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# BMJ Open

## Physical Activity, Sedentarism, and Obesity in Spanish youth (PASOS): Study protocol.

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Complete List of Authors:	<p>Gómez, Santiago Felipe; Gasol Foundation, Programs; University of Lleida, GREpS, Health Education Research Group, Nursing and Physiotherapy Department</p> <p>Homs, Clara; Gasol Foundation, Programs; Blanquerna Ramon Llull University Faculty of Health Sciences, GRoW, Global Research on Wellbeing</p> <p>Wärnberg, Julia; University of Málaga, Faculty of Health Sciences, Institute of Biomedical Research of Malaga (IBIMA); Carlos III Health Institute, Centro de Investigación Biomédica en Red Fisiopatología de la Obesidad y la Nutrición (CIBEROBN)</p> <p>Medrano, Maria; Public University of Navarre, ELIKOS group, Institute for Innovation &amp; Sustainable Development in Food Chain (IS-FOOD)</p> <p>Gonzalez-Gross, Marcela ; Universidad Politecnica de Madrid, ImFINE Research Group. Department of Health and Human Performance; Carlos III Health Institute, Centro de Investigación Biomédica en Red Fisiopatología de la Obesidad y la Nutrición (CIBEROBN)</p> <p>Gusi, Narcis; University of Extremadura, Physical Activity and Quality of Life Research Group (AFYCAV), Faculty of Sport Sciences</p> <p>Aznar, Susana; University of Castilla-La Mancha - Toledo Campus, PAFS Research Group, Faculty of Sports Sciences</p> <p>Cascales, Elena ; San Antonio Catholic University of Murcia, Research Center for High Performance Sport</p> <p>González-Valeiro, Miguel; Universidade da Coruña, Faculty of Sports Sciences and Physical Education</p> <p>Serra-Majem, Lluís; University of Las Palmas de Gran Canaria, Research Institute of Biomedical and Health Sciences (IUIBS); Canarian Health Service, Preventive Medicine Service, Centro Hospitalario Universitario Insular Materno Infantil (CHUIMI)</p> <p>Terrados, Nicolás; Municipal Sports Foundation of Avilés, Regional Unit of Sports Medicine</p> <p>Tur, Josep A.; University of the Balearic Islands, Research Group of Community Nutrition &amp; Oxidative Stress</p> <p>Segu, Marta; Probitas Foundation</p> <p>Lassale, Camille; Carlos III Health Institute, Ciber Epidemiology and Public Health (CIBERESP); Hospital del Mar Institute for Medical Research, Cardiovascular Risk and Nutrition Research Group</p> <p>Benavente-Marín, Juan Carlos; University of Málaga, Faculty of Health Sciences</p> <p>Labayen, Idoia; Public University of Navarre, ELIKOS group, Institute for Innovation &amp; Sustainable Development in Food Chain (IS-FOOD)</p> <p>Zapico, Augusto García; Universidad Politécnica de Madrid, ImFINE</p>

	<p>Research Group. Department of Health and Human Performance; Universidad Complutense de Madrid, Department of Didactics of Language, Arts and Physical Education</p> <p>Sánchez-Gómez, Jesús; University of Extremadura, Physical Activity and Quality of Life Research Group (AFYCAV), Faculty of Sport Sciences</p> <p>Jiménez-Zazo, Fabio; University of Castilla-La Mancha - Toledo Campus, PAFS Research Group, Faculty of Sports Sciences</p> <p>Alcaraz, Pedro Emilio; San Antonio Catholic University of Murcia, Research Center for High Performance Sport; San Antonio Catholic University of Murcia, Faculty of Sport Sciences</p> <p>Sevilla-Sanchez, Marta; Universidade da Coruña, Faculty of Sports Sciences and Physical Education</p> <p>Herrera-Ramos, Estefania; University of Las Palmas de Gran Canaria, Research Institute of Biomedical and Health Sciences (IUIBS)</p> <p>Pulgar, Susana; Municipal Sports Foundation of Avilés, Regional Unit of Sports Medicine</p> <p>Bibiloni, Maria del Mar; University of the Balearic Islands, Research Group of Community Nutrition &amp; Oxidative Stress; Carlos III Health Institute, Centro de Investigación Biomédica en Red Fisiopatología de la Obesidad y la Nutrición (CIBEROBN)</p> <p>Sancho, Olga; Probitas Foundation</p> <p>Schröder, Helmut; Carlos III Health Institute, Ciber Epidemiology and Public Health (CIBERESP); Hospital del Mar Institute for Medical Research, Cardiovascular Risk and Nutrition Research Group</p>
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# Physical Activity, Sedentarism, and Obesity in Spanish youth

## (PASOS): Study protocol.

Corresponding author: Gómez SF, Santiago F. Gómez Santos ([sgomez@gasolfoundation.org](mailto:sgomez@gasolfoundation.org))

Gómez SF<sup>1,2</sup>, Homs C<sup>1,3</sup>, Wärnberg J<sup>4,5</sup>, Medrano M<sup>6</sup>, González-Gross M<sup>5,7</sup>, Gusi N<sup>8</sup>, Aznar S<sup>9</sup>, Marín-Cascales E<sup>10</sup>, González-Valeiro MA<sup>12</sup>, Serra-Majem L<sup>5,13,14</sup>, Terrados N<sup>15</sup>, Tur JA<sup>5,16</sup>, Segu M<sup>17</sup>, Lassale C<sup>18</sup>, Benavente-Marín JC<sup>4</sup>, Labayen I<sup>6</sup>, Zapico AG<sup>12,19</sup>, Sánchez-Gómez J<sup>8</sup>, Jiménez-Zazo F<sup>9</sup>, Alcaraz Pedro E<sup>10,11</sup>, Sevilla-Sanchez M<sup>12</sup>, Herrera-Ramos E<sup>13</sup>, Pulgar S<sup>15</sup>, Bibiloni MM<sup>5,16</sup>, Sancho-Moron O<sup>17</sup>, Schröder H<sup>18</sup>

1. Gasol Foundation, Sant Boi de Llobregat, Spain
2. GREpS, Health Education Research Group, Nursing and Physiotherapy Department, University of Lleida, Lleida, Spain
3. GRoW, Global Research on Wellbeing, Blanquerna School of Life Sciences, University Ramon Llull, Barcelona, Spain
4. Faculty of Health Sciences, University of Málaga-Institute of Biomedical Research of Malaga (IBIMA), Málaga, Spain
5. Centro de Investigación Biomédica en Red Fisiopatología de la Obesidad y la Nutrición (CIBEROBN), Institute of Health Carlos III, Madrid, Spain
6. ELIKOS group, Institute for Innovation & Sustainable Development in Food Chain (IS-FOOD), Public University of Navarra, Navarra, Spain
7. ImFINE Research Group. Department of Health and Human Performance. Universidad Politécnica de Madrid, Madrid, Spain
8. Physical Activity and Quality of Life Research Group (AFYCAV), Faculty of Sport Sciences, University of Extremadura, Cáceres, Spain
9. PAFS Research Group, Faculty of Sports Sciences, University of Castilla-La Mancha, Toledo, Spain
10. Research Center for High Performance Sport, Catholic University of Murcia, Murcia, Spain
11. Faculty of Sport Sciences, UCAM, Catholic University of Murcia, Murcia, Spain
12. Faculty of Sports Sciences and Physical Education, University of A Coruña, A Coruña, Spain
13. Research Institute of Biomedical and Health Sciences (IUIBS), University of Las Palmas de Gran Canaria, Las Palmas, Spain
14. Preventive Medicine Service, Centro Hospitalario Universitario Insular Materno Infantil (CHUIMI), Canarian Health Service, Las Palmas, Spain
15. Regional Unit of Sports Medicine, Municipal Sports Foundation of Avilés, Asturias, Spain
16. Research Group of Community Nutrition & Oxidative Stress, University of the Balearic Islands, Palma de Mallorca, Spain

- 1
- 2
- 3 17. Probitas Foundation, Barcelona, Spain
- 4 18. Ciber Epidemiology and Public Health (CIBERESP), Instituto de Salud Carlos III,
- 5 Spain; Cardiovascular Risk and Nutrition Research Group, IMIM (Hospital del Mar
- 6 Medical Research Institute), Spain
- 7
- 8 19. Department of Didactics of Language, Arts and Physical Education. Universidad
- 9 Complutense de Madrid, Madrid, Spain.
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17 **Trial registration number: ISRCTN34251612**

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3 **INTRODUCTION:** Physical activity (PA) is essential to healthy mental and physical  
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5 development in early life. However, the prevalence of physical inactivity, which is  
6  
7 considered a key modifiable driver of childhood obesity, has reached alarming levels among  
8  
9 European youth. There is a need to update the data for Spain, in order to establish if current  
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11 measures are effective or new approaches are needed.  
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14  
15 **METHODS AND ANALYSIS:** We present the protocol for Physical Activity,  
16  
17 Sedentarism, and Obesity in Spanish youth (PASOS). This cross-sectional, observational,  
18  
19 nationally representative, multi-centre study aims to determine the PA levels, sedentary  
20  
21 behaviours, and prevalence of physical inactivity (defined as <60 minutes of moderate to  
22  
23 vigorous PA per day) in a representative sample of Spanish children and adolescents.  
24  
25 The PASOS study will recruit a representative random sample of children and adolescents  
26  
27 aged 8 to 16 years from 245 educational centres in the 17 “autonomous regions” into which  
28  
29 Spain is divided. The aim is to include a total of 4508 youth participants and their families.  
30  
31 Weight, height, and waist circumference will be measured by standardized procedures.  
32  
33 Adherence to the Mediterranean diet, quality of life, sleep duration, PA and sedentary  
34  
35 behaviour will be measured by validated questionnaires. PA will be measured by the  
36  
37 Physical Activity United 7-item Screener (PAU-7S). A representative sub-sample (10% of  
38  
39 participants) will be randomly selected to wear accelerometers for 9 days in order to obtain  
40  
41 objective data on PA. Following the validated methodology used in previous studies, parents  
42  
43 will be asked about their educational level, time spent doing PA, diet quality, self-perceived  
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45 stress, smoking habit, weight, height, their child’s birthweight and if the child was breastfed.  
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52 **ETHICS AND DISSEMINATION:** The study was approved by the ethics committee of  
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54 the Fundació Sant Joan de Déu, Barcelona, Spain. According to the principles of the  
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56 GASOL Foundation, which coordinates the PASOS study, main findings of the study will  
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58 not only be disseminated to the scientific community through peer-review journals and  
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3 scientific conferences but also will be communicated by media conferences, press releases,  
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5 social media and an accessible website so that the general public and the families benefit  
6  
7 from the results and participate in the solutions.  
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### 17 **Strengths and limitations of this study**

- 20 • The PASOS study is a representative nationwide survey in Spain.
- 21  
22 • It will provide representative data on subjectively and objectively measured data on  
23 the participants' levels of physical activity and the prevalence of general and  
24 abdominal obesity among children and adolescents.
- 25  
26 • Sociodemographic data and lifestyle variables of participating youth and their  
27 parents will be recorded by validated questionnaires.
- 28  
29 • The study is not designed to provide representative data for each autonomous  
30 community; therefore, differences associated with distinctive social, cultural or  
31 educational variables in each area will not be described.  
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## INTRODUCTION

Physical inactivity is one of the leading risk factors for premature death worldwide (1), putting an enormous economic burden on the public health system (2). The 2018 Physical Activity Guidelines for Americans underline the paramount importance of this modifiable health behaviour in children and adults of all ages (3). Physical inactivity is associated with an increased risk of overweight and obesity in children and adolescents (4). Therefore, the high level of insufficient physical activity (PA), particularly in western countries (5), is of great concern. Perhaps more alarming is a 2012 report (6) indicating that 80.3% of adolescents worldwide did not meet the minimum 60 minutes of moderate to vigorous PA (MVPA) per day recommended by the World Health Organization (1) for children and adolescents. Objectively measured PA data from the Healthy Lifestyle in Europe by Nutrition in Adolescence (HELENA) study showed that over half of the boys and nearly one-third of the girls met the PA recommendations, but spent on average 70% of their waking time in sedentary behaviours (7). The IDEFICS study (Identification and Prevention of Dietary and Lifestyle-induced Health Effects in Children and Infants) reported similar data for Europe (8). Self-reported data from the Health Behaviour in School-aged Children (HBSC) study on secular trends of European adolescents not meeting the PA recommendation showed mixed results across countries (9).

Most large epidemiological studies, such as HBSC, use questionnaires because self-reported data collection by validated questionnaires is cost-effective and therefore feasible to implement. However, self-reporting presents inherent limitations, as it is prone to response and classification bias, and therefore to measurement error (10). Therefore, the recently published Report on Physical Activity for Spanish Children and Adolescents (11,12) underlines the need to obtain objectively measured data in order to better estimate the number of Spanish youths not meeting the PA recommendations. Objective PA

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3 measurement can also be used to calibrate self-reported PA data, when both types of data are  
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5 collected in the same individuals. This can reduce measurement error in questionnaire-  
6  
7 derived PA estimates.  
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11 Furthermore, the identification and understanding of PA correlates and determinants is  
12  
13 essential for the creation and implementation of intervention programs aiming to increase  
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15 PA in children and adolescents. Associations between PA and demographic, socioeconomic,  
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17 psychological, social, and behavioural factors have been reported in children, but the  
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19 evidence is inconclusive (13).  
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23 This manuscript describes the rationale and design of the PASOS study, which aims to  
24  
25 determine PA levels and its correlates in Spanish children and adolescents.  
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## 28 **METHODS/DESIGN**

### 29 **Study design**

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31 This is a multicentre, cross-sectional, nationally representative, population-based study.  
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### 34 **Inclusion criteria**

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36 Children and adolescents aged 8 to 16 years who are enrolled in a participating school are  
37  
38 eligible for inclusion.  
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### 41 **Exclusion criteria**

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43 Individuals with an intellectual disability that prevents response to the lifestyle  
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45 questionnaires will be excluded. Each case will be evaluated with the corresponding teachers  
46  
47 and parents or legal guardians before exclusion.  
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### 50 **Randomization**

51  
52 Randomization was performed by a four-stage sampling procedure. To obtain a sample of  
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54 4508 children/adolescents, assuming a mean of 18-20 pupils per classroom, 242  
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56 participating classrooms are required from the 17 “autonomous communities” into which  
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Spain is divided: 121 from primary schools (grades 3-6) and 121 from secondary schools (levels 1-4). In the first step, 121 municipalities were randomized 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 its share of the youth population of Spain aged 8 to 16 years (14). 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. A sub-sample of 23 classrooms (10%) was randomized for the objective measurement of PA by accelerometers.

### **Sample size**

The calculation of the sample size was based on the prevalence of non-adherence to PA recommendations of at least 1 hour of PA per day (15). According to the published data of the Spanish Report of Physical Activity (11,12), we assumed 50% non-adherence among Spanish children and adolescents. Based on this assumption and considering a population increase of 8% as a relevant indicator, a total of 3994 participants are needed, 1997 in each of the two age groups (primary school: 8-11 years, and secondary school: 12-16 years), to achieve a statistical power of  $\geq 80\%$  to identify an increase of 8% as significant ( $p \leq 0.05$ ). A dropout rate of 20% was anticipated. To take into account the cluster effect, sample size was increased by 10%, leading to a sample size of 4394 participants. Finally, to ensure proportionality among the 17 autonomous communities studied, the number of municipalities was increased to 121 and the final sample to 4508 participants.

## Data collection

Data will be collected from March to October, 2019, in 242 primary and secondary schools.

Two visits will be carried out in each school by 2 field workers who have completed a one-day training session on the project methodology, hosted by the Gasol Foundation. An additional visit is made to the 10% of the schools included in the accelerometer protocol.

Lifestyle data of children/adolescents are self-reported online at participating schools, with the assistance of trained personnel. Parental sociodemographic and lifestyle (PA and smoking) data are collected in paper format. Additional data on parental health habits are recorded via an online system.

## Participants and recruitment process

The aim is to recruit 4508 children and their parents from 242 participating schools in the 17 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 included for logistical reasons.

This study is coordinated by the Gasol Foundation, whose aim is to reduce childhood obesity rates through the promotion of sports and PA, healthy eating, sleep quality, and the emotional well-being of children, adolescents and their families in the United States and Spain. Field and scientific work will be performed together with 13 highly experienced research groups working at universities and research centers in several regions of Spain (**Supplementary file 1**). 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 autonomous community's departments of education and/or health and sports and from Spain's Ministry of Education and Vocational Training; Ministry of Health, Consumer Affairs and Social Welfare; Council of Sports and High Commission against Child Poverty.

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3 In a second step, Gasol Foundation staff will call the invited educational centres to confirm  
4 their interest in participating. The principal investigators at these centres are well-known  
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6 experts in the investigation of the relationship between lifestyle and disease. In a third step,  
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8 the regional coordinators of the PASOS project will contact interested educational centres to  
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10 introduce them to the study and invite them to participate. In the participating schools,  
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12 parents (or legal guardians) are contacted by teachers designated by school administrators  
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14 and receive an envelope containing instructions to complete the requested documentation,  
15  
16 two copies of the informed consent form, and two copies of the short questionnaires to be  
17  
18 completed by an adult. When the school receives a signed copy of the informed consent  
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20 form, the child participant and family are included in the PASOS study. The study was  
21  
22 approved by the ethics committee of the Fundació Sant Joan de Déu, Barcelona, Spain.  
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## 28 **Objectives**

### 29 *Main objective*

30  
31 To determine the PA levels, sedentary behaviours, and prevalence of physical inactivity in a  
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33 representative sample of Spanish children and adolescents.  
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### 37 *Secondary objectives*

- 38 1. To determine the prevalence of general and abdominal obesity.
- 39 2. To calibrate the self-reported Physical Activity Unified questionnaire - 7-item Screener  
40 (PAU-7S) using objective accelerometer data from a representative sub-sample of 10% of  
41  
42 the cohort.
- 43 3. To examine the interrelationships between PA and demographic, lifestyle, socioeconomic,  
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45 behavioural, anthropometric and environmental factors.  
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## 53 **Study variables**

### 54 *Children and adolescents*

#### 55 *Physical activity*

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3 The PAU-7S, a 7-item self-reported questionnaire will be used to assess PA levels in each  
4 participating child or adolescent. A previous pilot validation study (**supplementary file 2**)  
5 revealed a reasonable validity ( $r= 0.33$ ) and moderate reliability (intra class correlation  
6 coefficient = 0.55) of this questionnaire in children aged 8 to 12 years.  
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10 Six questions ask about PA frequency and duration in the previous week: 1. How many days  
11 did you go for a walk? 2. How many days did you participate in movement-play during  
12 recess time? 3. How many days did you participate in movement-play during free time after  
13 school or during the weekend? 4. How many days did you have Physical Education (PE)  
14 class at school? 5. How many days did you play a team sport? 6. How many days did you  
15 play an individual sport? The response options for these questions about PA are shown in a  
16 table with a box for each day of the week, in which children can mark if they have spent (i)  
17 0 minutes (no activity), (ii) less than 30 minutes; (iii) between 30 minutes and one hour; (iv)  
18 between one hour and one hour and a half; or (v) more than one hour and a half. The final  
19 question asks about health status with a Yes/No response option: Were you sick last week or  
20 did anything prevent you from performing your usual PA?  
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37 In addition, PA will be objectively measured by accelerometers in 10% of the participants,  
38 randomly selected from the entire sample. For 9 days, these children will wear the  
39 ActiGraph wGT3X-BT (Pensacola, FL, USA) accelerometer. Total-PA, PA intensity,  
40 sedentary time, and sleep duration will be recorded. Furthermore, children will report non-  
41 wear time, bedtime and wake time in a daily log. Trained personnel will instruct them how  
42 to report this information.  
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#### 51 *Anthropometric variables*

52 Anthropometrics for each individual will be measured by trained personnel following a  
53 standardized protocol. Body weight, height, and waist circumference are measured with the  
54 children in light clothing, without shoes. The measurements are performed using an  
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3 electronic SECA 899 scale (recorded to the nearest 100 g), a portable SECA 217 stadiometer  
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5 (to the nearest 1 mm), and a flexible, non-stretch SECA 201 metric tape (to the nearest 1  
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7 mm), respectively. Waist circumference is measured in the narrowest zone between the  
8  
9 lower costal rib and iliac crest, in the supine decubitus and horizontal positions.  
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#### 12 *Other child/adolescent lifestyle variables*

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14 Sedentary behaviour is assessed by the Screen-time Sedentary Behaviour Questionnaire  
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16 (16), which asks about time spent in 4 activities: [1] watching TV, [2] playing computer  
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18 games, [3] playing console (video) games, [4] using a mobile phone, separately for  
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20 weekdays and weekends.  
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23  
24 Diet is assessed by the 16-item KIDMED questionnaire that measures adherence to the  
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26 Mediterranean diet (17). The KIDMED index, derived on the basis of dichotomous response  
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28 options (Yes/No), was created to estimate adherence to the Mediterranean diet in children  
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30 and young adults, based on the principles that sustain Mediterranean dietary patterns and  
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32 those that undermine it. Items denoting lower adherence are assigned a value of -1 (4 items)  
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34 and those related to higher adherence are scored +1 (12 items).  
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38 Sleep duration is recorded by 4 questions on hours of sleep from the Sleep Habits Survey for  
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40 Adolescents that ask about bedtime and time of waking up on weekdays and weekends (18).  
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43 In addition, adults will be asked to complete the BEARS questionnaire on sleep quality in  
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45 their participating children/adolescents (19), responding (Yes/No) to questions about 5 main  
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47 sleep domains: A = bedtime problems, B = excessive daytime sleepiness, C = awakening  
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49 during the night, D = regularity and duration of sleep, E = snoring.  
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51  
52 Quality of life is measured by the “EQ-5D-Y-5L” –a short, child-friendly EuroQuality  
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54 questionnaire on 5 health-related dimensions (mobility, self-care, usual activities,  
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56 pain/discomfort, anxiety/depression) with 5 response levels, recently validated in an  
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58 international sample (including Spain) of children and adolescents aged 8 to 15 years (20).  
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To facilitate comparison with other studies, the 3-level version (EQ-5D-Y-3L) will also be administered (21).

### ***Parental variables***

Two sets of questionnaires are delivered to each participating child/adolescent, to be answered separately by up to two parents/legal guardians. The validated REGICOR Short PA Questionnaire (22) and the following standardized questions are included: sex, weight, height, smoking habit, educational level, employment status, general health status, and sleep duration. Parents are also asked about their child's birthweight and if the child was breastfed.

Additionally, parents/legal guardians are asked to respond to the following online questionnaires:

- Diet Quality Screener, a short questionnaire about the frequency of consumption of 18 foods/food groups (23,24).
- Perceived Stress Scale (PSS), a subjective 14-item questionnaire asking about self-perception of stress experienced during the previous month (25).
- Environmental questions such as access to cycling lanes or sports facilities are asked to capture information that can be used to estimate the level of exposure to contaminants such as air pollution and noise levels or access to green spaces.
- Quality of life, measured by adult response to the child-friendly EQ-5D-Y-5L (20).

### **Patient and public involvement**

Patients and the public were not involved in the development of the research question or in the design of the study. The parents and legal tutors of participant children receive the informed consent and a letter inviting them to participate in the study. Also, parents and legal tutors will receive a one-page plain language summary of the results of the



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3 anthropometric measurements. The results of the PASOS study will be disseminated to the  
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5 general public.  
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## 7 **DISCUSSION**

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10 The PASOS study is intended to provide an estimation of PA among Spanish children and  
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12 adolescents and, conversely, the magnitude of physical inactivity and sedentarism. The  
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14 representative design of the study is of particular importance because estimates of physical  
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16 inactivity can vary widely by population (26). Moreover, data obtained by accelerometers in  
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18 a representative sub-sample of 10% of the entire cohort will be used to calibrate self-  
19  
20 reported PA data obtained from the PAU-7S and to provide an objective and representative  
21  
22 measure of PA levels and of the prevalence of physical inactivity in Spanish children and  
23  
24 adolescents.  
25  
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28  
29 Some technical considerations must be kept in mind. First, accelerometer-derived  
30  
31 calculation of time spent in MVPA is based on the count-per-minute threshold for MVPA  
32  
33 that is applied (27-29). Differences in this parameter can strongly affect the estimate of PA  
34  
35 and the classification of adherence to PA guidelines (27,28). For example, Gaba and  
36  
37 colleagues (27) showed that adherence to the PA guidelines ranged from 1% to 100%  
38  
39 depending on the algorithm used. Therefore, the comparability of accelerometer-based PA  
40  
41 measurements is limited across studies.  
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44

45  
46 To improve comparability of accelerometer-driven MVPA data from the PASOS study with  
47  
48 other research, several different accelerometer MVPA cut-off points and epoch lengths used  
49  
50 in other studies will be analysed and made public. In addition, calibration of the PAU-7S  
51  
52 will be stratified by sex and age group (primary vs secondary school students).  
53

54  
55 The association between physical inactivity and increased risk of overweight and obesity in  
56  
57 children and adolescents (4) has multiple potential consequences (30) that persist into  
58  
59 adulthood. In addition, psychosocial restrictions such as impaired quality of life, self-esteem,  
60

1  
2  
3 and school performance are to be expected (31). A recent meta-analysis showed that  
4  
5 children aged 5 to 15 years who are overweight or obese have more cardiometabolic  
6  
7 complications than children of normal weight (32). Furthermore, a cohort study found that  
8  
9 some risk factors, including fatty liver, are detectable even in overweight or obese  
10  
11 preschoolers.  
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14  
15 Spain is among the European countries with the highest prevalence of overweight, obesity,  
16  
17 and severe obesity in children and adolescents (33, 34). However, representative data on the  
18  
19 nationwide prevalence of abdominal obesity in Spanish children and adolescents aged 8 to  
20  
21 16 years has not been published since 2000 (35). Results of the PASOS study will provide  
22  
23 timely data on PA behaviours, the prevalence of overweight and obesity, and estimated  
24  
25 secular trends in abdominal obesity in a representative sample of this population. Finally,  
26  
27 our analysis of potential determinants of PA behaviours will improve our understanding of  
28  
29 which of these determinants are modifiable and accessible for intervention. Our findings will  
30  
31 contribute essential knowledge for the development and implementation of effective PA  
32  
33 promotion strategies in multilevel intervention programs designed to tackle childhood  
34  
35 obesity.  
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#### 41 **Ethics and dissemination**

42  
43  
44 Ethical approval was obtained from the ethics committee of the Fundació Sant Joan de Déu,  
45  
46 Barcelona, Spain. Findings will be disseminated in seminars, conference presentations, and  
47  
48 in peer-reviewed international journals.  
49  
50

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21  
22

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26  
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28

### 29 **Contributorship**

30  
31 SFG, CH and HS conceptualised and designed the study, drafted the initial manuscript and  
32  
33 incorporated the suggestions of all the consortium authors. JW, MM, SA and IL, made  
34  
35 relevant contributions to the accelerometry protocol and formed with SFG, CH and HS the  
36  
37 accelerometry commission of the PASOS study. MGG, NG and JAT made substantial  
38  
39 contributions to the study protocol and the representative randomization of the Spanish  
40  
41 population. JW, MM, MGG, SA, IL and AGZ critically revising the manuscript for  
42  
43 important intellectual content. All authors defined the strategy to deploy the study protocol  
44  
45 in their assigned schools and approved the final manuscript as submitted.  
46  
47  
48

### 49 **Competing interest**

50  
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53

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5 preparation of the manuscript.  
6

### 7 **Data sharing**

8  
9  
10 Data is available for the PASOS study research consortium.  
11

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## PASOS INVESTIGATORS

Steering Committee – SF. Gomez, H. Schröder

Gasol Foundation, Sant Boi de Llobregat, Spain: C. Homs, P. Berruezo, G. Según, M. Bellver, S. Torres, M. Picas, E. Lopez-Puertas, J. Antoni-Fernandez, A. Cosolo, S. Scarrone, A. Marin, V. Marzini, G. Zonta, S. Bernal

Cardiovascular Risk and Nutrition Research Group, IMIM (Hospital del Mar Medical Research Institut), Barcelona, Spain: M. Fitó, C. Lassale. I. Subirana, J. Vila, M. Grau

ELIKOS group, Institute for Innovation & Sustainable Development in Food Chain (IsFood), Public University of Navarra, Navarra, Spain: I. Labayen, M. Medrano, M. Oses, L. Arenaza

Faculty of Health Sciences, University of Málaga, Málaga, Spain: J. Wärnberg, J.C. Benavente-Marín, N. Pérez-Farinós, E. Crespo-Oliva, F.J. Barón López, J. Pérez-López, N. Moreno-Morales, P. Romero-Cazorla

Faculty of Sports Sciences and Physical Education, University of A Coruña, A Coruña, Spain: M.A. González-Valeiro, M. Sevilla-Sanchez

ImFINE Research Group. Department of Health and Human Performance. Universidad Politécnica de Madrid, Madrid, Spain: M. González-Gross, A.G. Zapico, E. Gesteiro, A.G. Carro, R. Torres-Peralta

PAFS Research Group, Faculty of Sports Sciences, University of Castilla-La Mancha, Toledo, Spain: S. Aznar, F. Jiménez-Zazo, E. Cabanillas, C. Romero-Blanco, A. Dorado.

Physical Activity and Quality of Life Research Group (AFYCAV), Faculty of Sport Sciences, University of Extremadura, Caceres, Spain: N. Gusi, J. Sánchez-Gómez

Probitas Foundation, Barcelona, Spain: M. Segú-Estruch, O. Sancho, C. Sístac

Regional Unit of Sports Medicine-Municipal Sports Foundation of Avilés, Asturias, Spain: N. Terrados, S. Pulgar

Research Center for High Performance Sport, Catholic University of Murcia, Murcia, Spain: Pedro E Alcaraz, E. Marín-Cascales

Research Group of Community Nutrition & Oxidative Stress, University of the Balearic Islands, Palma de Mallorca, Spain: J.A. Tur, M.M. Bibiloni, L. Gallardo-Alfaro

Research Institute of Biomedical and Health Sciences (IUIBS), University of Las Palmas de Gran Canaria, Las Palmas, Spain: L. Serra-Majem, E. Herrera-Ramos

**Table 1.** Test-retest reliability of physical activities recorded at baseline and after 1 week.<sup>1</sup>

	All	Boys	Girls
	(n=138)	(n=78)	(n=60)
Total physical activity (min/d)	0.55	0.62	0.40
Walking (min/d)	0.45	0.52	0.39
Movement play (min/d) <sup>2</sup>	0.50	0.44	0.54
Physical education (min/d)	-0.02	-0.15	0.08
Movement play (min/d) <sup>3</sup>	0.42	0.44	0.38
Team sport (min/d)	0.68	0.60	0.77
Individual sport (min/d)	0.66	0.53	0.70

<sup>1</sup> Intra-class correlation coefficient.

<sup>2</sup> School recess.

<sup>3</sup> Free time outside of school.

*P* < 0.05 for all correlations with exception of physical education.

**Table 2.** Correlation coefficients<sup>1</sup> of physical activities recorded by the questionnaire and moderate to vigorous physical activity measured by accelerometers.

	All	Boys	Girls
	(n=138)	(n=78)	(n=60)
Total physical activity (min/d)	0.33*	0.34*	0.21
Walking (min/d)	0.17*	0.21	0.16
Movement play (min/d) <sup>2</sup>	0.23*	0.16	0.21
Movement play (min/d) <sup>3</sup>	0.14	0.19	-0.17
Physical education (min/d)	0.18*	0.37*	-0.16
Team sport (min/d)	0.33*	0.29*	0.32*
Individual sport (min/d)	-0.10	-0.07	0.10

<sup>1</sup> *r* for total physical activity and *rho* for the rest of activities.

<sup>2</sup> School recess.

<sup>3</sup> Free time outside school.

\**P* < 0.05

# BMJ Open

## Study protocol of a population-based cohort investigating Physical Activity, Sedentarism, lifestyles and Obesity in Spanish youth: The PASOS study.

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Date Submitted by the Author:	16-Jul-2020
Complete List of Authors:	<p>Gómez, Santiago Felipe; Gasol Foundation, Programs; University of Lleida, GREpS, Health Education Research Group, Nursing and Physiotherapy Department  Homs, Clara; Gasol Foundation, Programs; Blanquerna Ramon Llull University Faculty of Health Sciences, GRoW, Global Research on Wellbeing  Wärnberg, Julia; University of Málaga, Faculty of Health Sciences, Institute of Biomedical Research of Malaga (IBIMA); Carlos III Health Institute, Centro de Investigación Biomédica en Red Fisiopatología de la Obesidad y la Nutrición (CIBEROBN)  Medrano, Maria; Public University of Navarre, ELIKOS group, Institute for Innovation &amp; Sustainable Development in Food Chain (IS-FOOD)  Gonzalez-Gross, Marcela ; Universidad Politecnica de Madrid, ImFINE Research Group. Department of Health and Human Performance; Carlos III Health Institute, Centro de Investigación Biomédica en Red Fisiopatología de la Obesidad y la Nutrición (CIBEROBN)  Gusi, Narcis; University of Extremadura, Physical Activity and Quality of Life Research Group (AFYCAV), Faculty of Sport Sciences  Aznar, Susana; University of Castilla-La Mancha - Toledo Campus, PAFS Research Group, Faculty of Sports Sciences  Cascales, Elena ; San Antonio Catholic University of Murcia, Research Center for High Performance Sport  González-Valeiro, Miguel; Universidade da Coruña, Faculty of Sports Sciences and Physical Education  Serra-Majem, Lluís; University of Las Palmas de Gran Canaria, Research Institute of Biomedical and Health Sciences (IUIBS); Canarian Health Service, Preventive Medicine Service, Centro Hospitalario Universitario Insular Materno Infantil (CHUIMI)  Terrados, Nicolás; Municipal Sports Foundation of Avilés, Regional Unit of Sports Medicine  Tur, Josep A.; University of the Balearic Islands, Research Group of Community Nutrition &amp; Oxidative Stress  Segu, Marta; Probitas Foundation  Lassale, Camille; Carlos III Health Institute, Ciber Epidemiology and Public Health (CIBERESP); Hospital del Mar Institute for Medical Research, Cardiovascular Risk and Nutrition Research Group  Benavente-Marín, Juan Carlos; University of Málaga, Faculty of Health Sciences  Labayen, Idoia; Public University of Navarre, ELIKOS group, Institute for</p>

	Innovation & Sustainable Development in Food Chain (IS-FOOD) Zapico, Augusto García; Universidad Politécnica de Madrid, ImFINE Research Group. Department of Health and Human Performance; Universidad Complutense de Madrid, Department of Didactics of Language, Arts and Physical Education Sánchez-Gómez, Jesús; University of Extremadura, Physical Activity and Quality of Life Research Group (AFYCAV), Faculty of Sport Sciences Jiménez-Zazo, Fabio; University of Castilla-La Mancha - Toledo Campus, PAFS Research Group, Faculty of Sports Sciences Alcaraz, Pedro Emilio; San Antonio Catholic University of Murcia, Research Center for High Performance Sport; San Antonio Catholic University of Murcia, Faculty of Sport Sciences Sevilla-Sanchez, Marta; Universidade da Coruña, Faculty of Sports Sciences and Physical Education Herrera-Ramos, Estefania; University of Las Palmas de Gran Canaria, Research Institute of Biomedical and Health Sciences (IUIBS) Pulgar, Susana; Municipal Sports Foundation of Avilés, Regional Unit of Sports Medicine Bibiloni, Maria del Mar; University of the Balearic Islands, Research Group of Community Nutrition & Oxidative Stress; Carlos III Health Institute, Centro de Investigación Biomédica en Red Fisiopatología de la Obesidad y la Nutrición (CIBEROBN) Sancho, Olga; Probitas Foundation Schröder, Helmut; Carlos III Health Institute, Ciber Epidemiology and Public Health (CIBERESP); Hospital del Mar Institute for Medical Research, Cardiovascular Risk and Nutrition Research Group
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3 **1 Study protocol of a population-based cohort investigating**  
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6 **2 Physical Activity, Sedentarism, lifestyles and Obesity in Spanish**  
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9 **3 youth: The PASOS study.**  
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11  
12 Corresponding author: Gómez SF, Santiago F. Gómez Santos ([sgomez@gasolfoundation.org](mailto:sgomez@gasolfoundation.org))  
13  
14

15 Gómez SF<sup>1,2</sup>, Homs C<sup>1,3</sup>, Wärnberg J<sup>4,5</sup>, Medrano M<sup>6</sup>, González-Gross M<sup>5,7</sup>, Gusi N<sup>8</sup>, Aznar  
16 S<sup>9</sup>, Marín-Cascales E<sup>10</sup>, González-Valeiro MA<sup>12</sup>, Serra-Majem L<sup>5,13,14</sup>, Terrados N<sup>15</sup>, Tur  
17 JA<sup>5,16</sup>, Segu M<sup>17</sup>, Lassale C<sup>18</sup>, Benavente-Marín JC<sup>4</sup>, Labayen I<sup>6</sup>, Zapico AG<sup>12,19</sup>, Sánchez-  
18 Gómez J<sup>8</sup>, Jiménez-Zazo F<sup>9</sup>, Alcaraz PE<sup>10,11</sup>, Sevilla-Sanchez M<sup>12</sup>, Herrera-Ramos E<sup>13</sup>, Pulgar  
19 S<sup>15</sup>, Bibiloni MM<sup>5,16</sup>, Sancho O<sup>17</sup>, Schröder H<sup>18</sup>  
20  
21

- 22  
23  
24 1. Gasol Foundation, Sant Boi de Llobregat, Spain  
25 12 2. GREpS, Health Education Research Group, Nursing and Physiotherapy Department,  
26 13 University of Lleida, Lleida, Spain  
27 14 3. GRoW, Global Research on Wellbeing, Blanquerna School of Life Sciences,  
28 15 University Ramon Llull, Barcelona, Spain  
29 16 4. Faculty of Health Sciences, University of Málaga-Institute of Biomedical Research  
30 17 of Malaga (IBIMA), Málaga, Spain  
31 18 5. Centro de Investigación Biomédica en Red Fisiopatología de la Obesidad y la  
32 19 Nutrición (CIBEROBN), Institute of Health Carlos III, Madrid, Spain  
33 20 6. ELIKOS group, Institute for Innovation & Sustainable Development in Food Chain  
34 21 (IS-FOOD), Public University of Navarra, Navarra, Spain  
35 22 7. ImFINE Research Group. Department of Health and Human Performance.  
36 23 Universidad Politécnica de Madrid, Madrid, Spain  
37 24 8. Physical Activity and Quality of Life Research Group (AFYCAV), Faculty of Sport  
38 25 Sciences, University of Extremadura, Cáceres, Spain  
39 26 9. PAFS Research Group, Faculty of Sports Sciences, University of Castilla-La  
40 27 Mancha, Toledo, Spain  
41 28 10. Research Center for High Performance Sport, Catholic University of Murcia,  
42 29 Murcia, Spain  
43 30 11. Faculty of Sport Sciences, UCAM, Catholic University of Murcia, Murcia, Spain  
44 31 12. Faculty of Sports Sciences and Physical Education, University of A Coruña, A  
45 32 Coruña, Spain  
46 33 13. Research Institute of Biomedical and Health Sciences (IUIBS), University of Las  
47 34 Palmas de Gran Canaria, Las Palmas, Spain  
48 35 14. Preventive Medicine Service, Centro Hospitalario Universitario Insular Materno  
49 36 Infantil (CHUIMI), Canarian Health Service, Las Palmas, Spain  
50 37 15. Regional Unit of Sports Medicine, Municipal Sports Foundation of Avilés, Asturias,  
51 38 Spain  
52 39



- 1  
2  
3 40 16. Research Group of Community Nutrition & Oxidative Stress, University of the  
4 41 Balearic Islands, Palma de Mallorca, Spain  
5 42  
6 42 17. Probitas Foundation, Barcelona, Spain  
7 43  
8 43 18. Ciber Epidemiology and Public Health (CIBERESP), Instituto de Salud Carlos III,  
9 44 Spain; Cardiovascular Risk and Nutrition Research Group, IMIM (Hospital del Mar  
10 45 Medical Research Institute), Spain  
11 46  
12 46 19. Department of Didactics of Language, Arts and Physical Education. Universidad  
13 47 Complutense de Madrid, Madrid, Spain.  
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20 50 **Trial registration number: ISRCTN34251612**

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**77 INTRODUCTION:** Physical activity (PA) is essential to healthy mental and physical  
78 development in early life. However, the prevalence of physical inactivity, which is  
79 considered a key modifiable driver of childhood obesity, has reached alarming levels among  
80 European youth. There is a need to update the data for Spain, in order to establish if current  
81 measures are effective or new approaches are needed.

**82 METHODS AND ANALYSIS:** We present the protocol for Physical Activity,  
83 Sedentarism, and Obesity in Spanish youth (PASOS). This observational, nationally  
84 representative, multi-centre study aims to determine the PA levels, sedentary behaviours,  
85 and prevalence of physical inactivity (defined as <60 minutes of moderate to vigorous PA  
86 per day) in a representative sample of Spanish children and adolescents.  
87 The PASOS study has recruited a representative random sample of children and adolescents  
88 aged 8 to 16 years from 242 educational centres in the 17 “autonomous regions” into which  
89 Spain is divided. The aim is to include a total of 4508 youth participants and their families.  
90 Weight, height, and waist circumference will be measured by standardized procedures.  
91 Adherence to the Mediterranean diet, quality of life, sleep duration, PA and sedentary  
92 behaviour are being measured by validated questionnaires. PA is measured by the Physical  
93 Activity United 7-item Screener (PAU-7S). A representative sub-sample (10% of  
94 participants) was randomly selected to wear accelerometers for 9 days to obtain objective  
95 data on PA. Parents are asked about their educational level, time spent doing PA, diet  
96 quality, self-perceived stress, smoking habit, weight, height, their child’s birthweight and if  
97 the child was breastfed.

**98 ETHICS AND DISSEMINATION:** The study was approved by the ethics committee of  
99 the Fundació Sant Joan de Déu, Barcelona, Spain. Main findings of the study will be  
100 disseminated to the scientific community and to general public by media conferences, social  
101 media and a website.

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3 102 **Strengths and limitations of this study**  
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6 103 • The PASOS study is a representative nationwide survey among Spanish youth.  
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8 104 • It provides data about physical activity, lifestyles, and weight status.  
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10 105 • Sociodemographic data and parents' lifestyles variables are also evaluated.  
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13 106 • The study is not designed to provide representative data for each region.  
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## 108 INTRODUCTION

109 Physical inactivity is one of the leading risk factors for premature death worldwide (1),  
110 putting an enormous economic burden on the public health system (2). The 2018 Physical  
111 Activity Guidelines for Americans underlined the paramount importance of this modifiable  
112 health behaviour in children and adults of all ages (3). Physical inactivity is associated with  
113 an increased risk of overweight and obesity in children and adolescents (4). Therefore, the  
114 high level of insufficient physical activity (PA), particularly in western countries (5), is of  
115 great concern. Perhaps more alarming was a 2012 report (6) because indicated that 80.3% of  
116 adolescents worldwide did not meet the minimum 60 minutes of moderate to vigorous PA  
117 (MVPA) per day recommended by the World Health Organization (1) for children and  
118 adolescents. Objectively measured PA data from the Healthy Lifestyle in Europe by  
119 Nutrition in Adolescence (HELENA) study showed that over half of the boys and nearly  
120 one-third of the girls met the PA recommendations, but spent on average 70% of their  
121 waking time in sedentary behaviours (7). The IDEFICS study (Identification and Prevention  
122 of Dietary and Lifestyle-induced Health Effects in Children and Infants) reported similar  
123 data for Europe (8). Results from a recently published review on objectively measured  
124 physical activity (9) revealed that 71% of European children and adolescents were  
125 physically active less than 1 hour per day and with considerable variability between  
126 countries. Furthermore, physical activity level decreased from north to south Europe (9).  
127 Self-reported data from the Health Behaviour in School-aged Children (HBSC) study on  
128 secular trends of European adolescents not meeting the PA recommendation showed mixed  
129 results across countries (10).

130 Most large epidemiological studies, such as HBSC, use questionnaires because self-reported  
131 data collection by validated questionnaires is cost-effective and therefore feasible to  
132 implement. However, self-reporting presents inherent limitations, as it is prone to response

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3 133 and classification bias, and therefore to measurement error (11). Therefore, the Report on  
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5 134 Physical Activity for Spanish Children and Adolescents (12,13) underlined the need to  
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8 135 obtain objectively measured data in order to better estimate the number of Spanish youths  
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10 136 not meeting the PA recommendations. Objective PA measurement can also be used to  
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12 137 calibrate self-reported PA data, when both types of data are collected in the same  
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14 138 individuals. This can reduce measurement error in questionnaire-derived PA estimates.  
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17 139 Furthermore, the identification and understanding of PA correlates and determinants is  
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19 140 essential for the creation and implementation of intervention programs aiming to increase  
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21 141 PA in children and adolescents. Associations between PA and demographic, socioeconomic,  
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23 142 psychological, social, and behavioural factors have been reported in children, but the  
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25 143 evidence is inconclusive (14, 15, 16, 17).

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30 144 This manuscript describes the rationale and design of the PASOS study, which aims to  
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32 145 determine PA levels and its correlates in Spanish children and adolescents.

## 33 34 35 146 **Objectives**

### 36 37 38 147 ***Main objective***

39  
40 148 To determine the PA levels, sedentary behaviours, and prevalence of physical inactivity in a  
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42 149 representative sample of Spanish children and adolescents.

### 43 44 45 150 ***Secondary objectives***

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47 151 1. To determine the prevalence of general and abdominal obesity.  
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49 152 2. To calibrate the self-reported Physical Activity Unified questionnaire - 7-item Screener  
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51 153 (PAU-7S) using objective accelerometer data from a representative sub-sample of 10% of  
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53 154 the cohort.  
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55 155 3. To examine the interrelationships between PA and demographic, lifestyle, socioeconomic,  
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57 156 behavioural, anthropometric and environmental factors.  
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3 157 Incidences of obesity and physical inactivity in addition with a prospective data analysis of  
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5 158 objective 3 will be addressed with follow up data at the end of 2022.  
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## 10 11 12 160 **METHODS/DESIGN**

### 13 14 15 161 **Study design**

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17 162 This is a multicentre, cross-sectional, nationally representative, population-based study. A  
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19 163 follow-up of the study participants is planned for 2022 with a repeated collection of all  
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21 164 baseline data.  
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### 24 25 165 **Inclusion criteria**

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27 166 Children and adolescents aged 8 to 16 years who were enrolled in a participating school  
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29 167 were eligible for inclusion.  
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### 31 32 168 **Exclusion criteria**

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34 169 Individuals with an intellectual disability that prevents response to the lifestyle  
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36 170 questionnaires were excluded of the baseline data collection. Each case was evaluated with  
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38 171 the corresponding teachers and parents or legal guardians before exclusion.  
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### 40 41 172 **Randomization**

42  
43 173 Randomization was performed by a multi-stage sampling procedure (18, 19) including four-  
44  
45 174 stages . To obtain a sample of 4508 children/adolescents, assuming a mean of 18-20 pupils  
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47 175 per classroom, 242 participating classrooms were required from the 17 “autonomous  
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49 176 communities” into which Spain is divided: 121 from primary schools (grades 3-6) and 121  
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51 177 from secondary schools (levels 1-4). In the first step, 121 municipalities were randomized  
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53 178 across 3 population strata: 2000-30,000, 30,001 to 200,000, and more than 200,000  
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55 179 inhabitants. The total number of selected municipalities in each autonomous community was  
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57 180 proportional to its share of the youth population of Spain aged 8 to 16 years (20). In a  
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3 181 second step, 242 schools were randomized from the selected municipalities, along with up to  
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5 182 three replacements for each selected school to account for census data error or centres not  
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7 183 willing to participate. In a third step, scholar-year per school was randomized. In the fourth  
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9 184 and final step, a classroom for each scholar-year was randomized and invited to participate.  
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11 185 A sub-sample of 23 classrooms (10%) was randomized for the objective measurement of PA  
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13 186 by accelerometers. The software used for the sampling procedure were R, package mstage.  
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### 17 187 **Sample size**

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21 188 The calculation of the sample size was based on the prevalence of non-adherence to PA  
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23 189 recommendations of at least 1 hour of PA per day (21). According to the published data of  
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25 190 the Spanish Report of Physical Activity (12,13), we assumed 50% non-adherence among  
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27 191 Spanish children and adolescents. Based on this assumption and considering a population  
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29 192 increase of 8% as a relevant indicator, a total of 3994 participants were needed, 1997 in each  
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31 193 of the two age groups (primary school: 8-11 years, and secondary school: 12-16 years), to  
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33 194 achieve a statistical power of  $\geq 80\%$  to identify an increase of 8% as significant ( $p \leq 0.05$ ). A  
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35 195 dropout rate of 20% was anticipated. To take into account the cluster effect, sample size was  
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37 196 increased by 10%, leading to a sample size of 4394 participants. Finally, to ensure  
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39 197 proportionality among the 17 autonomous communities studied, the number of  
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41 198 municipalities was increased to 121 and the final sample to 4508 participants.  
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### 46 199 **Data collection**

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50 200 Baseline data were collected from March 2019 to February 2020, in 242 primary and  
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52 201 secondary schools. Two visits were carried out in each school by 2 field researchers with a  
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54 202 background in physical education, nutrition, or other health sciences. They completed a one-  
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56 203 day training session on the project methodology, hosted by the Gasol Foundation. An  
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58 204 additional visit was made to the 10% of the schools included in the accelerometer protocol.  
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3 205 Lifestyle data of children/adolescents were self-reported online at participating schools, with  
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5 206 the assistance of trained personnel. Parental sociodemographic and lifestyle (PA and  
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7 207 smoking) data were collected in paper format. Additional data on parental health habits were  
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9 208 recorded via an online system.  
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### 13 209 **Participants and recruitment process**

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16 210 The aim was to recruit 4508 children and their parents from 242 participating schools in the  
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18 211 17 autonomous communities. Ceuta and Melilla, two autonomous cities in North Africa with  
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20 212 less than 0.8% of the total Spanish population aged 8 to 16 years, were not included for  
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22 213 logistical reasons.  
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26 214 This cohort study is coordinated by the Gasol Foundation, whose aim is to reduce childhood  
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28 215 obesity rates through the promotion of sports and PA, healthy eating, sleep quality, and the  
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30 216 emotional well-being of children, adolescents and their families in the United States and  
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32 217 Spain. Field and scientific work is being performed together with 13 highly experienced  
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34 218 research groups working at universities and research centers in several regions of Spain  
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36 219 **(Supplementary file 1)**. Selected educational centres first received an invitation letter  
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38 220 signed by the president of the Gasol Foundation (Pau Gasol) and accompanied by support  
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40 221 letters from the autonomous community's departments of education and/or health and sports  
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42 222 and from Spain's Ministry of Education and Vocational Training; Ministry of Health,  
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44 223 Consumer Affairs and Social Welfare; Council of Sports and High Commission against  
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46 224 Child Poverty. In a second step, Gasol Foundation staff called the invited educational  
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48 225 centres to confirm their interest in participating. The principal investigators at these centres  
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50 226 are well-known experts in the investigation of the relationship between lifestyle and disease.  
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52 227 In a third step, the regional coordinators of the PASOS project contacted the interested  
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54 228 educational centres to introduce them to the study and invited them to participate. In the  
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3 229 participating schools, parents (or legal guardians) were contacted by teachers designated by  
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5 230 school administrators and received an envelope containing instructions to complete the  
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7 231 requested documentation, two copies of the informed consent form, and two copies of the  
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9 232 short questionnaires to be completed by an adult. When the school received a signed copy of  
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11 233 the informed consent form, the child participant and family were included in the PASOS  
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13 234 study. The study was approved by the ethics committee of the Fundació Sant Joan de Déu,  
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15 235 Barcelona, Spain.

## 19 236 **Study variables**

### 21 237 *Children and adolescents*

23 238 All the children and adolescent variables were gathered during school hours, using an online  
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25 239 system for questionnaires and with the logistical help of teachers to organize evaluation  
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27 240 sessions.

### 30 241 *Physical activity*

32 242 The PAU-7S, a 7-item self-reported questionnaire was used to assess PA levels in each  
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34 243 participating child or adolescent.

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37 244 Six questions ask about PA frequency and duration in the previous week: 1. How many days  
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39 245 did you go for a walk? 2. How many days did you participate in movement-play during  
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41 246 recess time? 3. How many days did you participate in movement-play during free time after  
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43 247 school or during the weekend? 4. How many days did you have Physical Education (PE)  
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45 248 class at school? 5. How many days did you play a team sport? 6. How many days did you  
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47 249 play an individual sport? The response options for these questions about PA are shown in a  
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49 250 table with a box for each day of the week, in which children can mark if they have spent (i)  
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51 251 0 minutes (no activity), (ii) less than 30 minutes; (iii) between 30 minutes and one hour; (iv)  
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53 252 between one hour and one hour and a half; or (v) more than one hour and a half. The final  
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3 253 question asks about health status with a Yes/No response option: Were you sick last week or  
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5 254 did anything prevent you from performing your usual PA?

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8 255 In addition, PA was objectively measured by accelerometers in 10% of the participants,  
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10 256 randomly selected from the entire sample. For 9 days, these children wore the ActiGraph  
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12 257 wGT3X-BT (Pensacola, FL, USA) accelerometer. Total-PA, PA intensity, sedentary time,  
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14 258 and sleep duration were recorded. Furthermore, children reported non-wear time, bedtime  
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17 259 and wake time in a daily log. Trained personnel instructed them how to report this  
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19 260 information.

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21 261 *Anthropometric variables*

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24 262 Anthropometrics for each individual were measured by trained personnel following the  
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26 263 WHO standardized protocol (22). Body weight, height, and waist circumference were  
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28 264 measured with the children in light clothing, without shoes. The measurements were  
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30 265 performed using an electronic SECA 899 scale (recorded to the nearest 100 g), a portable  
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32 266 SECA 217 stadiometer (to the nearest 1 mm), and a flexible, non-stretch SECA 201 metric  
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34 267 tape (to the nearest 1 mm), respectively. Waist circumference was measured in the narrowest  
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37 268 zone between the lower costal rib and iliac crest, in the supine decubitus and horizontal  
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39 269 positions.

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42 270 *Other child/adolescent lifestyle variables*

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44 271 Sedentary behaviour was assessed by the Screen-time Sedentary Behaviour Questionnaire  
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46 272 (23), which asks about time spent in 4 activities: [1] watching TV, [2] playing computer  
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48 273 games, [3] playing console (video) games, [4] using a mobile phone, separately for  
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50 274 weekdays and weekends.

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53 275 Diet was assessed by the 16-item KIDMED questionnaire that measures adherence to the  
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55 276 Mediterranean diet (24). The KIDMED index, derived on the basis of dichotomous response  
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57 277 options (Yes/No), was created to estimate adherence to the Mediterranean diet in children  
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3 278 and young adults, based on the principles that sustain Mediterranean dietary patterns and  
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5 279 those that undermine it. Items denoting lower adherence are assigned a value of -1 (4 items)  
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8 280 and those related to higher adherence are scored +1 (12 items).

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10 281 Sleep duration was recorded by 4 questions on hours of sleep from the Sleep Habits Survey  
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12 282 for Adolescents that ask about bedtime and time of waking up on weekdays and weekends  
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15 283 (25).

16  
17 284 In addition, adults were asked to complete the BEARS questionnaire on sleep quality in their  
18  
19 285 participating children/adolescents (26), responding (Yes/No) to questions about 5 main sleep  
20  
21 286 domains: A = bedtime problems, B = excessive daytime sleepiness, C = awakening during  
22  
23  
24 287 the night, D = regularity and duration of sleep, E = snoring.

25  
26 288 Quality of life was measured by the “EQ-5D-Y-5L” –a short, child-friendly EuroQuality  
27  
28 289 questionnaire on 5 health-related dimensions (mobility, self-care, usual activities,  
29  
30 290 pain/discomfort, anxiety/depression) with 5 response levels, recently validated in an  
31  
32  
33 291 international sample (including Spain) of children and adolescents aged 8 to 15 years (27).  
34  
35 292 To facilitate comparison with other studies, the 3-level version (EQ-5D-Y-3L) was also be  
36  
37 293 administered (28).

#### 38 39 40 294 ***Parental variables***

41  
42  
43  
44 295 Two sets of questionnaires were delivered to each participating child/adolescent, to be  
45  
46 296 answered separately by up to two parents/legal guardians. The validated REGICOR Short  
47  
48 297 PA Questionnaire (29) and the following standardized questions were included: sex, weight,  
49  
50 298 height, smoking habit, educational level, employment status, general health status, and sleep  
51  
52 299 duration. Parents were also asked about their child’s birthweight and if the child was  
53  
54  
55 300 breastfed.

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3 301 Additionally, parents/legal guardians were asked to respond to the following online  
4  
5 302 questionnaires:  
6  
7 303 - Diet Quality Screener, a short questionnaire about the frequency of consumption of  
8  
9 304 18 foods/food groups (30,31).  
10  
11 305 - Perceived Stress Scale (PSS), a subjective 14-item questionnaire asking about self-  
12  
13 306 perception of stress experienced during the previous month (32).  
14  
15 307 - Environmental questions such as access to cycling lanes or sports facilities are asked  
16  
17 308 to capture information that can be used to estimate the level of exposure to  
18  
19 309 contaminants such as air pollution and noise levels or access to green spaces.  
20  
21 310 - Quality of life, measured by adult response to the child-friendly EQ-5D-Y-5L (27).  
22  
23 311 Parental variables will be used to study the cross-sectional and prospective association  
24  
25 312 between parental lifestyle, such as physical activity and diet quality, with the  
26  
27 313 corresponding child lifestyle.  
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### 315 **Statistical Analysis**

316 A descriptive analysis of the data and a depuration of the database will be carried out to  
317 minimize errors. Before the construction of statistical models, quantitative variables will be  
318 checked according to their distribution, and, if necessary, logarithmic transformation will be  
319 carried out. Multivariate logistic and linear regression models will be carried out to  
320 determine the associations of exposures and outcomes of interest in cross-sectional and  
321 prospective analysis. Additionally, general linear models with post-hoc Bonferroni  
322 correction for repeated measurements will be executed. To address specific research  
323 questions appropriate statistical models, such as principal component analysis, cluster  
324 analysis, and mediation analysis, will be applied. Linear and logistic regression models with

1  
2  
3 325 cubic spline functions will be fitted to determine the dose-response relationship between  
4  
5 326 exposure and outcome.  
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10 327

### 11 328 **Patient and public involvement**

12  
13 329 Patients and the public were not involved in the development of the research question or in  
14  
15 330 the design of the study. The parents and legal tutors of participant children received the  
16  
17 331 informed consent and a letter inviting them to participate in the study. Also, parents and  
18  
19 332 legal tutors received a one-page plain language summary of the results of the anthropometric  
20  
21 333 measurements. The baseline results of the PASOS study are being disseminated to the  
22  
23 334 general public, an activity that will continue during the cohort study.  
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### 31 336 **DISCUSSION**

32  
33 337 The PASOS study is intended to provide an estimation of PA among Spanish children and  
34  
35 338 adolescents and, conversely, the magnitude of physical inactivity and sedentarism. The  
36  
37 339 representative design of the study is of particular importance because estimates of physical  
38  
39 340 inactivity can vary widely by population (33). Moreover, data obtained by accelerometers in  
40  
41 341 a representative sub-sample of 10% of the entire cohort will be used to calibrate self-  
42  
43 342 reported PA data obtained from the PAU-7S and to provide an objective and representative  
44  
45 343 measure of PA levels and of the prevalence of physical inactivity in Spanish children and  
46  
47 344 adolescents.  
48  
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50

51  
52 345 Some technical considerations must be kept in mind. First, accelerometer-derived  
53  
54 346 calculation of time spent in MVPA is based on the count-per-minute threshold for MVPA  
55  
56 347 that is applied (34-36). Differences in this parameter can strongly affect the estimate of PA  
57  
58 348 and the classification of adherence to PA guidelines (34,35). For example, Gaba and  
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2  
3 349 colleagues (34) showed that adherence to the PA guidelines ranged from 1% to 100%

4  
5 350 depending on the algorithm used. Therefore, the comparability of accelerometer-based PA  
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7 351 measurements is limited across studies.

8  
9  
10 352 To improve comparability of accelerometer-driven MVPA data from the PASOS study with  
11  
12 353 other research, several different accelerometer MVPA cut-off points and epoch lengths used  
13  
14 354 in other studies will be analysed and made public. In addition, calibration of the PAU-7S  
15  
16 355 will be stratified by sex and age group (primary vs secondary school students).

17  
18 356 The association between physical inactivity and increased risk of overweight and obesity in  
19  
20 357 children and adolescents (4) has multiple potential consequences (37) that persist into  
21  
22 358 adulthood. In addition, psychosocial restrictions such as impaired quality of life, self-esteem,  
23  
24 359 and school performance are to be expected (38). A recent meta-analysis showed that  
25  
26 360 children aged 5 to 15 years who are overweight or obese have more cardiometabolic  
27  
28 361 complications than children of normal weight (39). Furthermore, a cohort study found that  
29  
30 362 some risk factors, including fatty liver, are detectable even in overweight or obese  
31  
32 363 preschoolers.

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37  
38 364 Spain is among the European countries with the highest prevalence of overweight, obesity,  
39  
40 365 and severe obesity in children and adolescents (40,41). However, representative data on the  
41  
42 366 nationwide prevalence of abdominal obesity in Spanish children and adolescents aged 8 to  
43  
44 367 16 years has not been published since 2000 (42). Results of the PASOS study will provide  
45  
46 368 timely data on PA behaviours, the prevalence of overweight and obesity, and estimated  
47  
48 369 secular trends in abdominal obesity in a representative sample of this population. Finally,  
49  
50 370 our analysis of potential determinants of PA behaviours will improve our understanding of  
51  
52 371 which of these determinants are modifiable and accessible for intervention. Our findings will  
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54 372 contribute essential knowledge for the development and implementation of effective PA  
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3 373 promotion strategies in multilevel intervention programs designed to tackle childhood  
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5 374 obesity.

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8 375 **Ethics and dissemination**

9  
10  
11 376 Ethical approval was obtained from the ethics committee of the Fundació Sant Joan de Déu,  
12  
13 377 Barcelona, Spain. Findings will be disseminated in seminars, conference presentations, and  
14  
15 378 in peer-reviewed international journals.

16  
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18  
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42  
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47 393 Madrid, Spain.

48  
49  
50 394 **Contributors**

51  
52 395 SFG, CH and HS conceptualised and designed the study, drafted the initial manuscript and  
53  
54 396 incorporated the suggestions of all the consortium authors. JW, JCBM, MM, SA, FJZ, MM,

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2  
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4  
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6  
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8  
9  
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13  
14 402 MS, CL, JCBM, IL, AGZ, JSG, FJZ, PEA, MSS, EHR, SP, MMB, OS and HS defined the  
15  
16  
17 403 strategy to deploy the study protocol in their assigned schools and reviewed, contributed and  
18  
19 404 approved the final manuscript as submitted.

#### 21 405 **Competing interest**

22  
23  
24 406 None declared.

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35 411 preparation of the manuscript.

#### 36 37 412 **Data sharing**

38  
39  
40 413 Data is available for the PASOS study research consortium.

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## PASOS INVESTIGATORS

Steering Committee – SF. Gomez, H. Schröder

Gasol Foundation, Sant Boi de Llobregat, Spain: C. Homs, P. Berruezo, G. Según, M. Bellver, S. Torres, M. Picas, E. Lopez-Puertas, J. Antoni-Fernandez, A. Cosolo, S. Scarrone, A. Marin, V. Marzini, G. Zonta, S. Bernal

Cardiovascular Risk and Nutrition Research Group, IMIM (Hospital del Mar Medical Research Institut), Barcelona, Spain: M. Fitó, C. Lassale. I. Subirana, J. Vila, M. Grau

ELIKOS group, Institute for Innovation & Sustainable Development in Food Chain (IsFood), Public University of Navarra, Navarra, Spain: I. Labayen, M. Medrano, M. Oses, L. Arenaza

Faculty of Health Sciences, University of Málaga, Málaga, Spain: J. Wärnberg, J.C. Benavente-Marín, N. Pérez-Farinós, E. Crespo-Oliva, F.J. Barón López, J. Pérez-López, N. Moreno-Morales, P. Romero-Cazorla

Faculty of Sports Sciences and Physical Education, University of A Coruña, A Coruña, Spain: M.A. González-Valeiro, M. Sevilla-Sanchez

ImFINE Research Group. Department of Health and Human Performance. Universidad Politécnica de Madrid, Madrid, Spain: M. González-Gross, A.G. Zapico, E. Gesteiro, A.G. Carro, R. Torres-Peralta

PAFS Research Group, Faculty of Sports Sciences, University of Castilla-La Mancha, Toledo, Spain: S. Aznar, F. Jiménez-Zazo, E. Cabanillas, C. Romero-Blanco, A. Dorado.

Physical Activity and Quality of Life Research Group (AFYCAV), Faculty of Sport Sciences, University of Extremadura, Caceres, Spain: N. Gusi, J. Sánchez-Gómez

Probitas Foundation, Barcelona, Spain: M. Segú-Estruch, O. Sancho, C. Sistac

Regional Unit of Sports Medicine-Municipal Sports Foundation of Avilés, Asturias, Spain: N. Terrados, S. Pulgar

Research Center for High Performance Sport, Catholic University of Murcia, Murcia, Spain: Pedro E Alcaraz, E. Marín-Cascales

Research Group of Community Nutrition & Oxidative Stress, University of the Balearic Islands, Palma de Mallorca, Spain: J.A. Tur, M.M. Bibiloni, L. Gallardo-Alfaro

Research Institute of Biomedical and Health Sciences (IUIBS), University of Las Palmas de Gran Canaria, Las Palmas, Spain: L. Serra-Majem, E. Herrera-Ramos