

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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Registration date 19/03/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/03/2025	Condition category 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 Cardiff, 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?

PhD Santiago Felipe Gómez Santos, sgomez@gasolfoundation.org

Study website

<https://gasolfoundation.org/es/seismo/>

Contact information

Type(s)

Public, Principal Investigator

Contact name

Dr Santiago Felipe Gómez Santos

ORCID ID

<https://orcid.org/0000-0003-3352-2510>

Contact details

Jaume I Street 26-28 Local first floor

Sant Boi de Llobregat, Barcelona

Spain

08830

+34 (0)938346600

sgomez@gasolfoundation.org

Type(s)

Scientific

Contact name

Mr Genís Según Mercader

ORCID ID

<https://orcid.org/0000-0003-3035-1744>

Contact details

Jaume I Street 26-28 Local first floor

Sant Boi de Llobregat, Barcelona

Spain

08830

+34 (0)938346600

gsegun@gasolfoundation.org

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, 3^a 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

Spain

Study participating centre

Escola Pau Romeva

C/ del Pisuerga, 1

Barcelona

Spain

08028

Study participating centre

Centre d'Estudis Montseny

C/ de Pallars, 410

Barcelona
Spain
08019

Study participating centre

Col·legi Paideia

C/ del Montnegre, 36
Barcelona
Spain
08029

Study participating centre

Escola el Turó

C/ de Peñalara, 19-55
Barcelona
Spain
08031

Study participating centre

Escola Baloo

C/ Harmonia 37
Barcelona
Spain
08035

Study participating centre

Escola Piaget

C/del Llobregós, 194
Barcelona
Spain
08032

Study participating centre

Escola Pare Poveda

Av. de Vallcarca, 220
Barcelona
Spain
08023

Study participating centre
Escola Padre Damián
Av. de Vallvidrera, 10
Barcelona
Spain
08017

Study participating centre
Escola Lluís Vives
C/ de Canalejas, 107
Barcelona
Spain
08028

Study participating centre
Escola Ferran Sunyer
C/ de Viladomat, 2
Barcelona
Spain
08015

Study participating centre
Escola Mercè Rodoreda
C/ del Vesuvi, 35
Barcelona
Spain
08016

Study participating centre
Col·legi Amor de Dios
C/del Teide, 27
Barcelona
Spain
08031

Study participating centre
Escola Ferrer i Guàrdia
C/ del Pedraforca, 3,
Barcelona
Spain
08033

Study participating centre

Escola Ciutat Comtal

C/ Pujalt, 6,

Barcelona

Spain

08033

Study participating centre

Escola Pia Sant Antoni

Rda. de Sant Pau, 72

Barcelona

Spain

08001

Study participating centre

Escola La Pau

C/ d'Extremadura, 15

Barcelona

Spain

08020

Study participating centre

Escola Alfonsa Cavin

Av. dels Rasos de Peguera, 57

Barcelona

Spain

08033

Study participating centre

Escola Prínceps

C/ de l'Artesania, 38

Barcelona

Spain

08042

Study participating centre

Escola Eduard Marquina

C/Jaume Huguet, 22

Barcelona
Spain
08019

Study participating centre

Escola Sant Lluís

C/Arítjols, 12
Barcelona
Spain
08016

Study participating centre

Escola Prim

C/ Bernat Metge, 20
Barcelona
Spain
08019

Study participating centre

Escola Cal Maiol

C/Sagunt, 92
Barcelona
Spain
08014

Study participating centre

Escola Tibidabo

C/ de Joaquim Valls, 10
Barcelona
Spain
08016

Study participating centre

Escola Sant Gervasi

C/ Bòbiles, 37
L'Hospitalet de Llobregat, Barcelona
Spain
08905

Study participating centre

Escola Charlie Rivel

C/ de Llançà, 20

L'Hospitalet de Llobregat, Barcelona

Spain

08904

Study participating centre

Escola Pep Ventura

Plaça Guernica, s/n

L'Hospitalet de Llobregat, Barcelona

Spain

08903

Study participating centre

Col·legi Alegre

C/ d'Andorra, 23, 25

L'Hospitalet de Llobregat, Barcelona

Spain

08906

Study participating centre

Escola Pau Casals

C/ Almería, 1

L'Hospitalet de Llobregat, Barcelona

Spain

08905

Study participating centre

Escola Pau Vila

C/ Menorca, 1

L'Hospitalet de Llobregat, Barcelona

Spain

08905

Study participating centre

Escola Josep Maria Folch i Torres

Av. d'Isabel la Catòlica, 61

L'Hospitalet de Llobregat, Barcelona

Spain

08906

Study participating centre

Escola Sant Josep Obrer

C/Covadonga, 2

L'Hospitalet de Llobregat, Barcelona, España

Spain

08906

Study participating centre

Escola Ernest Lluch

Passatge Colom, 19

L'Hospitalet de Llobregat, Barcelona

Spain

08904

Study participating centre

Escola Utmar Hospitalet

C/ Mina, 24

L'Hospitalet de Llobregat, Barcelona

Spain

08906

Study participating centre

Escola Lola Anglada:

Av. d'Isabel la Catòlica, 41

L'Hospitalet de Llobregat, Barcelona

Spain

08906

Study participating centre

Escola Pablo Neruda

C/ Cornellà, 37

L'Hospitalet de Llobregat, Barcelona

Spain

08906

Study participating centre

Escola Utmar Esplugues

C/ del Molí, 48

Esplugues de Llobregat, Barcelona
Spain
08950

Study participating centre

Escola El Gornal

Av. Carmen Amaya, 44
L'Hospitalet de Llobregat, Barcelona
Spain
08902

Study participating centre

Escola Sant Miquel

C/ Lluís Domènech i Montaner, 1
Cornellà de Llobregat, Barcelona
Spain
08940

Study participating centre

Escola Alexandre Gali

C/Cirerer, 1-7
Cornellà de Llobregat, Barcelona
Spain
08940

Study participating centre

Escola Jacint Verdaguer

C/ Muralla, 8
Castelldefels, Barcelona
Spain
08860

Study participating centre

Escola Jacint Verdaguer

Av. de Salvador Allende, 14, 16
Cornellà de Llobregat, Barcelona
Spain
08940

Study participating centre
Escola Sant Antoni Maria Claret
C/Manuel Mariné, 11
Cornellà de Llobregat, Barcelona
Spain
08940

Study participating centre
Escola Tanit
C/ Pirineus, 5
Santa Coloma de Gramenet, Barcelona
Spain
08923

Study participating centre
Escola Beethoven
C/ Wagner, 16
Sta Coloma de Gramenet, Barcelona
Spain
08923

Study participating centre
Escola Rosello Porcel
Rambla de Sant Sebastià, 92
Sta Coloma de Gramenet, Barcelona
Spain
08922

Study participating centre
Escola Les Neus
Rambla del Fondo, 50
Santa Coloma de Gramenet, Barcelona
Spain
08922

Study participating centre
Escola FEDAC Santa Coloma
C/Sant Ramon, 2
Santa Coloma de Gramenet, Barcelona
Spain
08922

Study participating centre

Escola Folch i Torres

C/Wagner, 68-84
Badalona, Barcelona
Spain
08917

Study participating centre

Escola Baldomer Sola

Av. del Marquès de Mont-Roig, 178
Badalona, Barcelona
Spain
08918

Study participating centre

Escola Mare de Deu Salut

Passeig de la Salut, 36
Badalona, Barcelona
Spain
08914

Study participating centre

Escola Joan Llongueras

C/ Sant Fermí, 3
Badalona, Barcelona
Spain
08917

Study participating centre

Escola Baldiri Reixac

C/Juan Valera, 159
Badalona, Barcelona
Spain
08914

Study participating centre

Escola Maria Ward

C/Gravina, 1

Badalona, Barcelona
Spain
08913

Study participating centre
Escola Santísima Trinidad
C/ de Santiago, 57
Badalona, Barcelona
Spain
08918

Study participating centre
Escola Arrels
C/ Provença, 7
Badalona, Barcelona
Spain
08914

Study participating centre
Escola Joan Coret
Plaça Voluntaris Olímpics, 3
Badalona, Barcelona
Spain
08917

Study participating centre
Escola Antoni Botey
Av. del Doctor Bassols, 77
Badalona, Barcelona
Spain
08914

Study participating centre
Escola Ramiro de Maeztu
C/ Ramiro de Maeztu, s/n
Badalona, Barcelona
Spain
08913

Study participating centre

Escola Les Ciències

C/ de la Ciència, 19
Badalona, Barcelona
Spain
08917

Study participating centre

Escola Ginesta

C/ de la Circumval·lació, S/N
Montcada i Reixac, Barcelona
Spain
08110

Study participating centre

Escola Amat Verdú

C/ Marcelino Menéndez y Pelayo
Sant Boi de Llobregat, Barcelona
Spain
08830

Study participating centre

Escola Casablanca

Plaça dels Gegants, 2
Sant Boi de Llobregat, Barcelona, España
Spain
08830

Study participating centre

Escola Barrufet

Plaza Agricultura, 6
Sant Boi de Llobregat, Barcelona
Spain
08830

Study participating centre

Escola Antoni Gaudí

C/Pablo Picasso
Sant Boi de Llobregat, Barcelona
Spain
08830

Study participating centre

Escola Ciurana

C/Manuel de Falla, 2
Sant Boi de Llobregat, Barcelona
Spain
08830

Study participating centre

Escola Angel Tobies

Av. Riera de la Bisbal, 79
El Vendrell, Tarragona
Spain
43700

Study participating centre

Escola Gaspar Portolà

C/Escoles, 0,
Balaguer, Lleida
Spain
25600

Study participating centre

Escola Montroig

C/Marta Mata, 48
Balaguer, Lleida
Spain
25600

Study participating centre

Escola Pia Balaguer

C/Barcelona, 73
Balaguer, Lleida
Spain
25600

Study participating centre

Escola La Noguera

C/Joan Miró, 2,

Balaguer, Lleida
Spain
25600

Study participating centre
Escola Angel Guimerà
C/Àngel Guimerà, s/n,
Balaguer, Lleida
Spain
25600

Study participating centre
Escola Vedruna Balaguer
C/ Pare Sanahüja, 39
Balaguer, Lleida
Spain
25600

Study participating centre
Escola SAFA
C/ Nicolás Longaron, 6
La Llagosta, Barcelona
Spain
08120

Study participating centre
Escola Joan Maragall
Passeig del Pintor Sert, 1-9,
La Llagosta, Barcelona
Spain
08120

Study participating centre
Escola Les Planes
C/de la Constitució, 2,
La Llagosta, Barcelona
Spain
08120

Study participating centre

Escola Gilpe

Av. Primer de Maig, 6, 8,
La Llagosta, Barcelona
Spain
08120

Study participating centre

Institut Escola La Mina

Rambla de la Mina 36,
Sant Adrià de Besòs, Barcelona
Spain
08930

Study participating centre

Escola Catalunya

Plaça de Marie Curie, C. de Lleida, s/n,
Sant Adrià de Besòs, Barcelona
Spain
08930

Study participating centre

Escola Cascavell

C/d'Argentina, sn,
Sant Adrià de Besòs, Barcelona
Spain
08930

Study participating centre

Escola Sant Jordi

C/Verdaguer, 15,
Pineda de Mar, Barcelona
Spain
08397

Study participating centre

Escola Antoni Doltra

C/ Narcis Monturiol, 55,
Pineda de Mar, Barcelona
Spain
08397

Study participating centre

Escola Jaume I

C/Lluís Vives, 5, 7,
Pineda de Mar, Barcelona
Spain
08397

Study participating centre

Escola Montpalau

Av. Generalitat, s/n,
Pineda de Mar, Barcelona
Spain
08397

Study participating centre

Escola Mediterrania

Plaza Pau Casals, 0 S N (Urb Can Cornet)
Pineda de Mar, Barcelona
Spain
08397

Study participating centre

Escola Pràctiques I

C/Ballester, 21
Lleida
Spain
25002

Study participating centre

Escola Santa Maria de Gardeny

C/Rossinyol, 2
Lleida
Spain
25003

Study participating centre

Escola Gassó i Vidal

C/Rocabruna, 1,

Ripollet, Barcelona
Spain
08291

Study participating centre
Escola Francesc Escursell i Bartalot
Ctra. de l'Estació, 9
Ripollet, Barcelona
Spain
08291

Study participating centre
Escola Miquel Martí i Pol
Av. dels Jocs Olímpics, 7,
Viladecans, Barcelona
Spain
08840

Study participating centre
Escola Sant Josep
Travessera de Barcelona, 78, 82,
Sant Vicenç dels Horts, Barcelona
Spain
08620

Study participating centre
Escola Mare de Déu del Carme
C/ del Dr. Robert, 5, 9,
El Prat de Llobregat, Barcelona
Spain
08820

Study participating centre
Escola Auró
C/ del Germà Joaquim, 128,
Terrassa, Barcelona
Spain
08223

Study participating centre

Escola Joan XXIII

C/Joan XXIII, 27,
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 Iutera, 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?
Participant information sheet	version 6	01/11/2023	18/03/2025	No	Yes
Protocol file	version 6	01/11/2023	18/03/2025	No	No