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# Cohort study on child health, lifestyles and weight status in the municipality of Sant Boi de Llobregat

**Submission date**
14/05/2024

**Recruitment status**
No longer recruiting

**Registration date**
24/07/2024

**Overall study status**
Ongoing

**Last Edited**
24/07/2024

**Condition category**
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Spain is among the European countries with the highest prevalence of childhood obesity. However, the evidence from longitudinal studies including populations evaluated since early childhood is still scarce in Spain and globally. The environment where children grow in the first years of life is a key determinant of body weight status and other health issues in later stages of human development. Studying deeply the key determinants of the pediatric obesity epidemic is crucial to better plan structural and health promotion interventions capable of reversing the trend. The aim of this study is to investigate lifestyle and environmental factors associated with quality of life and weight status from the preschool ages (3 to 8 years old) in Sant Boi de Llobregat. In addition, the validation of the Physical Activity Unit- 7 items Screener (PAU-7S) questionnaire for the same age range population is included as a substudy.

Who can participate?
Children aged 3–8 years enrolled in a participating school in Sant Boi de Llobregat with positive informed consent signed by parents/legal guardians

What does the study involve?
The study consists of a cohort study of the population aged 3 to 8 years in the municipality of Sant Boi de Llobregat. The aim is to follow up with the participants until adulthood. For the baseline evaluation, the recruitment will be done through schools. All schools in the municipality will be invited to participate and through them the participants will be recruited and evaluated (19 of 22 have confirmed their participation). After the baseline assessment and the subsequent follow-up assessments, the families will receive a report with the results of their children's lifestyles, based on their answers to the questionnaires. A global report per school is also planned. Additionally, the results will be presented to the Sant Boi de Llobregat City Council with the aim of raising awareness of children's health status and stimulating the activation of actions to promote healthy habits among children and their families.

What are the possible benefits and risks of participating?
The study offers a range of significant benefits, including:

1. Community engagement: actively involving a population-based study on lifestyle and childhood obesity.
2. Raising awareness of healthy lifestyles: seeing actions of this type carried out in the school and reflecting on their own lifestyles.
3. Providing resources: distributing informative materials on the results to motivate and cultivate reflection on lifestyle and how to improve it.
4. Mobilize the key agents of the territory to start initiatives to promote healthy habits in the child population.
This study carries no inherent risks.

Where is the study run from?
Gasol Foundation with Sant Boi de Llobregat City Council (Spain)

When is the study starting and how long is it expected to run for?
December 2017 to December 2039

Who is funding the study?
Sant Boi de Llobregat City Council (Spain)

Who is the main contact?
1. Dr Santiago Felipe Gómez Santos, sgomez@gasolfoundation.orgb
2. Silvia Torres Escurriola, storres@gasolfoundation.org
3. Dra Cristina Vaqué-Crusellas, cristina.vaque@uvic.cat

# Contact information

### Type(s)
Principal investigator

### Contact name
Dr Santiago F. Gómez Santos

### ORCID ID
https://orcid.org/0000-0003-3352-2510

### Contact details
Jaume I
26-28 street
Office First Floor
Sant Boi de Llobregat, Barcelona
Spain
08830
+34 (0)938 34 66 00
sgomez@gasolfoundation.org

### Type(s)
Public

### Contact name
Miss Silvia Torres Escurriola

**ORCID ID**
https://orcid.org/0009-0002-3085-6531

**Contact details**
Jaume I
26-28 street
Office First Floor
Sant Boi de Llobregat, Barcelona
Spain
08830
+34 (0)938 34 66 00
storres@gasolfoundation.org

**Type(s)**
Scientific

**Contact name**
Dr Cristina Vaqué-Crusellas

**ORCID ID**
https://orcid.org/0000-0001-5637-3242

**Contact details**
Carrer Sagrada Família, 7
Vic
Spain
08500
+34 (0)938861222
cristina.vaque@uvic.cat

# Additional identifiers

**Protocol serial number**
PIC-144-18

# Study information

**Scientific Title**
Study protocol of the SANTBOISA study: a cohort investigating determinants and body weight status from preschool ages in Sant Boi de Llobregat

**Acronym**
SANTBOISA

**Study objectives**
The weight status, lifestyles and environmental factors of children from 3 to 8 years are able to determine the evolution of weight status, healthy habits and quality of life in the later stages of their growth.

**Ethics approval required**

Ethics approval required

## Ethics approval(s)
Approved 25/10/2018, CEIm Fundació Sant Joan de Déu (C. de Sta. Rosa, 39, 08950 Barcelona, Esplugues de Llobregat, 08950, Spain; +34 (0)936009751; frecerca.ceic@sjd.es), ref: PIC-144-18

## Primary study design
Observational

## Study design
Observational cohort study

## Study type(s)
Prevention

## Health condition(s) or problem(s) studied
Factors associated with pediatric obesity and quality of life from early childhood

## Interventions
SANTBOISA is a cohort study carried out in the municipality of Sant Boi de Llobregat. All 3- to 8-year-old students enrolled in the participating schools will be invited. The recruitment process and data collection will be conducted through 19 of 22 schools located in Sant Boi de Llobregat. The goal is to obtain as much participation as possible from all classes where children are enrolled. This means that following the Spanish educational system will be invited to participate all children from I3, I4 and I5 of early childhood education and 1st, 2nd and 3rd of primary education.

The first phase is dedicated to recruiting the participating schools. In this phase the researchers will be holding a meeting with the teachers to explain the study and invite them to participate. Afterwards, the documentation to recruit the families will be sent to the school in envelopes and the teachers will be in charge of delivering them to the families and collecting them back. Researchers will also offer the possibility of holding informative meetings with families.

In the second phase, data collection will be carried out and data will be collected as follows: The investigators will go to the school on the day agreed upon with the teaching team. They will collect, review and manage the documentation returned to the school by the families. Once the students authorized to participate have been confirmed, data collection will begin.

The data will be collected directly from the children are anthropometric data (weight, height and waist circumference). Additionally, 10% of the randomly selected sample will participate in the validation of the PAU-7S questionnaire for children aged 3-8 years old, because this questionnaire was originally validated for children and adolescents aged 8-16 years. For this purpose an ActiGraph wGT3X-BT accelerometer will be used as gold standard and for this reason these devices will be placed on the wrists of participant children. Moreover, an accelerometry diary will be distributed to their parents/legal guardians.

Data on children's lifestyles will be collected through their parents/legal guardians. This information will be obtained through validated questionnaires on physical activity, diet quality, psychological well-being, screen time and sleep that the parents/legal guardians will receive together with the informed consent just at the beginning of the study. They will complete these questionnaires in case they accept their participation. Within the gathered data will be specific

items about the postal address, the parents' perception of their children's weight and restrictive behaviors that parents have with their children in relation to food.

In addition, parents/legal guardians will be invited to complete two questionnaires about themselves. The first, delivered in paper, is very brief and asks about their date of birth, gender, weight, height, and socioeconomic data such as level of education, occupation and profession. The second questionnaire will be delivered using an online system, asks about lifestyles including physical activity, diet quality, sleep, screen time and psychological well-being.

The third phase of the study is dedicated to return the results to the participant families. The report will include the overall scores obtained in the different questionnaires and the recommendations in relation to that habit for the corresponding age. In addition, a report will also prepared and delivered to each school with the average result of all participants in their school and for all the municipality.

This methodology will be carried out for all the subsequent follow-up evaluations every 3 years. It is foreseen to be able to carry out the follow-up through the educational centers of the municipality until the participants reach 15-16 years of age when they will be attending 4th grade of secondary compulsory education.

In order to achieve this objective, the Sant Boi de Llobregat City Council is supporting and promoting the study in schools and it is expected that it will also be carried out in high schools in the coming years. Participants are expected to be followed into adulthood when an individual follow-up will be required because they will be out of the compulsory educational system.

## Intervention Type
Behavioural

## Primary outcome(s)
Measured at baseline and each follow-up every 3 years until adulthood. In the case of the quality of life variable, from the age of 9 years onwards, this variable will be collected through the same questionnaire, but it will be the children who will complete it.
1. Weight status: measured through weight (kg), height (m) and waist circumference (cm). Weight and height will be used to calculate the BMI (kg/m$^2$) and zBMI. Weight and height will be collected with light clothing and without shoes. For waist circumference measurement, the participant will be asked to lift the t-shirt while being measured. The SECA 899 scale will be used to measure weight, with a 100 g precision. Height will be measured with the SECA 217 portable stadiometer to the nearest 1 mm. Waist circumference will be measured with the tape SECA 201 to the nearest 1 mm. All measurements will be performed by trained field researchers and ensure children's comfortability
2. Quality of life recorded using the 11-item KIDSCREEN10 questionnaire. Children's families will ask this scientifically validated questionnaire that includes 10 items about physical, psychological and social well-being. The 11th item corresponds to an overall question about children's health status.

## Key secondary outcome(s)
The following children and adult variables will be collected through different questionnaires and this will be reported by the families at baseline and each follow-up every 3 years until the child’s adulthood. After 9 years of age, the children's variables will be collected through the same questionnaires, but they will be the children to complete them.
1. Children:

1.1. Adherence to the Mediterranean diet will be recorded by the 16 items of the KIDMED index questionnaire that enable a dichotomous answer (yes/no).
1.2. Physical activity will be assessed by the child's Physical Activity Unit - 7 items Screener (PAU-7S). An accelerometer (ActiGraph wGT3X-BT) will be worn during 9 days by a randomly selected 10% of the sample, to objectively measure physical activity and sleep data with the purpose of validating the questionnaire within 3-8-year-old children. This questionnaire was originally validated for children and adolescents aged 8-16 by our research group and the validation study is published elsewhere. The questionnaire collects the minutes of physical activity performed by the children during the week.
1.3. Sedentary behavior will be evaluated by the four-item Screen-time Sedentary Behavior Questionnaire (SSBQ). This questionnaire asks about the daily minutes of use of TV, computer /tablet, video games and smartphone during weekdays and weekends.
1.4. Sleep hours measured using four questions from the Sleep Survey for Adolescents questionnaire (SHSA). The questionnaire asks about the most common time to go to sleep and wake up on weekdays and weekend days in order to obtain total hours of sleep.
1.5. Additional indicators: gender, birth date, birth weight, birth country, number of years living in Spain, home address, number of adults (older than 18 years old) and children (minor than 18 years old) living in the household and breastfeeding. Additionally, they will be asked about the number of family meals per week and the weekly frequency of family physical activity during leisure time. The indicators birth date, birth weight, birth country and number of years living in Spain will be taken at the baseline only.

2. Parents:
2.1. Diet quality will be recorded by the four-question Short Diet Quality Screener Questionnaire (SDQS)
2.2. Physical activity and sedentary behavior will be assessed by the seven-item REGICOR short physical activity questionnaire
2.3. Sleep hours will be assessed using four questions from the Sleep Survey for Adolescents questionnaire (SHSA)
2.4. Self-perceived stress evaluated using the 10-item Perceived Stress Scale questionnaire (PSS)
2.5. Parental perception of the child's weight determined through one question of the questionnaire of the ALADINO study 2015. Parental feeding practices will be assessed by the 15 items from the Child Feeding Practice Questionnaire (CFQ). In the case of this variable, this will only be collected until the child is 12 years old.
2.6. Additional indicators: gender, weight, height, birth date, birth weight, birth country, number of years living in Spain, home address, educational level, occupation and labour market status, annual home income and smoking habit

### Completion date
31/12/2039

# Eligibility

### Key inclusion criteria
1. Children aged 3–8 years (I3, I4 and I5 of early childhood education and 1st, 2nd and 3rd of primary education) who were enrolled in a participating school in Sant Boi de Llobregat
2. Positive, informed consent signed by parents/legal guardians

### Participant type(s)
Learner/student

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
3 Years

### Upper age limit
8 Years

### Sex
All

### Key exclusion criteria
1. Children without parental or legal authorization
2. Each case with an intellectual disability was evaluated with the corresponding teachers and parents or legal guardians before exclusion
3. Children who don’t feel comfortable participating in the study when the research team will be in the school carrying out the measurements

### Date of first enrolment
01/09/2021

### Date of final enrolment
31/12/2024

## Locations

### Countries of recruitment
Spain

### Study participating centre
**Escola Benviure**
Carrer de Can Paulet, 1
Sant Boi de Llobregat, Barcelona
Spain
08830

### Study participating centre
**Escola Rafael Casanova**
Carrer de Joaquim Rubió i Ors, 97-99,
Sant Boi de Llobregat, Barcelona
Spain
08830

**Study participating centre**
**Escola Casablanca**
Plaça dels Gegants, 2
Sant Boi de Llobregat, Barcelona
Spain
08830

**Study participating centre**
**Escola Josep Maria Ciurana**
Carrer Manuel de Falla, 2
Sant Boi de Llobregat, Barcelona
Spain
08830

**Study participating centre**
**Escola Ciutat Cooperativa**
Carrer Ramon Llull, s/n
Sant Boi de Llobregat, Barcelona
Spain
08830

**Study participating centre**
**Escola Barrufet**
Plaza Agricultura, 6
Sant Boi de Llobregat, Barcelona
Spain
08830

**Study participating centre**
**Escola Marianao**
Carrer dels Xiprers, 15
Sant Boi de Llobregat, Barcelona
Spain
08830

**Study participating centre**
**Escola Vicente Ferrer**
Carrer de Salvador Aulestia i Barriac, 9
Sant Boi de Llobregat, Barcelona

Spain
08830

**Study participating centre**
**Escola Parellada**
Carrer Mossèn Pere Tarrés, 33
Sant Boi de Llobregat, Barcelona
Spain
08830

**Study participating centre**
**Escola Antoni Tàpies**
Carrer de Pau Claris, 6
Sant Boi de Llobregat, Barcelona
Spain
08830

**Study participating centre**
**Escola Montbaig**
Carrer Salvador Seguí, 7
Sant Boi de Llobregat, Barcelona
Spain
08830

**Study participating centre**
**Escola Amat Verdú**
Carrer de Marcelino Menéndez y Pelayo, s/n
Sant Boi de Llobregat, Barcelona
Spain
08830

**Study participating centre**
**Escola Vedruna**
Carrer de Lluís Castells, 20
Sant Boi de Llobregat, Barcelona
Spain
08830

**Study participating centre**

**Collegi Llor**
Carrer de Lluís Companys, 50
Sant Boi de Llobregat, Barcelona
Spain
08830

**Study participating centre**
**Escola Pedagogium Cos**
Carrer de Marià Fortuny, 75
Sant Boi de Llobregat, Barcelona
Spain
08830

**Study participating centre**
**Escola Molí Nou**
Carrer Joan Maragall, 5
Sant Boi de Llobregat, Barcelona
Spain
08830

**Study participating centre**
**Escola Antoni Gaudi**
Carrer Pablo Picasso
Sant Boi de Llobregat, Barcelona
Spain
08830

**Study participating centre**
**Colegio Santo Tomás**
Carrer d'Eusebi Güell, 35
Sant Boi de Llobregat, Barcelona
Spain
08830

**Study participating centre**
**Escola Joan Bardina**
Carrer de Marià Fortuny, 16, 18
Sant Boi de Llobregat, Barcelona
Spain
08830

# Sponsor information

### Organisation
Sant Boi de Llobregat Council

# Funder(s)

### Funder type
Government

### Funder Name
Sant Boi de Llobregat Council

# Results and Publications

### Individual participant data (IPD) sharing plan
All datasets will be available for research organizations from the initial project edition without any data limitations. Interested organizations can request access by contacting the Gasol Foundation's research and programs global director: Santiago Felipe Gómez Santos (sgomez@gasolfoundation.org). The research organization will be asked to inform about the name and legal status of the organization, contact name and email, and the main objective of using the dataset. Upon reviewing this information, if the main objective upholds the ethical standards and aligns with the Gasol Foundation's mission of the Gasol, the organization will sign a document outlining the following:
1. Ethical use of the data
2. The dataset analysis objective
3. Commitment to share analysis details with the Gasol Foundation

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |