

Effectiveness of oral nutritional supplements and nutrition education for improving growth among underweight preschool children in Kuala Lumpur

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Registration date 18/03/2026	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/03/2026	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Undernutrition among young children remains an important public health concern in Malaysia. Children who are underweight may experience inadequate energy and nutrient intake, which can affect their physical growth, immune function, and cognitive development. Oral nutritional supplements are sometimes used to provide additional nutrients to help support healthy growth in children who are underweight. However, there is limited research on the effectiveness of oral nutritional supplementation combined with nutrition education in community preschool settings in Malaysia. This study aims to evaluate whether oral nutritional supplementation together with nutrition education can improve growth and nutrient intake among underweight preschool children aged 4–6 years in Kuala Lumpur.

Who can participate?

Children aged 4 to 6 years attending selected KEMAS preschool centres in Kuala Lumpur who are identified as underweight

What does the study involve?

Children who are eligible will be assigned into two groups. Parents or guardians of children in both groups will attend nutrition education sessions that provide information about balanced diets, healthy eating habits, and ways to improve children's food intake. In addition to the nutrition education, children in the intervention group will receive oral nutritional supplements during school hours. The supplements will be prepared by the preschool teachers according to the recommended preparation instructions and provided to the children during school days. Children in the control group will receive nutrition education only. During the study, researchers will collect information about children's growth and dietary intake. Measurements such as weight and height will be taken at the beginning of the study and again at 30, 60, and 90 days. Information on children's dietary intake will also be collected at several

time points during the study. These measurements will help researchers determine whether oral nutritional supplementation together with nutrition education is effective in improving growth and nutrient intake among underweight preschool children.

What are the possible benefits and risks of participating?

Participation in this study may benefit children by improving their nutritional intake and supporting healthier growth. Parents and guardians may also gain useful knowledge about child nutrition and feeding practices through the nutrition education sessions. The risks associated with participating in this study are minimal. Some children may experience mild side effects such as stomach discomfort if they have allergies to certain ingredients in the supplement, although such reactions are uncommon. If any adverse symptoms occur, parents are advised to inform the research team immediately.

Where is the study run from?

This study is conducted by researchers from the Faculty of Health Sciences, Universiti Kebangsaan Malaysia, and is carried out in selected KEMAS preschool centres in Kuala Lumpur.

When is the study starting and how long is it expected to run for?

April 2025 to January 2026

Who is funding the study?

The research is funded by a research grant and supported by Quantum Upstream Sdn Bhd, which provides the oral nutritional supplements used in the study.

Who is the main contact?

Prof. Zahara Abdul Manaf, zaharamanaf@ukm.edu.my

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Additional identifiers**Study information****Scientific Title**

the effectiveness of oral nutritional supplementation combined with nutrition education on growth indicators and nutrient intake among underweight preschoolers aged 4–6 years in Kuala Lumpur, Malaysia: a community-based controlled intervention study

Study objectives**Ethics approval required**

Ethics approval required

Ethics approval(s)

approved 05/12/2024, Research Ethics Committee The National University Of Malaysia (RECUKM) (Tingkat 1, Blok Klinikal, Hospital Canselor Tuanku Muhriz, Pusat Perubatan UKM, Jalan Yaacob Latif, Bandar Tun Razak Cheras, Kuala Lumpur, 56000, Malaysia; +60 (0)391455046 /5048; sepukm@ukm.edu.my), ref: JEP-2024-778

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Supportive care

Study type(s)

Health condition(s) or problem(s) studied

Childhood undernutrition, specifically underweight among preschool children

Interventions

This study is a two-arm cluster randomized controlled trial conducted among underweight preschool children aged 4–6 years attending selected Tabika Kemajuan Masyarakat (KEMAS) preschool centres in Kuala Lumpur. Participants will be identified through a screening phase and recruited based on predefined inclusion and exclusion criteria.

Randomisation will be conducted at the study centre level, where each participating preschool centre will be assigned to either the intervention group or the control group. Therefore, all eligible children within the same centre will receive the same study condition to minimise contamination between participants.

The study consists of two groups: an intervention group and a control group.

Children in centres allocated to the intervention group will receive oral nutritional supplementation (ONS) together with nutrition education (NE). The ONS is a nutritionally complete supplement designed to provide additional energy, protein, and essential micronutrients to support catch-up growth among underweight children. The supplement will be provided during school hours, where the ONS will be prepared by the preschool teachers according to the recommended preparation instructions and administered to participating children under supervision.

Children in centres allocated to the control group will receive nutrition education only, which represents the standard nutritional management approach for underweight children. Caregivers in both groups will receive nutrition education sessions focusing on balanced diet, appropriate feeding practices, and strategies to improve children's dietary intake.

Anthropometric measurements, dietary intake, appetite, and health outcomes will be assessed at baseline, Day 30, Day 60, and at the end of the intervention period to evaluate the effectiveness of oral nutritional supplementation combined with nutrition education compared with nutrition education alone.

Intervention Type

Other

Primary outcome(s)

1. Weight-for-age z-score (WAZ) measured using WHO child growth standards at Day 30, 60 and 90

Key secondary outcome(s)

1. Height-for-age z-score (HAZ) measured using a stadiometer and converted to height-for-age z-scores using WHO child growth standards at Day 30, 60 and 90

2. BMI-for-age z-score (BAZ) measured using body mass index calculated from measured weight and height and converted to BMI-for-age z-scores using WHO growth standards at Day 30, 60 and 90
3. Energy and macronutrient intake measured using 3-day 24-hour dietary recall to estimate energy, protein, carbohydrate, and fat intake at Day 60 and 90
4. Appetite measured using caregiver-reported appetite assessment questionnaire at baseline and 90 days after intervention
5. Frequency of common illnesses measured using caregiver-reported incidence of common childhood illnesses (e.g., fever, flu, diarrhoea) at baseline and 90 days after intervention

Completion date

04/01/2026

Eligibility

Key inclusion criteria

1. Preschool children aged 4–6 years (date of birth between January 2019 and December 2021)
2. Enrolled in selected Tabika Kemajuan Masyarakat (KEMAS) preschool centres in Kuala Lumpur
3. Malaysian citizens
4. Classified as underweight according to WHO child growth standards based on anthropometric indicators (e.g., weight-for-age z-score < -2 SD)
5. Parent or legal guardian able to understand and communicate in Malay or English
6. Written informed consent obtained from parent or guardian prior to participation

Healthy volunteers allowed

No

Age group

Child

Lower age limit

40 months

Upper age limit

79 months

Sex

All

Total final enrolment

96

Key exclusion criteria

1. Children diagnosed with congenital abnormalities
2. Children with developmental or neurological disorders, including autism spectrum disorder, attention deficit hyperactivity disorder (ADHD), Down syndrome, or impaired brain development
3. Children with severe medical or chronic conditions that may affect growth, feeding ability, or

nutritional status

4. Children who are currently receiving specialised medical nutrition therapy or therapeutic feeding programmes for the last 6 months

5. Children who are intolerance towards milk or milk product and any of ingredients listed in the product

6. Children whose parents or guardians do not provide informed consent for participation in the study

Date of first enrolment

01/04/2025

Date of final enrolment

31/08/2025

Locations

Countries of recruitment

Malaysia

Sponsor information

Organisation

Quantum Upstream SDN BHD

Funder(s)

Funder type

Funder Name

Quantum Upstream SDN BHD

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Prof. Zahara Abdul Manaf (zaharamanaf@ukm.edu.my). Only statistical data will be provided after obtaining consent from the participants. The type of data that will be shared is the data in the manuscript.

IPD sharing plan summary

Available on request