STUDY PROTOCOL

Official Title:

Nutritional Status, Associated Factors, and Effectiveness of a Nutrition Health Education Intervention among Ethnic Minority Children Aged 5–16 Years in Tra Vinh Province, Vietnam

NCT Number: To be updated

Document Type: Study Protocol

Document Date: March 22, 2024

Sponsor: University of Medicine and Pharmacy at Ho Chi Minh City

Principal Investigator:

Truc T Thanh, PhD

Lan T H Bui, MSc

Faculty of Public Health

University of Medicine and Pharmacy at Ho Chi Minh City

1. Background

Malnutrition remains a major public health issue among children in low- and middle-income countries. Vietnam is currently facing a double burden of malnutrition, including undernutrition and overweight/obesity. These conditions have long-term consequences on health, physical capacity, and cognitive development.

Ethnic minority populations may experience more severe nutritional challenges due to disparities in socioeconomic status, education, and cultural dietary practices. However, there is limited evidence on effective community-based nutrition education interventions targeting ethnic minority children. Therefore, this study aims to evaluate the effectiveness of a multi-component nutrition health education intervention in improving nutritional status and related behaviors.

2. Objectives

This study aims to:

Phase 1: Assess the prevalence and determinants of nutritional status among ethnic minority children aged 5–16 years.

Phase 2: Evaluate the effectiveness of a community-based nutrition health education intervention on:

- BMI-for-age z-score and prevalence of malnutrition
- Nutrition knowledge, attitudes, and practices; Diet quality score; Physical activity levels, and Body composition.

3. Study Design and Methods

3.1. Study design

The study is conducted in two phases:

Phase 1: Cross-sectional assessment of nutritional status and associated factors. (September – October 2024)

Phase 2: Community-based controlled intervention with pre–post comparison. (November 2024 – April 2025)

- Study type: Interventional
- Model: Parallel
- Allocation: Controlled
- Masking: None

- Duration: 6 months (4-month intervention + 2-month follow-up)

3.2. Study Setting

The study will be conducted in Tra Vinh Province, Vietnam, including:

- Community health centers
- Ethnic minority boarding schools

3.3. Participants

Inclusion Criteria

- Children aged 5–16 years
- Belonging to ethnic minority groups
- Living or studying in selected areas
- Written informed consent from caregivers and children

Exclusion Criteria

- Severe illness affecting nutritional status
- Inability to participate in intervention activities

3.4. Sample Size

The sample size was calculated to detect a difference in BMI-for-age z-score between the intervention and control groups, with a significance level of 0.05 and 90% power. The estimates for mean and standard deviation were based on a previous study by Reginald et al. (2021) conducted among children aged 9–13 years. Assuming equal group sizes, the minimum required sample size was 113 participants per group.

3.5. Recruitment and Allocation

Participants will be recruited from selected schools and community health centers. They will be assigned to either: Intervention group and Control group

Intervention

Children aged 5–10 years: sessions at community health centers with caregiver participation

Children aged 11–16 years: sessions at ethnic minority boarding schools

A multi-component nutrition health education program will be implemented for 4 months. Key topics includes:

- Nutrients and health
- Prevention of undernutrition and overweight/obesity

- Healthy dietary habits
- Physical activity

Materials

- Presentations
- Videos
- Posters and leaflets
- Dietary and physical activity diaries

Follow-up: 2-month maintenance phase with reinforcement activities

Control Group

Participants will receive routine health education without additional structured intervention.

4. Outcomes

Primary Outcomes

- Change in BMI-for-age z-score
- Change in prevalence of malnutrition (including undernutrition and overweight/obesity)

Secondary Outcomes

- Change in nutrition-related knowledge, attitudes, and practices (KAP)
- Change in Diet quality score
- Change in physical activity levels
- Change in skeletal muscle mass
- Change in body fat mass
- Change in fat-free mass

5. Data Collection

- Height will be measured using a Microtoise stadionmeter
- Weight and body composition will be assessed by Inbody 270 (InBody Co., Ltd., Seoul, Korea)
- Structured questionnaires

6. Statistical Analysis

Descriptive statistics will summarize study variables. Group comparisons will use chi-square or Fisher's exact tests for categorical variables and t-tests for continuous

variables. Associations will be assessed using odds ratios (ORs) with 95% confidence intervals (CIs). Variables with $p < 0.20$ in univariate analysis and those supported by the literature will be included in multivariable logistic regression.

Intervention effects will be evaluated using a difference-in-differences (DiD) approach with generalized estimating equations (GEE), including group, time, and interaction terms. Results will be reported as coefficients or relative risks (RRs) with 95% CIs. Statistical significance are set at $p < 0.05$.

7. Ethical Considerations

This research received approval from the Institutional Review Board of the University of Medicine and Pharmacy at Ho Chi Minh City (IRB No. 493/HDDD-DHYD, March 22, 2024).

8. Data Management

Data will be de-identified

Stored securely

Access limited to authorized personnel

9. Funding and Sponsor

Funding: Department of Science and Technology

Sponsor: University of Medicine and Pharmacy at Ho Chi Minh City