

# Evaluation of the correlation between diet quality, weight status, and mental health in schoolchildren, with an emphasis on the identification of plasma biomarkers.

<b>Submission date</b> 09/03/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 12/03/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/06/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Obesity and mental health issues are growing concerns in children worldwide. Poor diet and excess weight can affect a child's physical and mental well-being. However, it's not always easy to tell when a child's weight and diet might lead to problems later on. Many children with excess body fat are not diagnosed with obesity because their BMI may appear normal. This study will help us better understand these connections, particularly by identifying children who may be at risk despite having a normal BMI. This study aims to explore how children's diet quality, weight, and mental health are connected.

### Who can participate?

Children aged 6-11 years old who attend school and have parental consent.

### What does the study involve?

The study will involve a one-time evaluation where the InBody device will be used to measure body composition (including fat and muscle mass). The study will also use questionnaires to assess the children's mental health and gather information about their diet. Finally, a blood sample will be collected to check for plasma biomarkers that can give us further insight into their metabolic and inflammatory health.

### What are the possible benefits and risks of participating?

The main goal of this study is to identify early signs of potential health problems related to diet, weight, and mental health. Understanding these connections better will help prevent obesity and related conditions in children. This research will contribute to improving children's health and well-being.

Participation in this study has minimal risks, including slight discomfort during blood sampling and potential emotional discomfort when responding to mental health questionnaires. All materials, including questionnaires and consent forms, are provided in Spanish. Participants will receive professional support if needed, and confidentiality is strictly maintained.

Where is the study run from?

The Institute for Obesity Research at Tecnológico de Monterrey, Mexico

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

May 2024 to September 2025

Who is funding the study?

The Institute for Obesity Research at Tecnológico de Monterrey, Mexico

Who is the main contact?

Dr Cipatli Ayuzo (Principal Investigator), cipatli@tecsalud.mx

## Contact information

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Evaluating the new 2025 obesity classification framework in pediatric athletes: a comparative study with traditional BMI-based classification

### Study objectives

The 2025 obesity classification provides a more accurate assessment of pediatric obesity by distinguishing excess adiposity from muscle mass. This new approach will improve the identification of children at risk for metabolic complications, including those with a normal BMI but excess body fat, allowing for earlier intervention and targeted management strategies.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

1. approved 24/05/2024, Ethics Committee of the Hospital la Mision (Ave Hospital 112, Monterrey, 64718, Mexico; +52 8114924050; investigacion@hospitallamision.com), ref: HZHRMA-te01-001

2. approved 30/05/2024, Hospital Zambrano (Batallon De San Patricio 1112, San Pedro, 66440, Mexico; +528188880000; gdejesus@tec.mx), ref: hzhrma-te01-001

### Study design

Non-interventional single-center cross-sectional study

### Primary study design

Observational

### Study type(s)

Quality of life, Screening

### Health condition(s) or problem(s) studied

Evaluation of nutritional status in Mexican children

## **Interventions**

This non-interventional single-center cross-sectional study will evaluate the correlation between diet quality, weight status, and mental health in schoolchildren. Participants will undergo a single assessment, including dietary intake analysis, anthropometric measurements, and mental health screening. Additionally, plasma biomarkers related to metabolic and inflammatory status will be analyzed. Statistical analyses will explore associations between these variables to identify potential risk factors and early indicators of health outcomes.

## **Intervention Type**

Mixed

## **Primary outcome(s)**

Diet quality and weight status (including excess adiposity and BMI) in schoolchildren measured using the InBody device, which uses bioelectrical impedance analysis (BIA) at one timepoint

## **Key secondary outcome(s)**

1. Diet quality measured using the Children's Diet Quality Questionnaire (Cuestionario de Calidad de la Dieta en Niños, validated in Spanish) at baseline.
2. Mental health measured using the Children's Anxiety and Depression Scale (Escala de Ansiedad y Depresión en Niños) at one timepoint
3. Plasma biomarkers associated with metabolic and inflammatory processes measured using ELISA and targeted metabolomic assays (LC-MS/MS and NMR) in blood at baseline.

## **Completion date**

04/09/2025

## **Eligibility**

### **Key inclusion criteria**

1. Schoolchildren aged 6-11 years
2. Parental/guardian consent for participation
3. Ability to follow study procedures, including completing questionnaires and undergoing assessments
4. Willingness to provide a blood sample for plasma biomarker analysis

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Child

### **Lower age limit**

5 years

### **Upper age limit**

11 years

**Sex**

All

**Total final enrolment**

111

**Key exclusion criteria**

1. Current chronic medical conditions that could affect weight, diet, or mental health (e.g., diabetes, psychiatric disorders, metabolic conditions)
2. Use of medications or supplements that may significantly alter metabolic or mental health status

**Date of first enrolment**

04/09/2024

**Date of final enrolment**

04/12/2024

**Locations****Countries of recruitment**

Mexico

**Study participating centre**

**Hospital Zambrano Hellion**

Batallon De Sa Patricio 1112

San Pedro

Mexico

66440

**Sponsor information****Organisation**

Tecnológico de Monterrey

**ROR**

<https://ror.org/03ayjn504>

**Funder(s)****Funder type**

Not defined

## Funder Name

Instituto Tecnológico y de Estudios Superiores de Monterrey

## Alternative Name(s)

Tecnológico de Monterrey, Tec de Monterrey, Monterrey Institute of Technology, Monterrey Institute of Technology and Higher Education, ITESM, Tec

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Other non-profit organizations

## Location

Mexico

# Results and Publications

## Individual participant data (IPD) sharing plan

The study will use RedCap for secure data collection and management, ensuring participant confidentiality. Individual participant data will not be shared publicly or with third parties without explicit consent, except in cases required by law or ethical review. De-identified data may be shared with other researchers upon request, in accordance with institutional guidelines and ethical standards, and only for research purposes related to obesity, nutrition, or mental health. Any data sharing will be done through secure platforms, ensuring privacy and data protection.

## IPD sharing plan summary

Published as a supplement to the results publication

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		22/05/2025	27/05/2025	Yes	No
<a href="#">Results article</a>		22/05/2025	10/06/2025	Yes	No
<a href="#">Protocol file</a>	version 1	12/04/2024	12/03/2025	No	No
<a href="#">Protocol file</a>			12/03/2025	No	No