ISRCTN12172320 https://doi.org/10.1186/ISRCTN12172320

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

Registration date
12/03/2025

Overall study status
Completed

Last Edited
10/06/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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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
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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?
Results article		22/05/2025	27/05/2025	Yes	No
Results article		22/05/2025	10/06/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1	12/04/2024	12/03/2025	No	No
Protocol file			12/03/2025	No	No