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Effects of oral nutrition supplement on the nutritional status of infants aged 6–12 months

Submission date 21/04/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 27/04/2026	**Overall study status** Completed	
Last Edited 23/04/2026	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
The first year of life is a critical time for growth and development. From six months of age, infants need foods in addition to breast milk to meet their increasing nutritional needs. In some communities, infants may not receive enough variety and nutrients from their diet, which can affect their growth and health. This study aims to find out whether giving an oral nutritional supplement in the form of fortified infant cereal, with or without nutrition education for parents or caregivers, can help support healthy growth in infants.

Who can participate?
Infants aged 6 to 8 months with normal weight for their age can take part in the study. Participants must live in selected communities in Cagayan de Oro City, Philippines. Parents /caregivers must be willing to give consent and take part in study activities. Both male and female infants can participate.

What does the study involve?
Participants are placed into one of three groups by chance (randomly):
• Infants who receive an oral nutritional supplement and whose parents/caregivers attend nutrition education sessions
• Infants who receive an oral nutritional supplement only
• Infants who continue with their usual diet and do not receive the oral nutritional supplement

The study lasts for four months or 120 days. Infants in the intervention (oral nutrition supplement: fortified infant cereal) groups are given one serving of the food supplement each day. Feeding is supervised during weekdays at a community site, and oral nutritional supplement is provided for home use during weekends.

Parents/caregivers in the nutrition education group attend a total of eight sessions on infant feeding and nutrition, conducted twice a month.

Researchers measure the infants' growth (weight, length, and mid-upper arm circumference) and collect information about their food intake and developmental milestones at baseline, midline, and endline of the study.

What are the possible benefits and risks of participating?
Participants may benefit from improved nutrition and regular monitoring of their child's growth and health. Parents/caregivers may also gain useful knowledge about proper infant feeding.
The risks are low. Some infants may experience mild digestive discomfort when trying new foods. Any health concerns are closely monitored, and appropriate care is provided if needed.

Where is the study run from?
The study is managed by the research team and conducted in selected barangays (Lapasan, Canitoan, Bulua, and Patag) in Cagayan de Oro City, Philippines.

When is the study starting and how long is it expected to run for?
Participant enrollment started in April 2, 2025 and ended in April 25, 2025. Each participant takes part in the study for about four months.

Who is funding the study?
Nestlé Philippines Inc.

Who is the main contact?
Principal Investigator: Imelda Angeles-Agdeppa, Ph.D.
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Study information

Scientific Title
Effects of consuming oral nutrition supplement on the nutritional status of infants aged 6–12 months: a randomized parallel-group trial

Study objectives
To determine the effect of oral nutrition supplementation (ONS) in the form of fortified infant cereal, with or without nutrition education (NE), on the maintenance of normal weight-for-age among infants aged 6 to 12 months, measured as change in body weight from baseline to endline.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/02/2025, Asian Hospital and Medical Center Research Ethics Committee (Research Ethics Committee Office, 7th Floor, Tower 2, Asian Hospital and Medical Center, 2205 Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa, 1780, Philippines; +63 8771-9000 local 8163; acabardo@asianhospital.com), ref: 2024-041

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Nutritional status of infants aged 6–12 months

Interventions
This study uses a randomized, parallel-group controlled design involving infants aged 6 to 12 months with normal weight-for-age at baseline. A total of 195 participants are enrolled and randomly assigned into three groups (n=65 per group) using stratified randomization by sex and study site.

The intervention consists of oral nutrition supplementation (ONS) in the form of fortified infant cereal, with or without nutrition education (NE), administered over a 120-day period. The study includes the following groups: (1) ONS combined with NE, (2) ONS alone, and (3) control group receiving no intervention and continuing their usual dietary intake.

Participants in the intervention groups receive ONS in the form of fortified infant cereal (40 g sachet mixed with 120 mL distilled water), consumed once daily under supervised feeding from Monday to Friday at a community site, with take-home rations provided for weekend consumption. The ONS is administered in four infant cereal variants (mixed vegetables and soya, wheat banana and milk, rice and soya, and mixed fruits and soya), given alternately.

The NE intervention is delivered to parents/caregivers in the ONS+NE group through eight structured sessions conducted twice monthly, focusing on infant and young child feeding practices.

Anthropometric measurements (weight, length, and mid-upper arm circumference) are collected at baseline, monthly, and endline using standardized procedures. Dietary intake is assessed using two non-consecutive 24-hour food recalls at baseline, midline, and endline, supplemented by weekly food diary records. Additional data collected include developmental milestones, gastrointestinal tolerance, nutrition knowledge, and acceptability of the ONS.

The study incorporates elements of an open-label design, as participants and selected Local Researchers (LRs) involved in intervention delivery and data validation are aware of group allocation. However, blinding is maintained among key study personnel, including LRs responsible for data collection, the database manager, the statistician, and the principal investigator, who remain blinded to group allocation until completion of data analysis to minimize bias and ensure objectivity. In addition, participants are not informed of the brand of the oral nutrition supplement (ONS), providing a degree of masking. The primary outcome is change in body weight from baseline to endline, used to assess maintenance of normal weight-for-age status across groups.

Intervention Type
Other

Primary outcome(s)
1. Body weight (kg) measured using a calibrated digital weighing scale; weight-for-age z-scores (WAZ) calculated based on WHO Child Growth Standards at Baseline, midline (≈day 60), and endline (≈day 120)

Key secondary outcome(s))

1. Nutritional status measured using Length (cm) and mid-upper arm circumference (MUAC, cm) measured using standard procedures; z-scores (length-for-age, weight-for-length, MUAC-for-age) computed using WHO standards at Baseline, monthly, and endline

2. Food and nutrient intake and dietary diversity measured using Two non-consecutive 24-hour food recalls; nutrient intake analyzed using dietary software; dietary diversity score (DDS) and nutrient adequacy assessed based on Philippine Dietary Reference Intakes (PDRI) at Baseline, midline, and endline

3. Developmental feeding milestones measured using Structured 15-item questionnaire assessing age-appropriate feeding and motor development at Baseline, midline, and endline

4. Nutrition knowledge of parents/caregivers measured using Structured questionnaire on infant and young child feeding (IYCF); pre-test and post-test scores at Baseline and endline

5. Acceptability of ONS in the Form of Fortified Infant Cereal measured using 9-point Smiley Face Child Testing Questionnaire at After 1 week of consumption and monthly until endline

Completion date
30/08/2025

Eligibility

Key inclusion criteria
1. Infants aged 6 months to 8 months at baseline with normal weight for age defined as between minus 2 and plus 2 weight for age z scores according to the WHO Child Growth Standards
2. No known allergy to wheat, soya or cow's milk
3. Not suffering from diarrhoea, respiratory infection or fever at baseline
4. Not currently participating in any complementary feeding programme
5. Not planning to move residence for the duration of the intervention
6. Written informed consent signed by a parent or legal guardian
7. Parents or caregivers willing to participate in nutrition education class activities
8. Infant parent or legal guardian is of the legal age of majority, able to understand the informed consent form and other relevant study documents, and willing and able to comply with the study protocol
9. Existing breastfeeding and or milk feeding practices will not be altered by the study. Feeding practices will be recorded and accounted for in the analysis as potential confounding variables. Infants with normal weight will be eligible regardless of feeding practices

Healthy volunteers allowed
Yes

Age group
Child

Lower age limit
6 months

Upper age limit
8 months

Sex
All

Total final enrolment
195

Key exclusion criteria
1. Undergoing treatment on any chronic ailment, diagnosed as suffering from any sort of illness e.g. fever, diarrhea, stomach ache, cough and colds at baseline
2. Participant in an on-going complementary feeding program
3. With allergy on wheat, soya, cow's milk
4. With physical disability that affects normal feeding of infants e.g. cleft lip or palate
5. Parents/caregivers who are not willing to participate in the feeding and NE class activities
6. Without signed parental ICF
7. Overweight, obese, undernourished
8. Low-birth-weight (LBW) or premature baby
9. Children identified with moderate acute malnutrition (MAM) or severe acute malnutrition (SAM) will be referred to the nearest health facility for appropriate management

Date of first enrolment
02/04/2025

Date of final enrolment
25/04/2025

Locations

Countries of recruitment
Philippines

Sponsor information

Organisation
Nestlé Philippines Inc.

Funder(s)

Funder type

Funder Name
Nestlé Philippines Inc.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available