children especially in low- and middle-income countries (WHO, 2007). Iron deficiency is the usual cause of anaemia resulted from a long-term negative iron balance due to insufficient iron intake (Moretti, 2017; Shubham *et al.*, 2020; WHO, 2007). Globally, iron deficiency anaemia affects 42% of children under five (WHO, 2021). The national estimates of anaemia in children under five in developed countries such as Australia, and Canada were 13.3% and 13.2% in 2019, respectively (WHO, 2021). It was reported that about 68.9% and 53% of children under five in Nigeria and Pakistan had anaemia, respectively (WHO, 2021). Similar with other developing countries, anaemia is prevalent (24.6%) in children under five in Malaysia, particularly among the rural and poor communities (WHO, 2021).

High prevalences of child undernutrition and iron deficiency have been reported mostly among communities with high rates of poverty, low education level, high food insecurity and lack of access to healthcare services such as the indigenous peoples (Coimbra, 2013;

Horta et al., 2013; Leite et al., 2013). Indigenous peoples are those through historical processes have been underprivileged and living in preserved traditional ways with linguistic and cultural diversities (IWGIA, 2018). They live predominantly in remote and rural areas, with minority reside in urban areas (IWGIA, 2010). It is estimated that there are more than 370 million indigenous people residing in 70 countries worldwide and representing 5% of the world's population (IWGIA, 2018). In Asia, there are about 260 million or two thirds of the world's indigenous peoples (International Labour Office., 2017).

Morbidity rates are also higher in the indigenous population than the general population due to various factors such as poor resistance to infections, acute lower respiratory infection and diarrhoeal disease (Binks et al., 2020; Brito et al., 2020; Wiseman et al., 2016). According to the United Nations Inter-Agency Support Group (IASG, 2014), the prevalence of tuberculosis among indigenous population in Bolivia was five to eight times higher compared to non-indigenous population while the indigenous people in Greenland were 45 times more likely to get active tuberculosis than the Danish population. Moreover, the same report mentioned that infant mortality rate among indigenous children in Latin America was 60 percent higher (48 per 1000 infants) than for non-indigenous children (30 per 1000 infants), ranging from 1.11 times higher in Chile to 3.09 times higher than the general population in Panama. Additionally, the prevalence of chronic diseases was alarmingly high among indigenous peoples worldwide even though undernutrition remains as the main health problem among indigenous peoples as reported by many studies (Burnette et al., 2020; IASG, 2014; Sullivan et al., 2020).

Globally, the prevalence of child undernutrition is much higher in the indigenous children than the general population. In Australia, 8% of indigenous children under five years are underweight (Sjoholm et al., 2020) compared to 4.8% of underweight children in the general population. Pereira et al. (2017) reported that the prevalence of underweight and stunting were substantially greater among indigenous children under five years in Brazil (4.4% and 20.2%) than those observed in Brazilian children nationally (2.9% and 10%). The prevalences of underweight, stunting and wasting among indigenous children in India were 65.2%, 54.2% and 20.1% compared to the national level of 29%, 39% and 15%, respectively (Stiller et al., 2020).

Malaysia has an estimated 13.9% of the 31 million global population of indigenous peoples (IWGIA, 2016). The *Orang Asli* (OA) are the indigenous peoples of Peninsular Malaysia, representing 0.84% of the population in Peninsular Malaysia (~ 24.5 million). OA are usually of low socioeconomic status with poor health and nutritional status (Murtaza et al., 2018; Tunbosun et al., 2017; Zakaria et al., 2019). Malaysia, like other developing countries, has a high burden of undernutrition among the indigenous groups, particularly children. The prevalence of child undernutrition is much higher in the OA than the general population. The national prevalences of underweight, stunting and wasting among children under five were 14.1%, 21.8% and 9.7%, respectively (NHMS, 2019). Studies published since the 1980's on nutritional status of OA children have consistently reported high prevalence of underweight (31-49%), stunting (32-76%) and

wasting (4-58.5%) (Al-Mekhlafi et al., 2005; Geik and Sidek, 2015; Mas-Harithulfadhli-Agus et al., 2018; Masroor et al., 2014; Murtaza et al., 2018; Norlida et al., 2007, Wong et al., 2015; Zalilah and Tham 2002). Moreover, the prevalence of anaemia and iron deficiency anaemia are noticeably higher among OA children under 15 years (41.5% and 36.5%) than those observed for the general population (26.2% and 16.9%) (Aini et al., 2007; Murtaza et al., 2018; Ngui et al., 2011).

Many strategies have been implemented to prevent undernutrition and micronutrient deficiencies in developing countries such as food fortification and nutritional supplementation (WHO & FAO, 2006). Although food fortification can improve micronutrient status at a reasonable cost, fortified foods require well-absorbed fortificants that do not change the sensory properties of foods and need to be consumed adequately (WHO & FAO, 2006). While food supplementation can supply nutrients fast to deficient individuals, poor compliance to supplement dosing schedule and the side effects were reported as barriers to success (Cardoso et al., 2016; WHO & FAO, 2006). Evaluation of feasible and acceptable strategies to deliver multiple micronutrients is, thus, a priority (WHO, 2011).

The Nutrition Guidance Expert Advisory Group (WHO, 2011) recommends the use of micronutrients powder (MNP) as home fortification of foods consumed by infants and children aged 6 to 59 months of age to prevent child undernutrition. MNP is a blend of micronutrients in powder form that can be sprinkled onto foods prepared either at home or in any other places where meals are to be consumed (for example schools, childcare centres, refugee camps). However, the use of MNP for infants under the age of six months is not recommended, as they should be exclusively breastfed in accordance with the WHO guidelines on breastfeeding. MNP is used in situations where local diets do not provide adequate quantities of micronutrients to meet the recommended intakes. It supports caregivers to improve the quality of their family's diet by adding micronutrients to locally available foods that are prepared at home or in any other places where meals are to be consumed. MNP has been used in many intervention trials among children aged 6 to 59 months with a duration of intervention between two months to one year in developing countries such as Israel, Iran, Indonesia, Pakistan, India and Kenya (Barth-Jaeggi et al., 2015; Bilenko et al., 2010; Inayati et al., 2012; Samadpour et al., 2011; Sazawal et al., 2014; Soofi et al., 2013).

1.2 Problem Statement

The effectiveness of MNP for prevention of underweight, stunting and wasting has not been extensively studied. Many studies demonstrated MNP as a recuperative strategy rather than a preventive strategy (Barffour et al., 2019; Barth-Jaeggi et al., 2015; Hess et al., 2019; Lanou et al., 2019; Neufeld et al., 2019; Osei et al., 2015; Rana and Schellenberg, 2019; Samuel et al., 2018; Shafique et al., 2016). These randomised controlled trials targeted children below two years or five years of age who were undernourished at baseline (underweight, stunted or wasted) as recuperative strategy.

The preventive strategy may have aided in reducing the negative impacts of childhood undernutrition, particularly among those from low socioeconomic backgrounds (Menon et al., 2007). Children under the age of two are more vulnerable to undernutrition and more responsive to nutrition interventions than older children. According to Menon et al., (2007) children who were received the preventive program for the entire period of maximum nutritional vulnerability (from 6-23 months of age) benefited more from the intervention than children who received it for a portion of this time.

To date, only few studies have investigated the effect of MNP among children with normal weight-for-age, length-for-age, and weight-for-length at baseline as preventive strategy (Cardoso et al., 2016; Oliveira et al., 2016). No significant difference in the prevalence of stunting was observed between intervention and control groups in a controlled trial in Brazil (Cardoso et al., 2016), while a significant increase in height-for-age z-scores was observed among Brazilian Amazonian children who were MNP-supplemented daily compared to the control group who received routine paediatric care in health clinics (Oliveira et al., 2016). Thus, the lack of proven benefits of MNP in young children with normal growth, make it difficult to define the best approach in reducing underweight, stunting and wasting.

The potential effect of MNP on protecting children with normal haemoglobin concentration ($Hb \geq 11$ g/dL) against anaemia is inconclusive with most previous MNP efficacy trials were aimed at reducing the prevalence of anaemia among anaemic children at baseline (Arcanjo et al., 2019; Barffour et al., 2019; Barth-Jaeggi et al., 2015; Ford et al., 2020; Goyena et al., 2018; Hess et al., 2019; Kejo et al., 2019; Luo et al., 2017; Neufeld et al., 2019; Rahman et al., 2019; Rana and Schellenberg, 2019; Samuel et al., 2018; Somasse et al., 2018). The impact of MNP on children may vary depending on the anaemia status of children at baseline. Pressman et al., (2017) highlighted that host-related factors such as nutritional status could influence the bioavailability of micronutrients. Children with micronutrient deficiencies commonly have affected mucosal integrity, which could affect the capacity of general absorptive, as well as specific mechanisms required for the uptake of various micronutrients (Costa, 2020). Moreover, Blanco-Rojo and Vaquero (2019) reported that iron status of the target population group could influence the efficacy of food fortification in the improvement of micronutrients status.

Although several MNP interventions have been shown to be safe and have no adverse events among the recipients in Laos, Bangladesh, Burkina Faso, Mali, Philippines, Eastern Uganda, Tanzania, Brazil and China (Barffour et al., 2019; Hess et al., 2019; Rana and Schellenberg 2019; Lanou et al., 2019; Mahfuz et al., 2020; Somasse et al., 2018; Goyena et al., 2018; Ford et al., 2020; Kejo et al., 2019; Arcanjo et al., 2018; Luo et al., 2017), the adverse events of MNP remain uncertain as a previous trial among children aged 6-18-months old in Pakistan discovered that MNP significantly increased the diarrhoea prevalence and incidence of bloody diarrhoea (Soofi et al., 2013). Moreover, a systematic review indicated that the most commonly reported side effects were diarrhoea, vomiting, and constipation (de Barros and Cardoso et al., 2016).

MNP with 15 micronutrients has the potential to increase the proportion of children meeting the recommended energy intake, protein requirement, vitamin A and iron intake (Goyena et al., 2018). Even so, the researchers reported that most of children's intakes remained insufficient in energy. The study also showed that the proportion of children who met iron requirement was significantly higher among children who received MNP with 15 micronutrients but lower in meeting protein requirement than those who received MNP with 9 micronutrients (Goyena et al., 2018). The importance of complementary feeding needs to be explained to the caregivers during MNP delivery in order to achieve the impact of MNP on child nutritional status (Siekman et al., 2017).

Many strategies and initiatives practiced by the government to address the problem of child undernutrition in the country under the Programme for the Rehabilitation of Malnourished Children since 1989 that provides food baskets to the undernourished children from low-income households. Furthermore, Community Feeding Programme is implemented since 2013 specifically to improve the nutritional status of OA children aged 6 months to below 6 years old in rural Perak, Pahang, Kelantan and the Penan Community in Sarawak. In addition to receiving food baskets and health education, undernourished OA children in this program are given complementary food includes milk, cereals, multivitamins with iron and fish oil, and Ready to Use Therapeutic Food (RUTF) by OA volunteers accompanied by their mothers. Even with successful implementation and findings from these programmes, the prevalence of underweight, stunting, wasting and anaemia in the OA children is much higher than the general population. Incorporating MNP as part of the programmes may have contributed in lowering the problems of undernutrition among children from poor households, particularly OA children.

Information on the potential effects of MNP as a preventive strategy of underweight, stunting, wasting and anaemia in children with normal nutritional status at baseline is limited. Thus, this study aimed to address the following questions:

1. Is the use of MNP feasible in OA children in terms of compliance, parental acceptance, child preference and adverse effects in a randomised-controlled trial among OA young children?
2. Is there any difference(s) (before and after MNP intervention) in growth, iron status and dietary intakes within the intervention and control groups?
3. Is there any difference(s) (before and after MNP intervention) in growth, iron status and dietary intakes between the intervention and control groups?

1.3 Research Objectives

Phase 1: Feasibility Study of Micronutrients Powder Supplementation

1.3.1 General Objective

To assess the feasibility of using Micronutrients Powder (MNP) among OA children in a randomised-controlled trial among OA children.

1.3.2 Specific Objective

To determine the feasibility of using MNP in terms of compliance, parental acceptance, child preference and adverse effects among OA children.

Phase 2: Micronutrients Powder Supplementation Trial

1.3.3 General Objective

To determine the effects of MNP on nutritional status (growth, iron status and dietary intakes) of OA young children (6 to 24 months) in Selangor.

1.3.4 Specific Objectives

- 1) To compare the differences between the intervention and control groups at baseline in:
 - i) growth [weight, length, weight-for-age (WAZ), length-for-age (LAZ) and weight-for-length (WLZ)],
 - ii) iron status (haemoglobin concentration),
 - iii) dietary intakes (energy, nutrients, and food group intakes).
- 2) To determine the differences (before and after MNP intervention) within the intervention and control groups related to:
 - i) growth [weight, length, weight-for-age (WAZ), length-for-age (LAZ) and weight-for-length (WLZ)],
 - ii) iron status (haemoglobin concentration),
 - iii) dietary intakes (energy, nutrients, and food group intakes).

- 3) To compare the differences (before and after MNP intervention) between the intervention and control groups related to:
 - i) growth [weight, length, weight-for-age (WAZ), length-for-age (LAZ) and weight-for-length (WLZ), prevalence of underweight/ stunting/ wasting],
 - ii) iron status (haemoglobin concentration), prevalence of anaemia,
 - iii) dietary intakes (energy, nutrients and food group intakes),

1.4 Research Hypotheses

- 1) There is no significant difference between the intervention and control groups at baseline in:
 - i) growth [weight, length, weight-for-age (WAZ), length-for-age (LAZ) and weight-for-length (WLZ)],
 - ii) iron status (haemoglobin concentration),
 - iii) dietary intakes (energy, nutrients and food group intakes).
- 2) There are significant differences (before and after MNP intervention) within the intervention and control groups related to:
 - i) growth [weight, length, weight-for-age (WAZ), length-for-age (LAZ) and weight-for-length (WLZ)],
 - ii) iron status (haemoglobin concentration),
 - iii) dietary intakes (energy, nutrients and food group intakes).
- 3) There are significant differences (before and after MNP intervention) between the intervention and control groups related to:
 - i) growth [weight, length, weight-for-age (WAZ), length-for-age (LAZ) and weight-for-length (WLZ), prevalence of underweight/ stunting/ wasting],
 - ii) iron status (haemoglobin concentration), prevalence of anaemia,
 - iii) dietary intakes (energy, nutrients and food group intakes),

1.5 Research Framework

The research framework for this study is shown in Figure 1.1. Phase 1 of this study was a feasibility study which assessed the compliance, parental acceptance, child preference and adverse effects of MNP among children aged 6 to 36 months old. The findings of this feasibility study provided support for the implementation of a randomised-controlled trial among OA children. The second phase of this study was a MNP supplementation trial conducted over 12 months which determined the effect of MNP as a preventive strategy of undernutrition among OA children aged 6 to 24 months old. The difference in age groups of children involved in Phase 1 and Phase 2 is because Phase 2 was a trial conducted over 12 months that involved OA children aged within 6 to 24 months at baseline and growing up to 18 to 36 months after 12 months of the supplementation. Thus, Phase 1 need to be conducted among children aged 6 to 36 months old as to determine the compliance, parental acceptance, child preference and adverse effects of MNP within the age range before the implementation of Phase 2. In Phase 2, the intervention group was supplemented with three sachets of MNP in powdered form each week for every other day, for a period of 12 months in addition to receiving health and nutrition advices. The control group received health and nutrition advices that were similar to the intervention group. This study reported the differences (before and after intervention) in weight, length, WAZ, LAZ, WLZ and blood haemoglobin as primary outcomes and dietary intakes (energy, nutrients and food group intake) as secondary outcomes within and between the intervention and control groups. Socio-economic and child factors, dietary intakes, vaccination and sanitation were examined as possible covariates in this study.

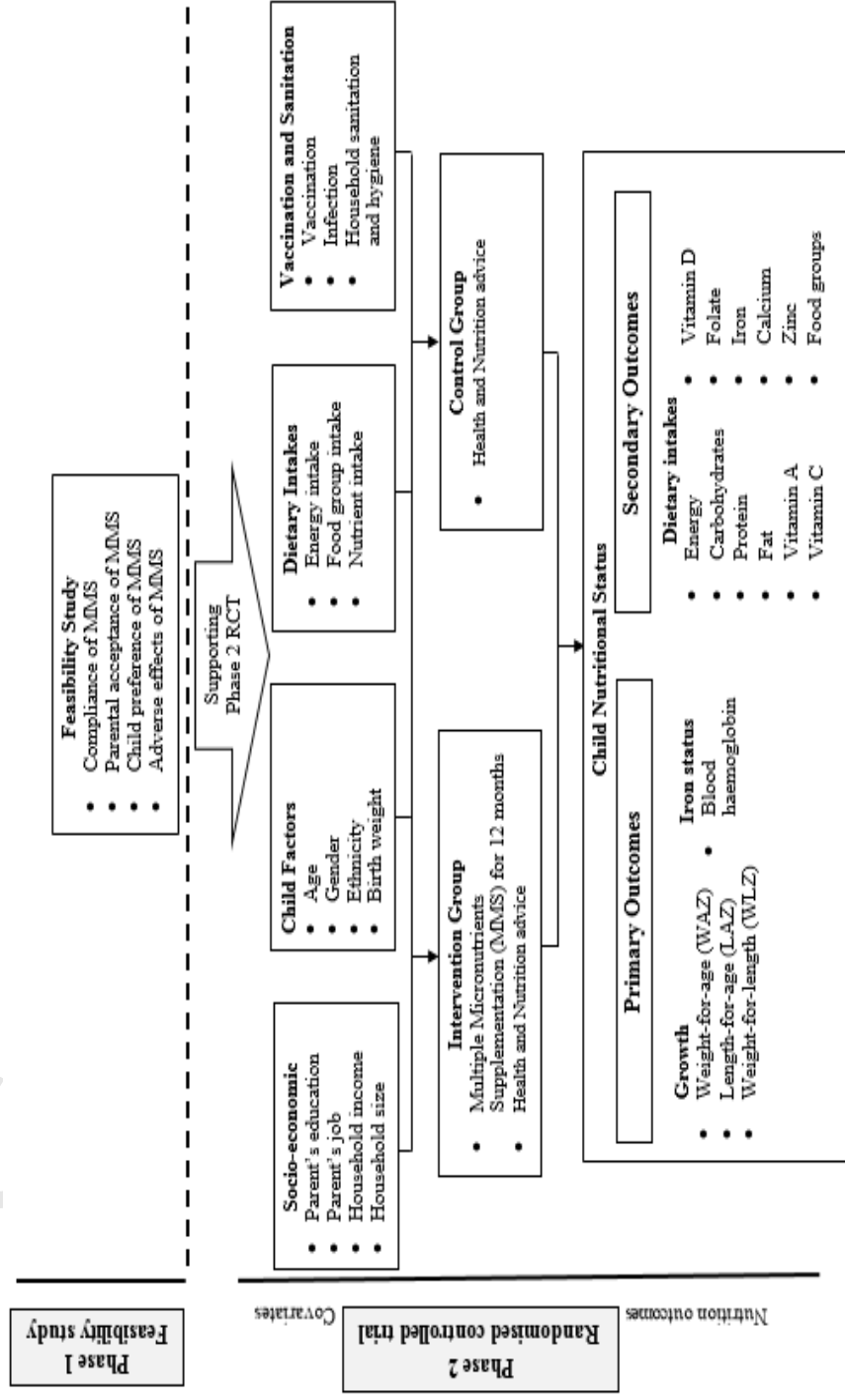


Figure 1.1 : Research framework

1.6 Significance of Study

In Malaysia, studies have shown that the prevalence of undernutrition and anaemia in OA children under five are relatively higher than those observed for the general population, even though many strategies have been implemented. Previous studies have demonstrated the effect of MNP as a recuperative strategy of undernutrition in children. Only a small number of MNP trials, have evaluated the use of MNP as a preventive strategy of undernutrition among children with normal growth. This present study is important as it attempted to find an effective preventive strategy of undernutrition among OA children (who had normal nutritional status at baseline) as they are known to have higher risks of undernutrition.

By determining the effect of MNP on growth indicators, health professionals can address the problem of undernutrition in children with normal growth through developing effective preventive strategies such as MNP program for this vulnerable group. Findings from this study also can be used as a reference for future studies or nutrition interventions in closing the gap of nutrition disparities between children of OA and general population. Moreover, findings of this study would help nutritionist involved in the design, implementation, and scaling-up of national nutrition actions in implementing MNP supplementation as part of a national infant and young child feeding programme, particularly for OA children.

Most previous MNP trials have demonstrated the curative effect of MNP on anaemia status among anaemic children at baseline and found varied effects between trials. Lack of studies on MNP as an approach for anaemia prevention, render it difficult to define the best strategy in protecting OA children against anaemia. This present study aimed to determine the effect of MNP on iron status of OA children with normal blood haemoglobin at baseline. This information is significant to gather a robust evidence on whether MNP has a positive effect in protecting children against anaemia.

Previous MNP trials have shown the impact of MNP supplementation towards improving dietary practices such as minimum dietary diversity, minimum acceptable diet, minimum meal frequency and continued breastfeeding at 2 years of age. However, the effect of MNP in improving child dietary practices in terms of adequacy of energy and nutrients in comparison with the Malaysian Recommended Nutrient Intakes (NCCFN, 2017) and food groups according to the recommended goals in the Malaysian Guidelines for Feeding of Infants and Young Children (MOH, 2008) are still unknown as OA households are widely known to have financial constraints and unique cultural feeding practices. Hence, the findings of this study will fill this information gap on the potential effectiveness of MNP in improving dietary practices of OA young children.

In designing and planning for a randomised controlled trial (RCT), factors such as compliance, parental acceptance, child preference and adverse effects of MNP are important to be assessed in order to investigate areas of uncertainty about MNP trial. A feasibility study plays an important role in modifying the design and conduct of MNP

trial, and consequently increasing the value of the research. Therefore, the feasibility study that was conducted before the MNP trial is important as a reference to other researchers and health professionals when designing a trial or MNP intervention in Malaysia.

1.7 Operational Definition

There are some terms in this study, which need clarification for better understanding of what they mean within the context of the study.

Underweight: Defined as below minus two standard deviations from median weight-for-age of reference population (<-2 SD from median weight-for-age).

Stunting: Defined as below minus two standard deviations from median length- or height-for-age of reference population (<-2 SD from median length- or height-for-age).

Wasting: Defined as below minus two standard deviations from median weight-for-length or -height of reference population (<-2 SD from median weight-for-length or -height).

Anaemia: Defined as below 11.0 g/dL of blood haemoglobin concentration.

Temuan: Defined as a Proto-Malay ethnic group indigenous of Peninsular Malaysia. The Temuans are classified as part of Orang Asli group according to the Malaysian government. They are also one of the largest (only smaller in population in comparison to the Semai people and Jakun people) and the most widespread of the Orang Asli ethnic groups.

Temuan cluster: Defined as having at least 80% of the households in the village are of Temuan ethnicity.

Micronutrients Powder (MNP): It is a mixture of micronutrients in powder form that can be mixed directly into any ready-to-eat semi-solid food. MNP is manufactured by DSM Singapore Industrial Pte. Ltd. Nutritional Products. MNP sachet weighed 1 gram, consisting of ten vitamins (A, C, D, E, B1, B2, B6, B12, folic acid, niacin) and five minerals (iron, zinc, copper, iodine, selenium).

Dietary intake: Daily eating patterns of an individual, including specific foods and calories consumed and relative quantities. Type and portion size of consumed foods and beverages were obtained by asking about the type and amount of consumed food items over the previous day (midnight to midnight) or over the last 24 hours using a method of 24-hour diet recall. The dietary intake includes intakes of energy, protein, carbohydrate, fat, vitamin A, vitamin C, vitamin D, folate, iron, calcium, and zinc.

Food groups: A collection of foods that share similar nutritional properties or biological classifications. Food groups include grains and cereals, meat and poultry, fish, legumes, milk and dairy products, fruits and vegetables.



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