Design and methods of a cluster randomised controlled trial addressed to investigate the effects of a school-based intervention on pediatric obesity and other associated outcomes

Submission date	Recruitment status Recruiting	Prospectively registered		
14/03/2025		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
19/03/2025	Ongoing	Results		
Last Edited	Condition category Nutritional, Metabolic, Endocrine	Individual participant data		
30/07/2025		[X] Record updated in last year		

Plain English summary of protocol

Background and study aims

Paediatric obesity, a multi-factorial issue, significantly impacts children's biopsychosocial and economic status, particularly those from lower socio-economic backgrounds, thereby exacerbating social health inequalities in Spain.

Obesity preventive interventions should be multilevel, multicomponent, led by a multidisciplinary team, integrated, equitable, person-centred, sensitive to social inequalities, and grounded in a strong psychosocial theoretical basis.

The SEISMO study aims to evaluate the effectiveness of a Multicomponent, Comprehensive, and Multilevel (MCM) school-based intervention, with follow-up for children until adulthood.

Who can participate?

The SEÍSMO study is a school-based intervention aimed at obesity prevention, involving two stages: innovation and development (I+D) and a multicomponent, comprehensive, multilevel intervention (MCM). The SEÍSMO I+D stage includes children aged 6-12 years and the SEÍSMO MCM stage will recruit children aged 3–12 years.

What does the study involve?

The SEISMO school-based intervention aims to improve healthy lifestyles, resilience, academic performance, and reduce obesity among children. It has two stages:

SEÍSMO I+D Stage (2020-2024): This stage involved creating and testing various modules like physical education, family involvement, healthy spaces, water promotion, and healthy eating in schools.

SEÍSMO MCM Stage (2024-2034): This stage will implement the tested modules over 6 years, focusing on promoting healthy habits, engaging the educational community, and improving school policies and environments.

The intervention uses a metaphor called the Healthy Galaxy to motivate children and families to adopt healthy lifestyles.

What are the possible benefits and risks of participating?

Potential benefits are associated with improved participant lifestyle, adoption of health-promoting schools to facilitate lifestyle, improved academic performance, individual resilience, and reduced incidence of paediatric obesity following the MCM SEISMO intervention. There is a risk from weight-based assessment that evidence suggests may exacerbate obesity numbers, so we aim to incorporate the variable of weight bias internationalization to study and minimise weight stigma through the intervention and incorporate other variables of interest into the assessment protocol to robustly assess the evolution of obesity away from weight-centrism.

Where is the study run from?

SEÍSMO I+D stage addressed 120 Spanish schools prioritizing these are located in disadvantaged communities.

SEÍSMO MCM stage will address 56 Catalan (Spain) schools located in disadvantaged communities.

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

The I+D stage baseline was conducted in 2021-2024 and the SEÍSMO MCM enrolled all the schools in three waves (2024-2025, 2025-2026, and 2026-2027). In both stages, it will be followed up at 18 years old. The final assessment of the last participant who reaches the age of 18 years old will be in December 2042.

Who is funding the study?

The SEÍSMO study is financially supported by Barça Foundation, BNP Paribas Cardif, Aigües de Barcelona & Agbar, Ajuntament de Barcelona, Agència de Salut Pública de Barcelona (ASPB), Ajuntament de Pineda de Mar, Ajuntament de Balaguer, and Ajuntament de Lleida.

Who is the main contact?

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

C.I. PIC-255-20

Study information

Scientific Title

A cluster randomised controlled trial of a School-based Educational Intervention to Stimulate Motivation towards pediatric Obesity prevention among children 3 to 12 years old: the SEÍSMO study

Acronym

SEÍSMO

Study objectives

It is hypothesised that multi-component, comprehensive, multi-level school-based interventions with collaborative approaches that empower the target community towards becoming healthy-promoting schools will have a greater impact on psychological resilience, psychosocial determinants, weight stigma, healthy lifestyles, quality of life, incidence of obesity, academic performance, and weight status (body mass index z-score [zBMI] and waist-to-height ratio [WHtR]).

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 22/10/2020, CEIm Fundació Sant Joan de Déu (Edifici Docent Sant Joan de Déu - c. Santa Rosa, 39-57, 3ª planta, Esplugues de Llobregat, Barcelona, 08950, Spain; +34 (0)93 600 97 51; info@fsjd.org), ref: C.I. PIC-255-20

Study design

School-based cluster randomized controlled trial

Primary study design

Interventional

Study type(s)

Prevention, Quality of life, Efficacy

Health condition(s) or problem(s) studied

Pediatric obesity

Interventions

The SEISMO school-based intervention was conceptualized to positively impact healthy lifestyles, psychological resilience, weight stigma, academic performance, quality of life, the incidence of obesity, zBMI and WHtR.

The creation of the SEÍSMO intervention methodology has been organized in two stages: 1) SEISMO innovation and development (I+D) stage from 2020 to 2024; 2) SEÍSMO multicomponent, comprehensive, and multilevel (MCM) stage expected from 2024 to 2034.

1. The SEISMO I+D

The I+D intervention were carried out along four editions (1st – 2020/2021; 2nd – 2021/2022; 3rd – 2022/2023; 4th – 2023/2024) of 12 months each. The periods between each academic year were dedicated to creating new intervention modules that progressively have been incorporated into the methodology and piloted for reaching the entire educational community: children, teaching staff, parents or caregivers, non-teaching staff, and school managers. The 1st edition served to pilot the physical education module. The 2nd edition included also the family module. During the 3rd edition, the healthy spaces module was additionally added to the intervention methodology, which finally was rounded with the incorporation of the water promotion module, and the healthy eating and sustainable schools' canteens module, during the 4th edition.

2. The SEÍSMO MCM intervention

The SEÍSMO MCM intervention was conceptualized using the SHE pillars approach for the promotion of the children's healthy lifestyles, equity, resilience, and quality of life. All the original intervention modules piloted on the SEÍSMO I+D have been integrated into the SEÍSMO MCM. The new intervention is structured for a minimum of 6 consecutive academic years, and it will be coordinated by the multidisciplinary GF team that will promote the implementation of 50 specific groups of actions structured in three pillars:

- A) Competencies pillar: to promote healthy habits as a comprehensive part of primary school's curricular project that is aligned with the most updated Spanish educational law. It includes eight specific actions organized in: i) five types of activities directly addressed to children and their families, and ii) three types of resources to reinforce these activities.
- B) Educational community pillar: to engage the entire educational community towards adopting the health-promoting schools' approach.

It includes 20 specific actions organized in three action types: i) the activities and resources to consolidate a motor group, ii) the formation and training plan addressed at the entire teaching staff to ensure awareness and skills towards the promotion of a healthy lifestyle, and iii) the communication plan to engage and inform the entire educational community about the

achievements in the creation of a health-promoting school.

C) Policy, environment, and cultural pillar: to lead and innovate the healthy governance of schools by enhancing and strengthening school policies, environment, and culture. It includes 22 specific actions organized into three types: i) the activities and resources to complete a comprehensive diagnosis, ii) the activities and resources to co-create, prioritize, and define the long-term health-promoting school action plan, and iii) the resources to implement and evaluate this action plan.

The full intervention will be progressively offered to the intervention schools. A total range of 1326 - 2178 actions and 289.75 - 363.75 implementation hours will be promoted. Specifically, nine specific groups of actions are directly addressed to children and 41 are indirect.

All the activities and resources addressed for children are adapted according to the child's developmental stage and the curricular standards in three age ranges: i) initial grades (6-7 years); ii) medium grades: 8-9 years; and iii) upper grades: 10-12 years.

The four theoretical bases of SEÍSMO MCM intervention are: i) the IChange model; ii) the Healthy Galaxy metaphor; iii) the Resiliency Theory, operationalized by the Search Institute through the 40 developmental assets, and iv) the motivation interviewing tool.

The Healthy Galaxy is a pedagogical metaphor for the determinants of pediatric obesity. It is based on a fantastic recent story of humanity, where healthy lifestyles decided to take off from planet Earth towards the Healthy Galaxy to create four planets: sleep duration, healthy eating, psychological well-being, and physical activity. This story motivates children and their families to become astronauts and visit each planet. The goal is discovering and reaching the Healthy Galaxy balance to return the healthy lifestyles to Earth. Back on Earth, they will have another mission: to spread everything they have learned. This metaphor guides all interventions and serves as a motivation and gamification strategy to involve the entire educational community.

The intervention will be coordinated by the multidisciplinary GF team and led by school managers and teaching staff. The main initial responsibility of the GF team is to motivate the engagement of the entire educational community to then facilitate and guide the transition towards becoming health-promoting schools.

Control group schools' implication

The following actions will be conducted by each control school: a) an evaluation plan; b) an annual health-related event; c) a comprehensive school diagnosis during the 1st academic year; d) a total of three follow-up meetings are planned for the 1st and 2nd academic years, and four for the subsequent academic years to ensure adherence and define the actions that will be progressively implemented after the baseline; e) a set of national and regional public resources, including training, guidelines, advisory services, health-related materials, and other initiatives, will be promoted equally in the intervention and control group.

Intervention Type

Behavioural

Primary outcome(s)

Weight status measured using Body Mass Index (BMI) and Waist Height to Ratio (WHtR) at baseline, 12, 24, 36 and 48 months, and at the 18-year-old age group.

Key secondary outcome(s))

- 1. Hours of sleep measured using the Sleep-Habits Survey for Adolescents (SHSA) questionnaire at baseline, 12, 24, 36, and 48 months, and at the 18-year-old age group
- 2. Screen time measured using the Screen-Time-based Sedentary Behaviour Questionnaire (SSBQ) at baseline, 12, 24, 36, and 48 months, and at the 18-year-old age group
- 3. Diet quality measured using the KIDMED index questionnaire at baseline, 12, 24, 36, and 48 months, and at the 18-year-old age group
- 4. Physical activity measured using the Physical Activity Unified-7 item Screener (PAU-7S) questionnaire at baseline, 12, 24, 36, and 48 months, and at the 18-year-old age group
- 5. Physical fitness measured using the International Fitness Scale (IFIS) self-rating questionnaire at baseline, 12, 24, 36, and 48 months, and at the 18-year-old age group
- 6. Quality of life measured using the EUROQOL questionnaire (EQ-5D-5L) at baseline, 12, 24, 36, 48 months, and at the 18-year-old age group
- 7. Academic performance measured using the school curricular ratings at baseline, 12, 24, 36, and 48 months. At the age of 18 years the academic level will be self-reported
- 8. Psychosocial determinants measured with an ad hoc questionnaire based on the ASE model through a Likert scale at baseline, 12, and 24 months
- 9. Psychological resilience measured with the Developmental Asset Profile (DAP) questionnaire at baseline, 12, 24 months, and at the 18-year-old age group
- 10. Weight stigma measured with the Weight Bias Internalization Scale (WBIS-M) questionnaire at baseline, 12, 24 months, and at the 18-year-old age group
- 11. Socioeconomic status measured using a self-reported questionnaire about sociodemographic characteristics, academic level, labour market status, and home address at baseline

Completion date

31/12/2042

Eligibility

Key inclusion criteria

1. Children aged 3–12 years and their families who will be enrolled in a participating school located in a census section with an average income per person under the mean in Spain (14.787€) 2. Informed consent signed by parents/legal guardians

Participant type(s)

Population

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 years

Upper age limit

18 years

Sex

Key exclusion criteria

Children or parents/legal guardians with a psychological or physical limitation that make it impossible to participate in some or all the evaluation procedures. Each case will be considered individually, and the GF team offer different evaluation options to include all the children and families.

Date of first enrolment 01/12/2020

Date of final enrolment 31/12/2026

Locations

Countries of recruitmentSpain

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Study participating centre Colegio San Miguel

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Sponsor information

Organisation

Gasol Foundation

ROR

https://ror.org/00jb67179

Funder(s)

Funder type

Industry

Funder Name

BNP Paribas Cardif

Alternative Name(s)

BNP Paribas

Funding Body Type

Private sector organisation

Funding Body Subtype For-profit companies (industry)

Location

France

Funder Name

Barça Foundation

Funder Name

Aigües de Barcelona

Funder Name

Agbar

Funder Name

Agència de Salut Pública de Barcelona

Alternative Name(s)

Barcelona Public Health Agency, ASPB

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Spain

Funder Name

Ajuntament de Barcelona

Funder Name

Ajuntament de Pineda de Mar

Funder Name

Ajuntament de Lleida

Funder Name

Ajuntament de Balaguer

Results and Publications

Individual participant data (IPD) sharing plan

Data sharing will be considered after request to sgomez@gasolfoundation or to gsegun@gasolfoundation.org. SEISMO webpage: https://gasolfoundation.org/es/seismo/

IPD sharing plan summary

Available on request

Study outputs

Outp	out type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Parti</u>	icipant information sheet	version 6	01/11/2023	18/03/2025	No	Yes
<u>Parti</u>	icipant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Prot	ocol file	version 6	01/11/2023	18/03/2025	No	No
<u>Stud</u>	<u>y website</u>	Study website	11/11/2025	11/11/2025	No	Yes