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

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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, and Obesity in Spanish youth (PASOS). This cross-sectional, observational, nationally representative, multi-centre study aims to determine the PA levels, sedentary behaviours, and prevalence of physical inactivity (defined as <60 minutes of moderate to vigorous PA per day) in a representative sample of Spanish children and adolescents. The PASOS study will recruit a representative random sample of children and adolescents aged 8 to 16 years from 245 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 standardized procedures. Adherence to the Mediterranean diet, quality of life, sleep duration, PA and sedentary behaviour will be measured by validated questionnaires. PA will be measured by the Physical Activity United 7-item Screener (PAU-7S). A representative sub-sample (10% of participants) will be randomly selected to wear accelerometers for 9 days in order to obtain objective data on PA. Following the validated methodology used in previous studies, parents will be asked about their educational level, time spent doing PA, diet quality, self-perceived stress, smoking habit, weight, height, their child's birthweight and if the child was breastfed.

ETHICS AND DISSEMINATION: The study was approved by the ethics committee of the Fundació Sant Joan de Déu, Barcelona, Spain. According to the principles of the GASOL Foundation, which coordinates the PASOS study, main findings of the study will not only be disseminated to the scientific community through peer-review journals and

scientific conferences but also will be communicated by media conferences, press releases, social media and an accessible website so that the general public and the families benefit from the results and participate in the solutions.

Strengths and limitations of this study

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

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

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 programs 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 (13).

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

METHODS/DESIGN

Study design

This is a multicentre, cross-sectional, nationally representative, population-based study.

Inclusion criteria

Children and adolescents aged 8 to 16 years who are enrolled in a participating school are eligible for inclusion.

Exclusion criteria

Individuals with an intellectual disability that prevents response to the lifestyle questionnaires will be excluded. Each case will be evaluated with the corresponding teachers and parents or legal guardians before exclusion.

Randomization

Randomization was performed by a four-stage sampling procedure. To obtain a sample of 4508 children/adolescents, assuming a mean of 18-20 pupils per classroom, 242 participating classrooms are 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 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 ≥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.

In a second step, Gasol Foundation staff will call 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 will contact interested educational centres to introduce them to the study and invite them to participate. In the participating schools, parents (or legal guardians) are contacted by teachers designated by school administrators and receive an envelope containing instructions to complete the requested documentation, two copies of the informed consent form, and two copies of the short questionnaires to be completed by an adult. When the school receives a signed copy of the informed consent form, the child participant and family are included in the PASOS study. The study was approved by the ethics committee of the Fundació Sant Joan de Déu, Barcelona, Spain.

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 Unified questionnaire - 7-item Screener (PAU-7S) using objective accelerometer data from a representative sub-sample of 10% of the cohort.

3. To examine the interrelationships between PA and demographic, lifestyle, socioeconomic, behavioural, anthropometric and environmental factors.

Study variables

Children and adolescents

Physical activity

The PAU-7S, a 7-item self-reported questionnaire will be used to assess PA levels in each participating child or adolescent. A previous pilot validation study **(supplementary file 2)** revealed a reasonable validity (r= 0.33) and moderate reliability (intra class correlation coefficient = 0.55) of this questionnaire in children aged 8 to 12 years.

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 Physical Education (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 (i) 0 minutes (no activity), (ii) less than 30 minutes; (iii) between 30 minutes and one hour; (iv) between one hour and one hour and a half; or (v) more than one hour and a half. 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 will be objectively measured by accelerometers in 10% of the participants, randomly selected from the entire sample. For 9 days, these children will wear the ActiGraph wGT3X-BT (Pensacola, FL, USA) accelerometer. Total-PA, PA intensity, sedentary time, and sleep duration will be recorded. Furthermore, children will report non-wear time, bedtime and wake time in a daily log. Trained personnel will instruct them how to report this information.

Anthropometric variables

Anthropometrics for each individual will be measured by trained personnel following a standardized protocol. Body weight, height, and waist circumference are measured with the children in light clothing, without shoes. The measurements are 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 is 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 is assessed by the Screen-time Sedentary Behaviour Questionnaire (16), which asks about time spent in 4 activities: [1] watching TV, [2] playing computer games, [3] playing console (video) games, [4] using a mobile phone, separately for weekdays and weekends.

Diet is assessed by the 16-item KIDMED questionnaire that measures adherence to the Mediterranean diet (17). 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 is recorded by 4 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 (18). In addition, adults will be asked to complete the BEARS questionnaire on sleep quality in their participating children/adolescents (19), responding (Yes/No) to questions about 5 main sleep domains: A = bedtime problems, B = excessive daytime sleepiness, C = awakening during the night, D = regularity and duration of sleep, E = snoring.

Quality of life is measured by the "EQ-5D-Y-5L" –a short, child-friendly EuroQuality questionnaire on 5 health-related dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) with 5 response levels, recently validated in an international sample (including Spain) of children and adolescents aged 8 to 15 years (20).

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

anthropometric measurements. The results of the PASOS study will be disseminated to the general public.

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 (26). Moreover, data obtained by accelerometers in a representative sub-sample 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 (27-29). Differences in this parameter can strongly affect the estimate of PA and the classification of adherence to PA guidelines (27,28). For example, Gaba and colleagues (27) 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 (30) that persist into adulthood. In addition, psychosocial restrictions such as impaired quality of life, self-esteem,

and school performance are to be expected (31). A recent meta-analysis showed that children aged 5 to 15 years who are overweight or obese have more cardiometabolic complications than children of normal weight (32). 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 (33, 34). However, representative data on the nationwide prevalence of abdominal obesity in Spanish children and adolescents aged 8 to 16 years has not been published since 2000 (35). 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 programs designed to tackle childhood obesity.

Ethics and dissemination

Ethical approval was obtained from the ethics committee of the Fundació Sant Joan de Déu, Barcelona, Spain. Findings will be disseminated in seminars, conference presentations, and in peer-reviewed international journals.

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Contributorship

SFG, CH and HS conceptualised and designed the study, drafted the initial manuscript and incorporated the suggestions of all the consortium authors. JW, MM, SA and IL, made relevant contributions to the accelerometry protocol and formed with SFG, CH and HS the accelerometry commission of the PASOS study. MGG, NG and JAT made substantial contributions to the study protocol and the representative randomization of the Spanish population. JW, MM, MGG, SA, IL and AGZ critically revising the manuscript for important intellectual content. All authors defined the strategy to deploy the study protocol in their assigned schools and approved the final manuscript as submitted.

Competing interest

None declared.

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funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Data sharing

Data is available for the PASOS study research consortium.

References

1.WHO Fact sheets. Physical Activity 2018. https://www.who.int/news-room/fact-sheets/detail/physical-activity

2. Ding D, Lawson KD, Kolbe-Alexandar TL, Finkelstein EA, Katzmarzyk PT, van Mechelen W, Pratt M; Lancet Physical Activity Series 2 Executive Committee. The economic burden of physical inactivity: a global analysis of major non-communicable diseases. Lancet 2016; 388-1311-24. doi: 10.1016/S0140-6736(16)30383-X.

3. Piercy KL, Troiano RP, Ballard RM, Carlson SA, Fulton JE, Galuska DA, George SM, Olson RD. The Physical Activity Guidelines for Americans. JAMA. 2018 Nov 20;320(19):2020-2028. doi: 10.1001/jama.2018.14854

4. Hills AP, Andersen LB, Byrne NM. Physical activity and obesity in children. Br J Sports Med. 2011 Sep;45(11):866-70. doi: 10.1136/bjsports-2011-090199.

5. Guthold R, Stevens GA, Riley LM, Bull FC. Worldwide trends in insufficient physical activity from 2001 to 2016: a pooled analysis of 358 population-based surveys with 1·9 million participants. Lancet Glob Health. 2018 Oct;6(10):e1077-e1086. doi: 10.1016/S2214-109X(18)30357-7

6. Hallal PC, Andersen LB, Bull FC, Guthold R, Haskell W, Ekelund U; Lancet Physical Activity Series Working Group. Global physical activity levels: surveillance progress,

pitfalls, and prospects. Lancet. 2012 Jul 21;380(9838):247-57. doi: 10.1016/S0140-6736(12)60646-1.

7. Ruiz JR, Ortega FB, Martínez-Gómez D, Labayen I, Moreno LA, De Bourdeaudhuij I, Manios Y, Gonzalez-Gross M, Mauro B, Molnar D, Widhalm K, Marcos A, Beghin L, Castillo MJ, Sjöström M; HELENA Study Group. Objectively measured physical activity and sedentary time in European adolescents: the HELENA study. Am J Epidemiol. 2011 Jul 15;174(2):173-84. doi: 10.1093/aje/kwr068.

8. Konstabel K, Veidebaum T, Verbestel V, Moreno LA, Bammann K,Tornaritis M, Eiben G, Molnár D, Siani A, Sprengeler O, Wirsik N, Ahrens W, Pitsiladis Y; IDEFICS consortium. Objectively measured physical activity in European children: the IDEFICS study. Int J Obes (Lond). 2014 Sep;38 Suppl 2:S135-43. doi: 10.1038/ijo.2014.144.

9. Sirard JR, Pate RR. Physical activity assessment in children and adolescents. Sports Med. 2001;31(6):439-454.

10. Kalman M, Inchley J, Sigmundova D, Iannotti RJ, Tynjälä JA, Hamrik Z, Haug E, Bucksch J. Secular trends in moderate-to-vigorous physical activity in 32 countries from 2002 to 2010: a cross-national perspective. Eur J Public Health. 2015 Apr;25 Suppl 2:37-40. doi: 10.1093/eurpub/ckv024.

11. Informe 2016: Actividad Física en niños y adolescentes en España. Fundación para la Investigación Nutricional. https://www.activehealthykids.org/wp-content/uploads/2016/11/spain-report-card-long-form-2016.pdf

12. Roman-Viñas B, Marin J, Sánchez-López M, Aznar S, Leis R, Aparicio-Ugarriza R, Schroder H, Ortiz-Moncada R, Vicente G, González-Gross M, Serra-Majem L. Results

From Spain's 2016 Report Card on Physical Activity for Children and Youth. J Phys Act Health. 2016 Nov;13(11 Suppl 2):S279-S283. doi: 10.1123/jpah.2018-0464.

13. Craggs C, Corder K, van Sluijs EM, Griffin SJ. Determinants of change in physical activity in children and adolescents: a systematic review. Am J Prev Med. 2011 Jun;40(6):645-58. doi: 10.1016/j.amepre.2011.02.025.

14. Instituto Nacional de Estadistica 2018. http://www.ine.es/jaxi/Tabla.htm?path=/t20/e245/p08/l0/&file=02002.px

15. WHO - World Health Organization. Recommended levels of physical activity for children aged 5–17 years. Global recommendations on physical activity for health. http://www.who.int/dietphysicalactivity/factsheet_young_people/en/.

16. Rey-López JP, Ruiz JR, Ortega FB, Verloigne M, Vicente-Rodriguez G, Gracia-Marco L, Gottrand F, Molnar D, Widhalm K, Zaccaria M, Cuenca-García M, Sjöström M, De Bourdeaudhuij I, Moreno LA; HELENA Study Group. Reliability and validity of a screen time-based sedentary behaviour questionnaire for adolescents: The HELENA study. Eur J Public Health. 2012 Jun;22(3):373-7. doi: 10.1093/eurpub/ckr040. Epub 2011 Apr 15.

17. Serra-Majem L, Ribas L, Ngo J, Ortega RM, García A, Pérez-Rodrigo C, Aranceta J. Food, youth and the Mediterranean diet in Spain. Development of KIDMED, Mediterranean Diet Quality Index in children and adolescents. Public Health Nutr. 2004 Oct;7(7):931-5.

18. Wolfson AR, Carskadon MA, Acebo C, Seifer R, Fallone G, Labyak SE, Martin JL. Evidence for the validity of a sleep habits survey for adolescents. Sleep. 2003 Mar 15;26(2):213-6.

19. Owens JA, Dalzell V. Use of the 'BEARS' sleep screening tool in a pediatric residents' continuity clinic: a pilot study. Sleep Med. 2005 Jan;6(1):63-9. Epub 2005 Jan 12.

20. Kreimeier S, Åström M, Burström K, Egmar AC, Gusi N, Herdman M, Kind P, Perez-Sousa MA, Greiner W. EQ-5D-Y-5L: developing a revised EQ-5D-Y with increased response categories. Qual Life Res. 2019 Jul;28(7):1951-1961. doi: 10.1007/s11136-019-02115-x. Epub 2019 Feb 9.

21. The EuroQol Group (1990). EuroQol-a new facility for the measurement of health-related quality of life. Health Policy 16(3):199-208.

22. Molina L, Sarmiento M, Peñafiel J, Donaire D, Garcia-Aymerich J, Gomez M, Ble M, Ruiz S, Frances A, Schröder H, Marrugat J, Elosua R. Validation of the Regicor Short Physical Activity Questionnaire for the Adult Population. PLoS One. 2017 Jan 13;12(1):e0168148. doi: 10.1371/journal.pone.0168148. eCollection 2017.

23. Schröder H, Benitez Arciniega A, Soler C, Covas MI, Baena-Díez JM, Marrugat J; REGICOR investigators; HERMES investigators. Validity of two short screeners for diet quality in time-limited settings. Public Health Nutr. 2012 Apr;15(4):618-26. doi: 10.1017/S1368980011001923. Epub 2011 Aug 23.

24. Funtikova A, Baena-Díez JM, Koebnick C, Gomez SF, Covas MI, Goday A, Schröder H. Validity of a short diet-quality index to predict changes in anthropometric and cardiovascular risk factors: a simulation study. Eur J Clin Nutr. 2012 Dec;66(12):1369-71. doi: 10.1038/ejcn.2012.131. Epub 2012 Sep 26.

25. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. J Health Soc Behav. 1983 Dec;24(4):385-96.

26. Guinhouya BC, Samouda H, de Beaufort C. Level of physical activity among children and adolescents in Europe: a review of physical activity assessed objectively by

accelerometry. Public Health. 2013 Apr;127(4):301-11. doi: 10.1016/j.puhe.2013.01.020. Epub 2013 Apr 10.

27. Gába A, Dygrýn J, Mitáš J, Jakubec L, Frömel K. Effect of Accelerometer Cut-Off Points on the Recommended Level of Physical Activity for Obesity Prevention in Children. 1. PLoS One. 2016 Oct 10;11(10):e0164282. doi: 10.1371/journal.pone.0164282. eCollection 2016.

28. Brazendale K, Beets MW, Rowlands AV, Chandler JL, Fairclough SJ, Boddy LM, Olds TS, Parfitt G, Noonan RJ, Downs SJ, Cliff DP. Converting between estimates of moderate-to-vigorous physical activity derived from raw accelerations measured at the wrist and from ActiGraph counts measure at the hip: the Rosetta Stone. J Sports Sci. 2018 Nov;36(22):2603-2607. doi: 10.1080/02640414.2018.1470373. Epub 2018 Apr 30.

29.Banda JA, Haydel KF, Davila T, Desai M, Bryson S, Haskell WL, Matheson D, Robinson TN. Effects of Varying Epoch Lengths, Wear Time Algorithms, and Activity Cut-Points on Estimates of Child Sedentary Behavior and Physical Activity from Accelerometer Data. PLoS One. 2016 Mar 3;11(3):e0150534. doi: 10.1371/journal.pone.0150534. eCollection 2016.

30. Whooten R, Kerem L, Stanley T. Physical activity in adolescents and children and relationship to metabolic health. Curr Opin Endocrinol Diabetes Obes. 2019 Feb;26(1):25-31. doi:10.1097/MED.0000000000000455.

31. de Greeff JW, Bosker RJ, Oosterlaan J, Visscher C, Hartman E. Effects of physical activity on executive functions, attention and academic performance in preadolescent children: a meta-analysis. J Sci Med Sport. 2018 May;21(5):501-507. doi: 10.1016/j.jsams.2017.09.595. Epub2017 Oct 10.

32. Friedemann C, Heneghan C, Mahtani K, Thompson M, Perera R, Ward AM. Cardiovascular disease risk in healthy children and its association with body mass index: systematic review and meta-analysis. BMJ. 2012 Sep 25;345:e4759. doi: 10.1136/bmj.e4759.

33. Sánchez-Cruz JJ, Jiménez-Moleón JJ, Fernández-Quesada F, Sánchez MJ. Prevalence of child and youth obesity in Spain in 2012. Rev Esp Cardiol (Engl Ed). 2013 May;66(5):371-6. doi: 10.1016/j.rec.2012.10.012. Epub 2013 Feb 1.

34. Cadenas-Sanchez C, Intemann T, Labayen I, Artero EG, Alvarez-Bueno C, Sanchis-Moysi J, Benito PJ, Beltran-Valls MR, Pérez-Bey A, Sanchez-Delgado G, Palou P, Vicente-Rodríguez G, Moreno LA, Ortega FB; PREFIT project group. Prevalence of severe/morbid obesity and other weight status and anthropometric reference standards in Spanish preschool children: The PREFIT project. Pediatr Res. 2019 Feb 18. doi: 10.1038/s41390-019-0325-8. [Epub ahead of print]

35. Schröder H, Ribas L, Koebnick C, Funtikova A, Gomez SF, Fíto M, Perez-Rodrigo C, Serra-Majem L. Prevalence of abdominal obesity in Spanish children and adolescents. Do we need waist circumference measurements in pediatric practice? PLoS One. 2014 Jan 27;9(1):e87549. doi: 10.1371/journal.pone.0087549. eCollection 2014.

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Table 1. Test-retest reliability of physical activities recorded at baseline and after 1 week.[1]

	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)[2]	0.50	0.44	0.54
Physical education (min/d)	-0.02	-0.15	0.08
Movement play (min/d)[3]	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

[1] Intra-class correlation coefficient.

[2] School recess.

[3] Free time outside of school.

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

Table 2. Correlation coefficients[1] of physical activities recorded by the questionnaire and moderate to vigorous physical activity measured by accelerometers.

	All (n=138)	Boys (n=78)	Girls (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)[2]	0.23*	0.16	0.21
Movement play (min/d)[3]	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

[1] *r* for total physical activity and *rho* for the rest of activities.

[2] School recess.

[3] Free time outside school.

*$P < 0.05$

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

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

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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, and Obesity in Spanish youth (PASOS). This observational, nationally representative, multi-centre study aims to determine the PA levels, sedentary behaviours, and prevalence of physical inactivity (defined as <60 minutes 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 to 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 standardized 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 United 7-item Screener (PAU-7S). A representative sub-sample (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 birthweight and if the child was breastfed.

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.

Strengths and limitations of this study

- The PASOS study is a representative nationwide survey among Spanish youth.
- It provides data about physical activity, lifestyles, and weight status.
- Sociodemographic data and parents' lifestyles 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 indicated 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). Results from a recently published review on objectively measured physical activity (9) revealed that 71% of European children and adolescents were physically active less than 1 hour per day and with considerable variability between countries. Furthermore, physical activity 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 programs 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, 15, 16, 17).

This manuscript describes the rationale and design of the 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 Unified questionnaire - 7-item Screener (PAU-7S) using objective accelerometer data from a representative sub-sample of 10% of the cohort.

3. To examine the interrelationships 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 to 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.

Randomization

Randomization was performed by a multi-stage 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 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 was proportional to its share of the youth population of Spain aged 8 to 16 years (20). In a

second step, 242 schools were randomized from the selected municipalities, along with up to three replacements for each selected school to account for census data error or centres not willing to participate. In a third step, scholar-year per school was randomized. In the fourth and final step, a classroom for each scholar-year was randomized and invited to participate. A sub-sample of 23 classrooms (10%) was randomized 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 ($p \leq 0.05$). 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

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 2 field researchers with a background in physical education, nutrition, or other health sciences. They completed a one-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 to 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 United States and Spain. Field and scientific work is being 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 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 organize 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 Physical Education (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 (i) 0 minutes (no activity), (ii) less than 30 minutes; (iii) between 30 minutes and one hour; (iv) between one hour and one hour and a half; or (v) more than one hour and a half. 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 standardized 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 4 activities: [1] watching TV, [2] playing computer games, [3] playing console (video) games, [4] using a mobile phone, separately for weekdays and weekends.

Diet was assessed by the 16-item KIDMED questionnaire that measures 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 4 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 questionnaire on sleep quality in their participating children/adolescents (26), responding (Yes/No) to questions about 5 main sleep domains: A = bedtime problems, B = excessive daytime sleepiness, C = awakening during the night, D = regularity and duration of sleep, E = snoring.

Quality of life was measured by the "EQ-5D-Y-5L" –a short, child-friendly EuroQuality questionnaire on 5 health-related dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) with 5 response levels, recently validated in an international sample (including Spain) of children and adolescents aged 8 to 15 years (27). To facilitate comparison with other studies, the 3-level version (EQ-5D-Y-3L) was also 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 Short PA Questionnaire (29) and the following standardized 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 birthweight and if the child was breastfed.

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 (PSS), 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 physical activity 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 minimize 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 sub-sample 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, Gaba 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 to 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 to 16 years has 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 programs designed to tackle childhood obesity.

Ethics and dissemination

Ethical approval was obtained from the ethics committee of the Fundació Sant Joan de Déu, Barcelona, Spain. Findings will be disseminated in seminars, conference presentations, and in peer-reviewed international journals.

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Contributors

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

and IL, made relevant contributions to the accelerometry protocol and formed with SFG, CH and HS the accelerometry commission of the PASOS study. MGG, NG and JAT made substantial contributions to the study protocol and the representative randomization of the Spanish population. JW, MM, MGG, SA, IL and AGZ made a relevant intellectual input to the manuscript content. SFG, CH, JW, MM, MGG, NG, SA, EMC, MAGV, LSM, NT, JAT MS, CL, JCBM, IL, AGZ, JSG, FJZ, PEA, MSS, EHR, SP, MMB, OS and HS defined the strategy to deploy the study protocol in their assigned schools and reviewed, contributed and approved the final manuscript as submitted.

Competing interest

None declared.

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Data sharing

Data is available for the PASOS study research consortium.

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References

1.WHO Fact sheets. Physical Activity 2018. https://www.who.int/news-room/fact-sheets/detail/physical-activity

2. Ding D, Lawson KD, Kolbe-Alexandar TL, Finkelstein EA, Katzmarzyk PT, van Mechelen W, Pratt M; Lancet Physical Activity Series 2 Executive Committee. The

economic burden of physical inactivity: a global analysis of major non-communicable diseases. Lancet 2016; 388-1311-24. doi: 10.1016/S0140-6736(16)30383-X.

3. Piercy KL, Troiano RP, Ballard RM, Carlson SA, Fulton JE, Galuska DA, George SM, Olson RD. The Physical Activity Guidelines for Americans. JAMA. 2018 Nov 20;320(19):2020-2028. doi: 10.1001/jama.2018.14854

4. Hills AP, Andersen LB, Byrne NM. Physical activity and obesity in children. Br J Sports Med. 2011 Sep;45(11):866-70. doi: 10.1136/bjsports-2011-090199.

5. Guthold R, Stevens GA, Riley LM, Bull FC. Worldwide trends in insufficient physical activity from 2001 to 2016: a pooled analysis of 358 population-based surveys with 1·9 million participants. Lancet Glob Health. 2018 Oct;6(10):e1077-e1086. doi: 10.1016/S2214-109X(18)30357-7

6. Hallal PC, Andersen LB, Bull FC, Guthold R, Haskell W, Ekelund U; Lancet Physical Activity Series Working Group. Global physical activity levels: surveillance progress, pitfalls, and prospects. Lancet. 2012 Jul 21;380(9838):247-57. doi: 10.1016/S0140-6736(12)60646-1.

7. Ruiz JR, Ortega FB, Martínez-Gómez D, Labayen I, Moreno LA, De Bourdeaudhuij I, Manios Y, Gonzalez-Gross M, Mauro B, Molnar D, Widhalm K, Marcos A, Beghin L, Castillo MJ, Sjöström M; HELENA Study Group. Objectively measured physical activity and sedentary time in European adolescents: the HELENA study. Am J Epidemiol. 2011 Jul 15;174(2):173-84. doi: 10.1093/aje/kwr068.

8. Konstabel K, Veidebaum T, Verbestel V, Moreno LA, Bammann K,Tornaritis M, Eiben G, Molnár D, Siani A, Sprengeler O, Wirsik N, Ahrens W, Pitsiladis Y; IDEFICS

consortium. Objectively measured physical activity in European children: the IDEFICS study. Int J Obes (Lond). 2014 Sep;38 Suppl 2:S135-43. doi: 10.1038/ijo.2014.144.

9. Steene-Johannessen J, Hansen BH, Dalene KE, Kolle E, Northstone K, Møller NC, et al. Variations in accelerometry measured physical activity and sedentary time across Europe - harmonized analyses of 47,497 children and adolescents. Int J Behav Nutr Phys Act. 2020;17(1):38.

10. Kalman M, Inchley J, Sigmundova D, Iannotti RJ, Tynjälä JA, Hamrik Z, Haug E, Bucksch J. Secular trends in moderate-to-vigorous physical activity in 32 countries from 2002 to 2010: a cross-national perspective. Eur J Public Health. 2015 Apr;25 Suppl 2:37-40. doi: 10.1093/eurpub/ckv024.

11. Sirard JR, Pate RR. Physical activity assessment in children and adolescents. Sports Med. 2001;31(6):439-454.

12. Informe 2016: Actividad Física en niños y adolescentes en España. Fundación para la Investigación Nutricional. https://www.activehealthykids.org/wp-content/uploads/2016/11/spain-report-card-long-form-2016.pdf

13. Roman-Viñas B, Marin J, Sánchez-López M, Aznar S, Leis R, Aparicio-Ugarriza R, Schroder H, Ortiz-Moncada R, Vicente G, González-Gross M, Serra-Majem L. Results From Spain's 2016 Report Card on Physical Activity for Children and Youth. J Phys Act Health. 2016 Nov;13(11 Suppl 2):S279-S283. doi: 10.1123/jpah.2018-0464.

14. Craggs C, Corder K, van Sluijs EM, Griffin SJ. Determinants of change in physical activity in children and adolescents: a systematic review. Am J Prev Med. 2011 Jun;40(6):645-58. doi: 10.1016/j.amepre.2011.02.025.

15. O'Donoghue G, Kennedy A, Puggina A, Aleksovska K, Buck C, Burns C, et al. Socio-economic determinants of physical activity across the life course: A "DEterminants of DIet and Physical ACtivity" (DEDIPAC) umbrella literature review. PLoS One. 2018;13(1):e0190737.

16. Condello G, Puggina A, Aleksovska K, Buck C, Burns C, Cardon G, et al. Behavioral determinants of physical activity across the life course: a "DEterminants of DIet and Physical ACtivity" (DEDIPAC) umbrella systematic literature review. Int J Behav Nutr Phys Act. 2017;14(1):58.

17. Cortis C, Puggina A, Pesce C, Aleksovska K, Buck C, Burns C, et al. Psychological determinants of physical activity across the life course: A "DEterminants of DIet and Physical ACtivity" (DEDIPAC) umbrella systematic literature review. PLoS One. 2017;12(8):e0182709.

18. Steel D. Multistage Sampling. In: Lovric M. (eds) International Encyclopedia of Statistical Science. Springer, Berlin, Heidelberg. 2011.

19. Sedgwick P. Multistage sampling. BMJ. 2015;351:h4155. doi:10.1136/bmj.h4155.

20. Instituto Nacional de Estadística 2018. http://www.ine.es/jaxi/Tabla.htm?path=/t20/e245/p08/l0/&file=02002.px

21. WHO - World Health Organization. Recommended levels of physical activity for children aged 5–17 years. Global recommendations on physical activity for health. http://www.who.int/dietphysicalactivity/factsheet_young_people/en/.

22. WHO – World Health Organization. Weighing and Measuring a Child. In: Training course and other tools. 2019. https://www.who.int/childgrowth/training/en/

23. Rey-López JP, Ruiz JR, Ortega FB, Verloigne M, Vicente-Rodriguez G, Gracia-Marco L, Gottrand F, Molnar D, Widhalm K, Zaccaria M, Cuenca-García M, Sjöström M, De Bourdeaudhuij I, Moreno LA; HELENA Study Group. Reliability and validity of a screen time-based sedentary behaviour questionnaire for adolescents: The HELENA study. Eur J Public Health. 2012 Jun;22(3):373-7. doi: 10.1093/eurpub/ckr040. Epub 2011 Apr 15.

24. Serra-Majem L, Ribas L, Ngo J, Ortega RM, García A, Pérez-Rodrigo C, Aranceta J. Food, youth and the Mediterranean diet in Spain. Development of KIDMED, Mediterranean Diet Quality Index in children and adolescents. Public Health Nutr. 2004 Oct;7(7):931-5.

25. Wolfson AR, Carskadon MA, Acebo C, Seifer R, Fallone G, Labyak SE, Martin JL. Evidence for the validity of a sleep habits survey for adolescents. Sleep. 2003 Mar 15;26(2):213-6.

26. Owens JA, Dalzell V. Use of the 'BEARS' sleep screening tool in a pediatric residents' continuity clinic: a pilot study. Sleep Med. 2005 Jan;6(1):63-9. Epub 2005 Jan 12.

27. Kreimeier S, Åström M, Burström K, Egmar AC, Gusi N, Herdman M, Kind P, Perez-Sousa MA, Greiner W. EQ-5D-Y-5L: developing a revised EQ-5D-Y with increased response categories. Qual Life Res. 2019 Jul;28(7):1951-1961. doi: 10.1007/s11136-019-02115-x. Epub 2019 Feb 9.

28. The EuroQol Group (1990). EuroQol-a new facility for the measurement of health-related quality of life. Health Policy 16(3):199-208.

29. Molina L, Sarmiento M, Peñafiel J, Donaire D, Garcia-Aymerich J, Gomez M, Ble M, Ruiz S, Frances A, Schröder H, Marrugat J, Elosua R. Validation of the Regicor Short Physical Activity Questionnaire for the Adult Population. PLoS One. 2017 Jan 13;12(1):e0168148. doi: 10.1371/journal.pone.0168148. eCollection 2017.

30. Schröder H, Benitez Arciniega A, Soler C, Covas MI, Baena-Díez JM, Marrugat J; REGICOR investigators; HERMES investigators. Validity of two short screeners for diet quality in time-limited settings. Public Health Nutr. 2012 Apr;15(4):618-26. doi: 10.1017/S1368980011001923. Epub 2011 Aug 23.

31. Funtikova A, Baena-Díez JM, Koebnick C, Gomez SF, Covas MI, Goday A, Schröder H. Validity of a short diet-quality index to predict changes in anthropometric and cardiovascular risk factors: a simulation study. Eur J Clin Nutr. 2012 Dec;66(12):1369-71. doi: 10.1038/ejcn.2012.131. Epub 2012 Sep 26.

32. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. J Health Soc Behav. 1983 Dec;24(4):385-96.

33. Guinhouya BC, Samouda H, de Beaufort C. Level of physical activity among children and adolescents in Europe: a review of physical activity assessed objectively by accelerometry. Public Health. 2013 Apr;127(4):301-11. doi: 10.1016/j.puhe.2013.01.020. Epub 2013 Apr 10.

34. Gába A, Dygrýn J, Mitáš J, Jakubec L, Frömel K. Effect of Accelerometer Cut-Off Points on the Recommended Level of Physical Activity for Obesity Prevention in Children. 1. PLoS One. 2016 Oct 10;11(10):e0164282. doi: 10.1371/journal.pone.0164282. eCollection 2016.

35. Brazendale K, Beets MW, Rowlands AV, Chandler JL, Fairclough SJ, Boddy LM, Olds TS, Parfitt G, Noonan RJ, Downs SJ, Cliff DP. Converting between estimates of moderate-to-vigorous physical activity derived from raw accelerations measured at the wrist and from ActiGraph counts measure at the hip: the Rosetta Stone. J Sports Sci. 2018 Nov;36(22):2603-2607. doi: 10.1080/02640414.2018.1470373. Epub 2018 Apr 30.

36. Banda JA, Haydel KF, Davila T, Desai M, Bryson S, Haskell WL, Matheson D, Robinson TN. Effects of Varying Epoch Lengths, Wear Time Algorithms, and Activity Cut-Points on Estimates of Child Sedentary Behavior and Physical Activity from Accelerometer Data. PLoS One. 2016 Mar 3;11(3):e0150534. doi: 10.1371/journal.pone.0150534. eCollection 2016.

37. Whooten R, Kerem L, Stanley T. Physical activity in adolescents and children and relationship to metabolic health. Curr Opin Endocrinol Diabetes Obes. 2019 Feb;26(1):25-31. doi:10.1097/MED.0000000000000455.

38. de Greeff JW, Bosker RJ, Oosterlaan J, Visscher C, Hartman E. Effects of physical activity on executive functions, attention and academic performance in preadolescent children: a meta-analysis. J Sci Med Sport. 2018 May;21(5):501-507. doi: 10.1016/j.jsams.2017.09.595. Epub2017 Oct 10.

39. Friedemann C, Heneghan C, Mahtani K, Thompson M, Perera R, Ward AM. Cardiovascular disease risk in healthy children and its association with body mass index: systematic review and meta-analysis. BMJ. 2012 Sep 25;345:e4759. doi: 10.1136/bmj.e4759.

40. Sánchez-Cruz JJ, Jiménez-Moleón JJ, Fernández-Quesada F, Sánchez MJ. Prevalence of child and youth obesity in Spain in 2012. Rev Esp Cardiol (Engl Ed). 2013 May;66(5):371-6. doi: 10.1016/j.rec.2012.10.012. Epub 2013 Feb 1.

41. Cadenas-Sanchez C, Intemann T, Labayen I, Artero EG, Alvarez-Bueno C, Sanchis-Moysi J, Benito PJ, Beltran-Valls MR, Pérez-Bey A, Sanchez-Delgado G, Palou P, Vicente-Rodríguez G, Moreno LA, Ortega FB; PREFIT project group. Prevalence of severe/morbid obesity and other weight status and anthropometric reference standards in Spanish preschool

children: The PREFIT project. Pediatr Res. 2019 Feb 18. doi: 10.1038/s41390-019-0325-8. [Epub ahead of print]

42. Schröder H, Ribas L, Koebnick C, Funtikova A, Gomez SF, Fíto M, Perez-Rodrigo C, Serra-Majem L. Prevalence of abdominal obesity in Spanish children and adolescents. Do we need waist circumference measurements in pediatric practice? PLoS One. 2014 Jan 27;9(1):e87549. doi: 10.1371/journal.pone.0087549. eCollection 2014.

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