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

Santiago Felipe Gómez [1,2] Clara Homs,[1,3] Julia Wärnberg,[4,5] Maria Medrano,[6] Marcela Gonzalez-Gross,[5,7] Narcis Gusi,[8] Susana Aznar,[9] Elena Marín Cascales,[10] Miguel González-Valeiro,[11] Lluis Serra-Majem,[12,13] Nicolás Terrados,[14] Josep A Tur,[15] Marta Segú,[16] Camille Lassale [17,18] Juan Carlos Benavente-Marín,[4] Idoia Labayen,[6] Augusto García Zapico,[7,19] Jesús Sánchez-Gómez,[8] Fabio Jiménez-Zazo,[9] Pedro Emilio Alcaraz,[10,20] Marta Sevilla-Sanchez [11] Estefania Herrera-Ramos,[12] Susana Pulgar,[14] Maria del Mar Bibiloni,[5,15] Olga Sancho,[16] Helmut Schröder[17,18]

Correspondence to
Dr Santiago Felipe Gómez;
sgomez@gasolfoundation.org

ABSTRACT

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

Methods and analysis We present the protocol for Physical Activity, Sedentarism, lifestyles and Obesity in Spanish youth (PASOS). This observational, nationally representative, multicentre study aims to determine the PA levels, sedentary behaviours and prevalence of physical inactivity (defined as <60 min of moderate to vigorous PA per day) in a representative sample of Spanish children and adolescents. The PASOS study has recruited a representative random sample of children and adolescents aged 8–16 years from 242 educational centres in the 17 'autonomous regions' into which Spain is divided. The aim is to include a total of 4508 youth participants and their families. Weight, height and waist circumference will be measured by standardised procedures. Adherence to the Mediterranean diet, quality of life, sleep duration, PA and sedentary behaviour are being measured by validated questionnaires. PA is measured by the Physical Activity Unit 7-item Screener. A representative subsample (10% of participants) was randomly selected to wear accelerometers for 9 days to obtain objective data on PA. Parents are asked about their educational level, time spent doing PA, diet quality, self-perceived stress, smoking habit, weight, height, their child's birth weight and if the child was breast fed.

Ethics and dissemination The study was approved by the Ethics Committee of the Fundació Sant Joan de Déu, Barcelona, Spain. Main findings of the study will be disseminated to the scientific community and to general public by media conferences, social media and a website.

Trial registration number ISRCTN34251612.

Strengths and limitations of this study

► The Physical Activity, Sedentarism, lifestyles and Obesity in Spanish youth study is a representative nationwide survey among Spanish youth.
► It provides data about physical activity, lifestyles and weight status.
► Sociodemographic data and parents' lifestyle variables are also evaluated.
► The study is not designed to provide representative data for each region.

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 underlined 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 was a 2012 report[6] because it indicated that 80.3% of adolescents worldwide did not meet the minimum 60 min of moderate to vigorous PA (MVPA) per day recommended by the WHO[1] for children and adolescents. Objectively measured PA data from the Healthy Lifestyle in Europe by Nutrition in Adolescence 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 Identification and Prevention of Dietary and Lifestyle-induced Health Effects in Children and Infants study reported similar data for Europe.[8] Results from a recently published review on objectively measured PA[9] revealed that 71% of European children and adolescents were physically active less than 1 hour/day and with considerable variability between countries. Furthermore, PA level decreased from north to south Europe.[9] 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.[10]

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.[11] Therefore, the Report on Physical Activity for Spanish Children and Adolescents[12 13] underlined the need to obtain objectively measured data in order to better estimate the number of Spanish youths not meeting the PA recommendations. Objective PA measurement can also be used to calibrate self-reported PA data, when both types of data are collected in the same individuals. This can reduce measurement error in questionnaire-derived PA estimates.

Furthermore, the identification and understanding of PA correlates and determinants is essential for the creation and implementation of intervention programmes aiming to increase PA in children and adolescents. Associations between PA and demographic, socioeconomic, psychological, social and behavioural factors have been reported in children, but the evidence is inconclusive.[14–17]

This manuscript describes the rationale and design of the Physical Activity, Sedentarism, lifestyles and Obesity in Spanish youth (PASOS) study, which aims to determine PA levels and its correlates in Spanish children and adolescents.

Objectives
Main objective
To determine the PA levels, sedentary behaviours and prevalence of physical inactivity in a representative sample of Spanish children and adolescents.

Secondary objectives
1. To determine the prevalence of general and abdominal obesity.
2. To calibrate the self-reported Physical Activity Unit 7-item Screener (PAU-7S) using objective accelerometer data from a representative subsample of 10% of the cohort.
3. To examine the inter-relationships between PA and demographic, lifestyle, socioeconomic, behavioural, anthropometric and environmental factors.

Incidences of obesity and physical inactivity in addition with a prospective data analysis of objective 3 will be addressed with follow-up data at the end of 2022.

METHODS/DESIGN
Study design
This is a multicentre, cross-sectional, nationally representative, population-based study. A follow-up of the study participants is planned for 2022 with a repeated collection of all baseline data.

Inclusion criteria
Children and adolescents aged 8–16 years who were enrolled in a participating school were eligible for inclusion.

Exclusion criteria
Individuals with an intellectual disability that prevents response to the lifestyle questionnaires were excluded of the baseline data collection. Each case was evaluated with the corresponding teachers and parents or legal guardians before exclusion.

Randomisation
Randomisation was performed by a multistage sampling procedure[18 19] including four stages. To obtain a sample of 4508 children/adolescents, assuming a mean of 18–20 pupils per classroom, 242 participating classrooms were required from the 17 'autonomous communities' into which 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 randomised across three population strata: 2000–30 000; 30 001–200 000; and more than 200 000 inhabitants. The total number of selected municipalities in each autonomous community was proportional to its share of the youth population of Spain aged 8–16 years.[20] In a second step, 242 schools were randomised 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 randomised. In the fourth and final step, a classroom for each scholar-year was randomised and invited to participate. A subsample of 23 classrooms (10%) was randomised for the objective measurement of PA by accelerometers. The software used for the sampling procedure were R, package mstage.

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.[21] According to the published data of the Spanish Report of Physical Activity,[12 13] 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 were 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 ≥80% to identify an increase of 8% as significant (p≤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

Baseline data were collected from March 2019 to February 2020, in 242 primary and secondary schools. Two visits were carried out in each school by two field researchers with a background in physical education (PE), nutrition or other health sciences. They completed a 1-day training session on the project methodology, hosted by the Gasol Foundation. An additional visit was made to the 10% of the schools included in the accelerometer protocol. Lifestyle data of children/adolescents were self-reported online at participating schools, with the assistance of trained personnel. Parental sociodemographic and lifestyle (PA and smoking) data were collected in paper format. Additional data on parental health habits were recorded via an online system.

Participants and recruitment process

The aim was 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 8–16 years, were not included for logistical reasons.

This cohort 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 USA and Spain. Field and scientific work is being performed together with 13 highly experienced research groups working at universities and research centres in several regions of Spain (online supplemental file 1). Selected educational centres first received 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. In a second step, Gasol Foundation staff called the invited educational centres to confirm their interest in participating. The principal investigators at these centres are well-known experts in the investigation of the relationship between lifestyle and disease. In a third step, the regional coordinators of the PASOS project contacted the interested educational centres to introduce them to the study and invited them to participate. In the participating schools, parents (or legal guardians) were contacted by teachers designated by school administrators and received 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 received a signed copy of the informed consent form, the child participant and family were included in the PASOS study. The study was approved by the Ethics Committee of the Fundació Sant Joan de Déu, Barcelona, Spain.

Study variables
Children and adolescents

All the children and adolescent variables were gathered during school hours, using an online system for questionnaires and with the logistical help of teachers to organise evaluation sessions.

Physical activity

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

Six questions ask about PA frequency and duration in the previous week: (1) How many days did you go for a walk? (2) How many days did you participate in movement play during recess time? (3) How many days did you participate in movement play during free time after school or during the weekend? (4) How many days did you have PE class at school? (5) How many days did you play a team sport? (6) How many days did you play an individual sport? The response options for these questions about PA are shown in a table with a box for each day of the week, in which children can mark if they have spent: (1) 0 min (no activity); (2) less than 30 min; (3) between 30 min and 1 hour; (4) between 1 hour and 1.5 hours; or (5) more than 1.5 hours. The final question asks about health status with a Yes/No response option: Were you sick last week or did anything prevent you from performing your usual PA?

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

Anthropometric variables

Anthropometrics for each individual were measured by trained personnel following the WHO standardised protocol.[22] Body weight, height and waist circumference were measured with the children in light clothing, without shoes. The measurements were performed using an electronic SECA 899 scale (recorded to the nearest 100 g), a portable SECA 217 stadiometer (to the nearest 1 mm) and a flexible, non-stretch SECA 201 metric tape (to the nearest 1 mm), respectively. Waist circumference was

measured in the narrowest zone between the lower costal rib and iliac crest, in the supine decubitus and horizontal positions.

Other child/adolescent lifestyle variables

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

Diet was assessed by the 16-item KIDMED questionnaire(Kids level of adherence to the Mediterranean diet).[24] The KIDMED index, derived on the basis of dichotomous response options (Yes/No), was created to estimate adherence to the Mediterranean diet in children and young adults, based on the principles that sustain Mediterranean dietary patterns and those that undermine it. Items denoting lower adherence are assigned a value of −1 (4 items) and those related to higher adherence are scored +1 (12 items).

Sleep duration was recorded by four questions on hours of sleep from the Sleep Habits Survey for Adolescents that ask about bedtime and time of waking up on weekdays and weekends.[25]

In addition, adults were asked to complete the BEARS (Bedtime, Excessive, Awakening, Regularity, Snoring) questionnaire on sleep quality in their participating children/adolescents,[26] responding (Yes/No) to questions about five main sleep domains: A=bedtime problems, B=excessive daytime sleepiness, C=awakening during the night, D=regularityand duration of sleep, E=snoring.

Quality of life was measured by the 'EQ-5D-Y-5L'—a short, child-friendly EuroQuality questionnaire on five health-related dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) with five response levels, recently validated in an international sample (including Spain) of children and adolescents aged 8–15 years.[27] To facilitate comparison with other studies, the 3-level version (EQ-5D-Y-3L) was also to be administered.[28]

Parental variables

Two sets of questionnaires were delivered to each participating child/adolescent, to be answered separately by up to two parents/legal guardians. The validated REGICOR (REgistre GIroní del COR) short PA Questionnaire[29] and the following standardised questions were included: sex, weight, height, smoking habit, educational level, employment status, general health status and sleep duration. Parents were also asked about their child's birth weight and if the child was breast fed.

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

▶ Diet Quality Screener, a short questionnaire about the frequency of consumption of 18 foods/food groups.[30 31]

▶ Perceived Stress Scale, a subjective 14-item questionnaire asking about self-perception of stress experienced during the previous month.[32]

▶ 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.[27]

Parental variables will be used to study the cross-sectional and prospective association between parental lifestyle, such as PA and diet quality, with the corresponding child lifestyle.

Statistical analysis

A descriptive analysis of the data and a depuration of the database will be carried out to minimise errors. Before the construction of statistical models, quantitative variables will be checked according to their distribution, and, if necessary, logarithmic transformation will be carried out. Multivariate logistic and linear regression models will be carried out to determine the associations of exposures and outcomes of interest in cross-sectional and prospective analysis. Additionally, general linear models with post hoc Bonferroni correction for repeated measurements will be executed. To address specific research questions, appropriate statistical models, such as principal component analysis, cluster analysis and mediation analysis, will be applied. Linear and logistic regression models with cubic spline functions will be fitted to determine the dose–response relationship between exposure and outcome.

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 received the informed consent and a letter inviting them to participate in the study. Also, parents and legal tutors received a one-page plain language summary of the results of the anthropometric measurements. The baseline results of the PASOS study are being disseminated to the general public, an activity that will continue during the cohort study.

DISCUSSION

The PASOS study is intended to provide an estimation of PA among Spanish children and adolescents and, conversely, the magnitude of physical inactivity and sedentarism. The representative design of the study is of particular importance because estimates of physical inactivity can vary widely by population.[33] Moreover, data obtained by accelerometers in a representative subsample of 10% of the entire cohort will be used to calibrate self-reported PA data obtained from the PAU-7S and to provide an objective and representative measure of PA levels and of

the prevalence of physical inactivity in Spanish children and adolescents.

Some technical considerations must be kept in mind. First, accelerometer-derived calculation of time spent in MVPA is based on the count-per-minute threshold for MVPA that is applied.[34–36] Differences in this parameter can strongly affect the estimate of PA and the classification of adherence to PA guidelines.[34 35] For example, Gába and colleagues[34] showed that adherence to the PA guidelines ranged from 1% to 100% depending on the algorithm used. Therefore, the comparability of accelerometer-based PA measurements is limited across studies.

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

The association between physical inactivity and increased risk of overweight and obesity in children and adolescents[4] has multiple potential consequences[37] that persist into adulthood. In addition, psychosocial restrictions such as impaired quality of life, self-esteem and school performance are to be expected.[38] A recent meta-analysis showed that children aged 5–15 years who are overweight or obese have more cardiometabolic complications than children of normal weight.[39] Furthermore, a cohort study found that some risk factors, including fatty liver, are detectable even in overweight or obese preschoolers.

Spain is among the European countries with the highest prevalence of overweight, obesity and severe obesity in children and adolescents.[40 41] However, representative data on the nationwide prevalence of abdominal obesity in Spanish children and adolescents aged 8–16 years have not been published since 2000.[42] Results of the PASOS study will provide timely data on PA behaviours, the prevalence of overweight and obesity, and estimated secular trends in abdominal obesity in a representative sample of this population. Finally, our analysis of potential determinants of PA behaviours will improve our understanding of which of these determinants are modifiable and accessible for intervention. Our findings will contribute essential knowledge for the development and implementation of effective PA promotion strategies in multilevel intervention programmes designed to tackle childhood obesity.

Author affiliations
[1]Programs, Gasol Foundation, Sant Boi de Llobregat, Barcelona, Spain
[2]GREpS, Health Education Research Group, Nursing and Physiotherapy Department, University of Lleida, Lleida, Catalunya, Spain
[3]Global Research on Wellbeing (GRoW), Blanquerna Ramon Llull University Faculty of Health Sciences, Barcelona, Catalunya, Spain
[4]Faculty of Health Sciences, Institute of Biomedical Research of Malaga (IBIMA), University of Málaga, Malaga, Andalucía, Spain
[5]Centro de Investigación Biomédica en Red-Fisiopatología de la Obesidad y la Nutrición (CIBEROBN), Carlos III Health Institute, Madrid, Spain
[6]ELIKOS Group, Institute for Innovation and Sustainable Development in Food Chain (IS-FOOD), Public University of Navarre, Pamplona, Navarra, Spain
[7]ImFINE Research Group, Department of Health and Human Performance, Universidad Politecnica de Madrid, Madrid, Comunidad de Madrid, Spain
[8]Physical Activity and Quality of Life Research Group (AFYCAV), Faculty of Sport Sciences, University of Extremadura, Caceres, Extremadura, Spain
[9]PAFS Research Group, Faculty of Sports Sciences, University of Castilla-La Mancha–Toledo Campus, Toledo, Castilla-La Mancha, Spain
[10]Research Center for High Performance Sport, San Antonio Catholic University of Murcia, Murcia, Spain
[11]Faculty of Sports Sciences and Physical Education, Universidade da Coruña, A Coruna, Galicia, Spain
[12]Research Institute of Biomedical and Health Sciences (IUIBS), University of Las Palmas de Gran Canaria, Las Palmas, Canary Islands, Spain
[13]Preventive Medicine Service, Centro Hospitalario Universitario Insular Materno Infantil (CHUIMI), Canarian Health Service, Las Palmas, Spain
[14]Regional Unit of Sports Medicine, Municipal Sports Foundation of Avilés, Avilés, Spain
[15]Research Group of Community Nutrition and Oxidative Stress, University of the Balearic Islands, Palma de Mallorca, Illes Balears, Spain
[16]Probitas Foundation, Barcelona, Spain
[17]CIBER Epidemiology and Public Health (CIBERESP), Carlos III Health Institute, Madrid, Spain
[18]Cardiovascular Risk and Nutrition Research Group, Hospital del Mar Institute for Medical Research, Barcelona, Catalunya, Spain
[19]Department of Didactics of Language, Arts and Physical Education, Universidad Complutense de Madrid, Madrid, Comunidad de Madrid, Spain
[20]Faculty of Sport Sciences, San Antonio Catholic University of Murcia, Murcia, Spain

ORCID iDs
Santiago Felipe Gómez http://orcid.org/0000-0003-3352-2510
Camille Lassale http://orcid.org/0000-0002-9340-2708
Marta Sevilla-Sanchez http://orcid.org/0000-0003-2004-9162

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