

# 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

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<b>Registration date</b> 19/03/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/07/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 SEÍSMO 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

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**Secondary study design**

Cluster randomised trial

**Study setting(s)**

School

**Study type(s)**

Prevention, Quality of life, Efficacy

**Participant information sheet**

See study outputs table

**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 measure**

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.

## **Secondary outcome measures**

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

## **Overall study start date**

22/10/2020

## **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

**Age group**

Child

**Lower age limit**

3 Years

**Upper age limit**

18 Years

**Sex**

Both

**Target number of participants**

A total of 56 clusters and 4760 participants (85 per cluster). A ratio 1:1 will be followed allocating 28 clusters to each group.

**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 recruitment**

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Terrassa, Barcelona  
Spain  
08227

**Study participating centre**

**Escola Marcel·li Moragas**

C/ Joan I, 5,  
Gavà, Barcelona  
Spain  
08850

**Study participating centre**

**Escola Sant Andreu de la Barca**

C/Josep Tarradellas, 30-38  
Sant Andreu de la Barca  
Spain  
08740

**Study participating centre**

**Escola Pintor Sorolla**

Av. de Ronda, 116,  
Elda, Alicante  
Spain  
03600

**Study participating centre**

**Escola Ballester Fandos**

Avinguda de la Malva-Rosa, 57,  
Valencia  
Spain  
46011

**Study participating centre**

**Escola San Juan de Ribera**

C/ de la Noria, 19,  
Alfara del Patriarca, Valencia  
Spain  
46115



**Study participating centre**

**Escola Gaspar Gil Polo**

C/Miquel Paredes, s/n,  
Valencia

Spain

46018

**Study participating centre**

**Escola Profesor Sanchis Guarner**

C/Pere Patrici Mey, 44,  
València, Valencia

Spain

46019

**Study participating centre**

**Escola Tomás de Villaroya**

Av. del Doctor Tomás Sala, s/n,  
Valencia

Spain

46017

**Study participating centre**

**Escola Santa Joaquina de Vedruna**

C/de la luteria, 40,  
Vinalesa, Valencia

Spain

46114

**Study participating centre**

**Escola San Blas**

Av. de les Cortes Valencianes, 34,  
Albal, Valencia

Spain

46470

**Study participating centre**

**Escola Lluís Guarner**

C/del Doctor Nicasi Benlloch, 128,

València, Valencia  
Spain  
46015

**Study participating centre**  
**Escola Ausias March**  
C/Parque de Nazaret, 3  
Valencia  
Spain  
46024

**Study participating centre**  
**Colegio Luis Feito**  
C/Luis Feito 19,  
Madrid  
Spain  
28047

**Study participating centre**  
**Colegio Nile**  
C/de Castilla la Vieja, 18,  
Fuenlabrada, Madrid  
Spain  
28941

**Study participating centre**  
**Colegio La Dehesa de Humanes**  
Av. de los Deportes, 8  
Humanes de Madrid (España)  
Spain  
28970

**Study participating centre**  
**Colegio Manuel Azaña**  
Av. del Ejército, 5,  
Alcalá de Henares, Madrid  
Spain  
28802

**Study participating centre**

**Colegio San José**

C/Francisco Laguna, 21,

Madrid

Spain

28053

**Study participating centre**

**Colegio Salesianos Carabanchel**

Rda. Don Bosco, 32

Madrid

Spain

8044

**Study participating centre**

**Colegio San José de Valdemoro**

Pl. del Conde,sn.

Valdemoro, Madrid

Spain

28340

**Study participating centre**

**Colegio María Reina**

Av. Orcasur, 42B,

Madrid

Spain

28041

**Study participating centre**

**Colegio Alonso Cano**

C/Alonso Cano, 1

Móstoles, Madrid

Spain

28933

**Study participating centre**

**Colegio Campohermoso**

C/Valdehondillo, 1

Humanes de Madrid, Madrid

Spain

28970

**Study participating centre**

**Colegio Juan Ocaña**

Av. Iker Casillas, 25

Móstoles, Madrid

Spain

28935

**Study participating centre**

**Colegio Pequeño Principe**

C/ de Aragón, 21

Leganés, Madrid

Spain

28914

**Study participating centre**

**Colegio San Miguel**

C/Miralcampo

Navalagamella, Madrid

Spain

28212

**Study participating centre**

**Colegio Carmen Cabezuelo**

C/ Cangas de Onís, 7

Madrid

Spain

28037

**Study participating centre**

**Colegio Santo Angel De La Guardia**

C/Rodetas, 17

Chapinería, Madrid

Spain

28694

**Study participating centre**

**Colegio República del Uruguay**

Av. de Ntra. Sra. de Valvanera, 120

Madrid  
Spain  
28047

**Study participating centre**  
**Colegio Velazquez**  
Av. de Nuevo Versailles, 16  
Fuenlabrada, Madrid  
Spain  
28942

**Study participating centre**  
**Colegio Doctor Severo Ochoa**  
C/Ezcaray, 3  
Madrid.  
Spain  
28032

**Study participating centre**  
**Colegio Nuestra Señora De Montserrat**  
C/Trevélez, 5  
Madrid  
Spain  
28041

**Study participating centre**  
**Colegio Doctora de Alcalá**  
C/Pedro Sarmiento de Gamboa, 11  
Alcalá de Henares, Madrid  
Spain  
28805

## **Sponsor information**

**Organisation**  
Gasol Foundation

**Sponsor details**

Jaume I Street 26-28 Local first floor  
Sant Boi de Llobregat  
Spain  
08830  
+34 (0)938346600  
contact@gasolfoundation.org

**Sponsor type**

Research organisation

**Website**

<https://www.gasolfoundation.org/>

**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

**Publication and dissemination plan**

1. Study protocol
2. Comparative between the weight status results of SEISMO with PASOS 2019, a national and representative Spain Study
3. Comparative between the healthy lifestyles results of SEISMO with PASOS 2019, a national and representative Spain Study

- 4. Results about the first pilot edition. Effects of intervention group vs control group
- 5. Results comparing first edition and second edition. Effects of intervention between both modules and separately
- 6. Results comparing first edition, second, and third edition. Effects of intervention between all modules and separately
- 7. Environment, weight status and healthy lifestyles
- 8. Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

31/12/2043

**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**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 6	01/11/2023	18/03/2025	No	Yes
<a href="#">Protocol file</a>	version 6	01/11/2023	18/03/2025	No	No