

Physical activity, sedentary behaviours and obesity in Spanish youth - PASOS study

Submission date 06/08/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/08/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/09/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Physical activity promotion is crucial to achieving an adequate development of children and adolescents. The scientific evidence and the international agencies recommendations state that a minimum of 60 minutes per day of moderate to vigorous physical activity should be recommended to children and adolescents. Although is well-recognized the importance of this field of intervention and research, Spain lacks previous evidence to determine the prevalence of physical inactivity among youth. For this reason, the aim of the PASOS study is to determine the prevalence of physical inactivity in Spain and the cross-sectional and prospective association of Physical Activity (PA) with obesity incidence in children and adolescents.

Who can participate?

Children aged 8-16 years old from 242 schools of the 17 autonomous communities of Spain and parents can take part in the study

What does the study involve?

Children and their parents will complete a number of questionnaires about their physical activity, lifestyle and health. Children will also have measurements taken of weight, height, and waist circumference. This session will take approximately one hour. A small number of children chosen randomly will also be asked to wear a device to measure activity for nine days.

What are the possible benefits and risks of participating?

No direct benefit but the obtaining of representative data about the physical inactivity prevalence of Spanish youth will benefit society.

No risks have been identified from the participation in this study.

Where is the study run from?

Gasol Foundation, Barcelona, Spain

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

March 2019 to December 2022

Who is funding the study?
Gasol Foundation, Spain

Who is the main contact?
Dr Santiago Felipe Gómez Santos
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Study website
<https://www.gasolfoundation.org/en/estudio-pasos/>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1

Study information

Scientific Title
Physical Activity, Sedentarism and Obesity of Spanish - PASOS study

Acronym
PASOS

Study objectives

Physical activity (PA) is a predictor of obesity incidence in children and adolescents. Furthermore, PA is prospectively associated with lifestyle factors such as eating behavior, sleep quality / duration and quality of life. Additionally, parental and environmental factors are predictive for changes in PA in children and adolescents.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 17/12/2018, CEIm Fundació Sant Joan de Déu (Medical Research Ethics Committee Sant Joan de Déu Foundation, Santa Rosa, 39-57 08950 Esplugues del Llobregat, Barcelona, Spain; 936 00 97 51; info@fsjd.org), ref: PIC-179-18

Study design

Cross-sectional cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

School

Study type(s)

Diagnostic

Participant information sheet

Not available in web format

Health condition(s) or problem(s) studied

Physical activity, lifestyles, obesity

Interventions

In this cross-sectional study, children, adolescents, and their parents randomly selected from schools in Spain will answer a set of questionnaires to assess physical activity and lifestyle, and have physical measurements taken as follows:

CHILDREN and ADOLESCENTS

- Anthropometric measurements (body weight, height, and waist circumference)
- Questionnaires (diet, physical activity, sleep, quality of life)
- An accelerometer was worn by a randomly selected 10% of the sample group, to objectively measure physical activity and sleep data. Children will wear the ActiGraph wGT3X-BT accelerometer for 9 days.

PARENTAL VARIABLES

Two questionnaires will be delivered to each participant children/adolescent in order to be answered separately by parents/legal representatives.

- Anthropometric data

- Lifestyle and work
- Birthweight of children and if they received breastfeeding

Parents also will answer online questionnaires about their own lifestyles:

- Diet quality
- Self-perceived stress
- Environmental variables

The main goal will be to capture information to estimate, in the future the level of exposure to certain environmental contaminants such as air pollution, level of noise or access to green spaces.

Parents also will answer online questionnaires about their children's lifestyles:

- Sleep quality
- Quality of life

Time points: The questionnaires were answered during an evaluation session in the school carried out by trained researchers. 1 session of 1 hour per group class for all the 242 participant schools, 2 sessions of 1 hour each for the 22 group class participants in the accelerometer protocol. The majority of the data collection has been carried out from April to June 2019 but 3 schools additional schools are going to participate until the end of October 2019.

Where: The questionnaires were answered in the computer room of each school.

Selection: Randomization was performed by a four-stage sampling procedure. To obtain a sample of 4508 children/adolescents, assuming a mean of 18-20 pupils per classroom, 242 classrooms from 17 Spanish autonomous communities are required: 121 from primary schools (grades 3-6) and 121 from secondary schools (levels 1-4). In the first step, 121 municipalities were randomized with equal distribution across 3 population strata: 2000-30,000, 30,001 to 200,000, and more than 200,000 inhabitants. The total number of selected municipalities in each autonomous community is proportional to the youth population of Spain aged 8 to 16 years living in the corresponding autonomous community (20). In a second step, 242 schools were randomized from the selected municipalities, along with up to three replacements for each selected school to account for census data error or centres not willing to participate. In a third step, scholar-year per school was randomized. In the fourth and final step, a classroom for each scholar-year was randomized and invited to participate. All the students of the selected classrooms were invited to participate.

As commented, the aim is to recruit 4508 children and their parents from 242 schools in 17 Spanish autonomous communities. Ceuta and Melilla, two autonomous cities in North Africa with less than 0.8% of the total Spanish population aged 8 to 16 years, are not be included for logistical reasons. Selected educational centres first receive an invitation letter signed by the president of the Gasol Foundation (Pau Gasol) and accompanied by support letters from the Spanish Ministry of Education, the Spanish Ministry of Health, Consumer Affairs and Social Welfare, the Spanish Council of Sports and the High Commissioner of Spain against childhood poverty, and each autonomous region's departments of education and/or health and sports. In a second step, Gasol Foundation staff call each invited centre to confirm their interest in participating. In a third step, the regional coordinators of the PASOS project contact interested educational centres to introduce them to the study and invite them to participate. In the participating schools, parents (or legal guardians) are invited by teachers designated by school administrators and receive an envelope containing instructions to complete the requested

documentation, two copies of the informed consent form, and two copies of the short questionnaires to be completed by an adult. When the school receives a signed copy of the informed consent, the child participant and their family are included in the PASOS study.

Intervention Type

Other

Primary outcome measure

Physical activity (PA) assessed by the child's Physical Activity Unified - 7 items Screener (PAU-7S) Also, Total-PA, PA intensities, sedentary time, and sleep duration were objectively measured by accelerometers in 10% of the participants randomly selected from the entire sample. Children wear the ActiGraph wGT3X-BT accelerometer for 9 days.

Secondary outcome measures

1. Children and adolescents:

1.1 Body weight, height, and waist circumferences will be measured with the subjects wearing a t-shirt and light trousers. The measurements will be performed without shoes and using an electronic scale (SECA 899), to the nearest of 100 g, a portable SECA 217 stadiometer (to the nearest 1 mm), and a metric tape SECA 201 (to the nearest 1 mm). Using a flexible non-stretch tape measure, waist circumference is measured by trained field researchers in the narrowest zone between the lower costal rib and iliac crest, in the supine decubitus and horizontal positions.

1.2 Sedentary behavior: Will be measured by the Screen-time Sedentary Behaviour Questionnaire (SSBQ)

1.3 Diet: Adherence to the Mediterranean diet will be recorded by the KIDMED index questionnaire

1.4 Sleep duration: The hours of sleep will be recorded by 4 questions from the Sleep Habits Survey for Adolescents (SHSA)

1.5 Quality of life: Will be measured by the EQ-5D-Y-5L.

2. Parents:

2.1 Gender; weight and height (self-reported), smoking habit, educational level, work situation, general health status, sleep duration, and the level of physical activity and sedentariness by the REGICOR Short PA Questionnaire

2.2 Birthweight of children and if they received breastfeeding or not, measured by self-report

2.3 Diet quality will be evaluated by the short Diet Quality Screener

2.4 Self-perceived stress will be measured by the Perceived Stress Scale (PSS)

2.5 Environmental variables: the living address and information about the size of the flat, and if the room where children/adolescent sleeps is open to the street or not

2.6 Sleep quality (of children) will be evaluated by the BEARS questionnaire

2.7 Quality of life (of children) will be measured by the EQ-5D-Y-5L

Overall study start date

01/11/2018

Completion date

31/12/2022

Eligibility

Key inclusion criteria

1. Be registered in a primary or secondary education school of an originally selected school
2. Have the informed consent signed positively by the parents/legal representatives

Participant type(s)

Healthy volunteer

Age group

Child

Sex

Both

Target number of participants

4508

Total final enrolment

3534

Key exclusion criteria

1. Students that elected to not participate
2. Student with a disability that impedes the planned measurements. Each case will be assessed with the teacher's team.

Date of first enrolment

01/03/2019

Date of final enrolment

31/10/2019

Locations**Countries of recruitment**

Spain

Study participating centre

Gasol Foundation

Sant Boi de Llobregat

Spain

08830

Sponsor information**Organisation**

Fundación PROBITAS

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Sponsor type

Charity

Website

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Organisation

Barça Foundation

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Sponsor type

Charity

Website

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Organisation

Banco Santander

Sponsor details

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Sponsor type

Industry

Website

Funder(s)

Funder type
Charity

Funder Name
Gasol Foundation

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal
- Cross-sectional main results - October 2019.
- PAU-7S questionnaire callibration in a representatives sample - December 2019.
- Lifestyles of Spanish children and Adolescents - November 2019.

Intention to publish date
31/10/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. At this stage the steering committee of the PASOS study haven't decided yet if the datasets will be available in the future or not. For this trial registration is preferable to state that the datasets will not be available before circling back the decisions to all the members of the steering committee. At the beginning of the data analysis the datasets will be available for all the 12 resesrch groups members of the PASOS consortium and in the future will be evaluated the possibility of open the datasets to other research groups.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/09/2020	25/09/2020	Yes	No
Interim results article	Validity, reliability, and calibration of the physical activity unit 7 item screener (PAU-7S)	17/06/2021	19/07/2021	Yes	No
Results article	Adherence to the Mediterranean Diet	09/02/2022	17/09/2024	Yes	No
Results article	Combined body mass index and waist-to-height ratio	06/01/2022	17/09/2024	Yes	No
Results article	Parents' diet quality and physical activity	17/08/2023	17/09/2024	Yes	No

Results article	Perceived quality of life	16/12 /2023	17/09 /2024	Yes	No
Results article	Socioeconomic indicators	20/04 /2023	17/09 /2024	Yes	No
Results article	Walkability and socio-economic status in relation to walking, playing and sports practice	15/03 /2024	17/09 /2024	Yes	No