MINISTRY OF HEALTH

NATIONAL INSTITUTE OF NUTRITION

ACCEPTANCE REPORT
GRASSROOT LEVEL SCIENCE AND TECHNOLOGY RESEARCH TOPIC

Study the Efficiency of Oral Nutritional Supplementation on Nutrition Status, Digestive Disorders, Respiratory Infection and Anorexic in Children Between 24 - 71 Months Old.

HANOI – 1/12/2023 NCT05551637

OBJECTIVES OF THE STUDY

Evaluate the effectiveness of using the nutritional product Kazu Gain Gold on nutritional status (anthropometric index, wasting malnutrition rate), diarrhea, constipation and anorexia in children aged 24 - 71 months.

Detail goals

1. Evaluate the effectiveness of using nutritional product Kazu Gain Gold on the improvement of anthropometric indicators (weight, height, Zscore weight/age, Zscore height/age and Zscore weight/height) , nutritional status (wasting malnutrition rate) in children 24 - 71 months old after 3 months of intervention.
2. Evaluate the effectiveness of using nutritional product Kazu Gain Gold on improving diarrhea, constipation and anorexia in children 24 - 71 months old after 3 months of intervention.

Research questions

- Anthropometric index (weight, height, Zscore weight/age, Zscore height/age and Zscore weight/height), nutritional status (wasting malnutrition rate) on children 24 to 71 months old. How does it change after 3 months of using and not using Kazu Gain Gold products?
- How does the situation of diarrhea, constipation, and anorexia in children 24 to 71 months old change after 3 months of using and not using Kazu Gain Gold products?

Research hypothesis

- Using Kazu Gain Gold product can improve statistically significant differences in the index (weight, height), ratio (wasting malnutrition) in children 24-71 months old compared to the following control group 3 months of intervention.
- Using Kazu Gain Gold product can improve digestive disorders (diarrhea, constipation) and anorexia in children 24-71 months old, with a statistically significant decrease compared to the control group after 3 months. intervention.

SCREENING STAGE

1.1. Study subjects, Locations, and Timeline

1.1.1. Study subjects

Inclusion Criteria:

- Children aged 24 to 71 months enrolled in 10 selected preschool schools in 10 communes.
- Families voluntarily agree to participate in the study.
- Children have lived in the selected communes for at least one year.

Exclusion Criteria

- Children with lactose intolerance.
- Children with a history of milk allergies or congenital diseases.
- Children with intellectual disabilities or chronic infectious diseases.

1.1.2. Study Locations

The communes: Vinh Kien, Phu Thinh, Bao An, Vu Linh, Tan Nguyen, Cam Nhan, Bach Ha, Phu An, Tan Hung, and Yen Thanh, located in Yen Binh District, Yen Bai Province.

1.1.3. Study Timeline

- From September 2023 to October 2023

1.2.Research Methodology

1.2.1. Study design

- Cross-sectional descriptive study, conducting screening and evaluating the nutritional status of all participants in the selected study areas

1.2.2. Sample Size

- Screening of 3,205 children aged 24 to 71 months across 10 communes in Yen Binh District, Yen Bai Province

1.2.3. Sampling Method

- Province Selection: The study was conducted in Yen Binh District, Yen Bai Province, selected due to the active cooperation of local health, education and government officials
- School Selection: Ten communes were selected based on the highest number of children under 5 years old
- Study Subject Selection
    - The entire preschool population aged 24-71 months across the 10 communes was surveyed to identify children meeting the study's inclusion criteria. A total of 3,205 children were screened.

1.3.Study Content

The collected data will include information on demographics, anthropometric measures, medical history and feeding practices

1.3.1. Demographic Information

- Information on age, gender, address family economic status, ethnicity, maternal education level, and occupation will be collected via interviews with mothers or

caregivers. The interviews will be conducted using a pre-designed questionnaire by trained research staff. The questionnaire will be tested prior to the study.

1.3.2. Anthropometric measurements

- Age calculation: Age will be calculated by subtracting the child's birthdate from the survey date and categorized according to WHO, 2006 standards
- Weight: Weight will be measured using a TANITA digital scale with 0.1 kg accuracy. The scale will be calibrated before each use. Children will wear light clothing and stand without shoes, ensuring proper balance on the scale
- Height: Heigth will be measured using a UNICEF wooden stadiumeter with 0.1 cm accuracy, ensuring the the child is standing upright, eyes looking forward, and their body fully aligned.

1.3.3. Feeding History and Milk Allergies

- Information on breastfeeding practices, milk allergies, and lactose intolerance will be collected through interviews with caregivers

1.4.Variables and Data Collection Methods for Screening

1.4.1. Study Variables

- Anthropometric Measures: Average weight and height
- Z-scores: Height-for-age (HAZ), weight-for-age (WAZ), weight-for-height (WHZ), and height-for-weight (BAZ) Z-scores will be calculated
- Inclusion Criteria for Study Participant: Children with Z-scores of WHZ/BAZ < -0.5 and WAZ/HAZ/WHZ/BAZ > -4.

1.4.2. Data Collection Methods

- The study team will prepare a deployment plan and obtain approval from the local Department of Health and Education to conduct the study.
- After receiving approval, the study team will notify local authorities about the plan, including the participant criteria, study objectives, methodology, timeline, and budget.
- Community health workers and teachers will compile a list of children aged 24–71 months in preschools and local communities for screening. Basic demographic data will be collected, and the children's nutritional status will be assessed.
- Before data collection, health workers and teachers will meet with parents or guardians to explain the study and seek consent for participation. Parents must sign an informed consent form before their child is included in the study.
- If any participant is found to not meet the inclusion criteria during screening, they will be excluded from the study.
- Data will be reviewed daily, and any discrepancies or missing data will be corrected immediately on-site.

- After data collection, researchers will clean the data, ensuring that only valid participants are included for further analysis.

1.5.Techniques and Tools Used in the Study

Variable Group	Measurement	Method/Tool	References
Nutritional Status of Children (24-71 months)	Age, Gender, Weight, Height	Interview/Questionnaire, TANITA Scale, UNICEF Stadiometer	WHO, 2006
Anthropometric Indicators	Weight, Height, Z-scores	TANITA Scale, UNICEF Stadiometer	WHO, 2006, Institute of Nutrition

1.6.Evaluation Indicators

Nutritional status will be evaluated based on WHO growth standards (2006, 2007) for children under 5 years old

Z-score Interpretation

- **Weight-for-Age (WAZ):**
  - Z-score < -3: Severe underweight
  - Z-score < -2: Underweight
  - Z-score ≥ -2: Normal weight
- **Height-for-Age (HAZ):**
  - Z-score < -3: Severe stunting
  - Z-score < -2: Stunting
  - Z-score ≥ -2: Normal height
- **Weight-for-Height (WHZ):**
  - Z-score < -3: Severe wasting
  - Z-score < -2: Wasting
  - Z-score ≥ -2: Normal weight-for-height
- **BMI-for-Age (for children aged 5 years):**
  - Z-score < -3: Severe underweight
  - Z-score < -2: Underweight
  - Z-score ≥ -2: Normal weight
  - Z-score > 1: Overweight
  - Z-score > 2: Obese