

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

Submission date 09/03/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/03/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/06/2025	Condition category 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

Type(s)

Public, Scientific, Principal Investigator

Contact name

Prof Norma Cipatli Ayuzo Del Valle

ORCID ID

<https://orcid.org/0000-0002-8110-3532>

Contact details

Tecnológico de Monterrey
Batallon De San Patricio 1112
San Pedro Garza García
Mexico
66440
+528181850805
cipatli@tecsalud.mx

Type(s)

Scientific

Contact name

Dr Perla Perez-Trevino

ORCID ID

<https://orcid.org/0000-0002-0076-5738>

Contact details

Tecnológico de Monterrey
Batallon De San Patricio 1112
San Pedro
Mexico

66440
+528182533814
perla.perez.trevino@tec.mx

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cross sectional study

Study setting(s)

Hospital

Study type(s)

Quality of life, Screening

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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.

Overall study start date

24/05/2024

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

Age group

Child

Lower age limit

5 Years

Upper age limit

11 Years

Sex

Both

Target number of participants

120

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

Sponsor details

Batallon De San Patricio 1112

San Pedro

Mexico

66440

+52 8115163692

gdejesusgarcia@tec.mx

Sponsor type

University/education

Website

<https://tec.mx/es/investigacion/instituto-de-investigacion-sobre-obesidad>

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

Publication and dissemination plan

Scientific Journals:

The study results will be submitted to peer-reviewed journals focused on pediatrics, nutrition, and obesity, such as Pediatric Obesity or Appetite.

Conference Presentations:

Findings will be presented at national and international conferences related to pediatric health, obesity, and mental health.

Institutional Dissemination:

Results will be shared within the Institute for Obesity Research at Tecnológico de Monterrey and through the university’s communications channels.

Media Outreach:

Key findings will be shared with local and national media outlets to raise awareness about the study’s implications for child health.

Community Engagement:

The research team will work with participating schools to share the findings and promote better health practices within the community.

Social Media and Online Platforms:

Summaries of the study will be shared through the research team’s social media accounts to reach a wider audience.

Intention to publish date

01/06/2025

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?
Protocol file	version 1	12/04/2024	12/03/2025	No	No
Protocol file			12/03/2025	No	No
Results article		22/05/2025	27/05/2025	Yes	No
Results article		22/05/2025	10/06/2025	Yes	No