

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Study protocol of a population-based cohort investigating Physical Activity, Sedentarism, lifestyles and Obesity in Spanish youth: The PASOS study.
AUTHORS	Gómez, Santiago Felipe; Homs, Clara; Wärnberg, Julia; Medrano, Maria; Gonzalez-Gross, Marcela; Gusi, Narcis; Aznar, Susana; Cascales, Elena; González-Valeiro, Miguel; Serra-Majem, Lluís; Terrados, Nicolás; Tur, Josep A.; Segú, Marta; Lassale, Camille; Benavente-Marín, Juan Carlos; Labayen, Idoia; Zapico, Augusto García; Sánchez-Gómez, Jesús; Jiménez-Zazo, Fabio; Alcaraz, Pedro Emilio; Sevilla-Sanchez, Marta; Herrera-Ramos, Estefania; Pulgar, Susana; Bibiloni, Maria del Mar; Sancho, Olga; Schröder, Helmut

VERSION 1 – REVIEW

REVIEWER	Giada Pietrabissa Faculty of Psychology, Catholic University of Milan
REVIEW RETURNED	12-Apr-2020

GENERAL COMMENTS	<p>The present manuscript presents the protocol of a cross-sectional, observational, nationally representative, multi-centre study aims to determine the physical activity levels of Spanish youth. Despite the study looks interesting in its premises it can't be accepted for publication in its current form – and substantial revisions are needed</p> <p>A few minor suggestions are reported below:</p> <p>According to the journal guidelines, bullet points should not be longer than one sentence each (heading “Strengths and limitations of this study”)</p> <p>Throughout the introduction section - I suggest the authors to refer to more recent research.</p> <p>Please, provide references for the randomization procedure. Was this method used in previous studies?</p> <p>Please, provide references for the method and software used for sample size calculation.</p> <p>I respectfully suggest the authors to use the same tense throughout the manuscript.</p> <p>P.11 line 9: 2 field workers – please explain which field.</p> <p>p.13 – line 54-55. The authors state that “Anthropometrics for each individual will be measured by trained personnel following a standardized protocol”, but no reference is provided.</p> <p>Word Count is not reported at the end of the manuscript. Please, consider that the manuscript should not exceed 4,000 words.</p> <p>I discourage the authors to include table describing result of other studies. Moreover, table should be referred in the text. The same tables of results are also reported in the supplementary file2. I</p>
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	<p>personally consider both the supplementary docs uploaded unnecessary.</p> <p>In order to address major concerns of the study, I suggest the authors:</p> <ul style="list-style-type: none"> -to provide a more detailed description of the study procedure (e.g. Lifestyle data of children/adolescents are self-reported online at participating schools). Did data collection happen during school hour? Were the teachers responsible for the students in the room during the administration? -to re-organize the manuscript as follow: the objectives of the study should be specified immediately after the introduction section. Then, the “methods and analysis section” should include: the design (inclusion/exclusion criteria, randomization procedure), participants, measures, procedure, sample size and statistical analysis. The discussion section – instead – is not required from the journal. -to provide a more meaningful description of all the self-report measures included, that will also include references for each of the validation articles and their Spanish adaptations, as well as the reliability indices of the scale. . to include the description of the intended statistical analysis. -to made clear to the reader how the parent’s data will be used for the aim of the present study <p>Moreover, the authors state that the sample size calculation is based on published data of the Spanish Report of Physical Activity – from 2016! I am wondering why they decided not to consider more recent records. Weren't they available?</p> <p>Notably, authors state that data collection WILL be implemented from March to October 2019 – Please explain. I am afraid this might be a problem for the publication of the protocol in 2020 – but I encourage the authors to submit the results of the study.</p>
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VERSION 1 – AUTHOR RESPONSE

Response to Reviewer 1:

Thank you for your review of our paper. We have answered each of your points below.

The present manuscript presents the protocol of a cross-sectional, observational, nationally representative, multi-centre study aims to determine the physical activity levels of Spanish youth. Despite the study looks interesting in its premises it can't be accepted for publication in its current form – and substantial revisions are needed

Reply: The originally submitted paper was described as a cross-sectional, observational, nationally representative, multi-center study. The possibility of transforming the PASOS study in a cohort study was an option but not confirmed when we submitted the paper (5th of December 2019). For this reason, the original protocol was submitted as a cross-sectional study.

During the last 7 months, we culminated the baseline data collection (17th of February 2020) and the study progressively generating more interest within the public and private sectors. Consequently, the option of transforming the study in a cohort was gaining relevance and nowadays the PASOS consortium has financially confirmed the possibility of incorporating follow-up measurements. We introduced some minor changes to better reflect the longitudinally PASOS study methodology and to make evident that follow-up measurements will be performed. In this paper are described the methodology and the collected variables during the baseline measurements and we specified that

follow-up measurements will be performed.

A few minor suggestions are reported below:

According to the journal guidelines, bullet points should not be longer than one sentence each (heading "Strengths and limitations of this study")

Reply: We have adapted the strengths and limitations section of the manuscript to be not longer than one sentence as follows:

- "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."

Throughout the introduction section - I suggest the authors to refer to more recent research.

Reply: Thank you for the suggestion. In the paper, seven out of 13 references of the introduction were published during the last 5 years. We recognize that findings on objectively measured physical inactivity from the HELENA and IDEFICS are not recent publications. However, both trials are of high quality with a large sample size. Indeed, we omit more recent data from small non-representative studies because these results are limited with respect to their generalizability. We have added results from a recently published (after the submission of the manuscript to the journal) of a harmonized analysis of physical activity in European children and adolescents (9). The reference also has been added in the references section (page: 19; lines: 511-514) as follows:

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.

We have modified the introduction as follows: "Results from a recently published review on objectively measured physical activity (1) 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)." (page: 5; lines: 134 - 137)

Additionally, we have added three more recent publications on determinants of physical activity in children (15, 16 and 17). (page: 6; line: 155). The three references also have been added in the references section (page: 20-21; lines: 536-547) as follows:

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 Dlet 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 Dlet 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 Dlet and Physical ACtivity" (DEDIPAC) umbrella systematic literature review. *PLoS One.* 2017;12(8):e0182709.

1. The reviewers comment: Please, provide references for the randomization procedure. Was this method used in previous studies?

Reply: Thank you for identifying this. We have added:

1) A more specific explanation in the methods section, subsection randomization as follows:

"Randomization was performed by a multi-stage sampling procedure (14, 15) including four-stages". (page: 7; line: 185).

2) Two additional references – numbers 14 and 15:

- Methods section, subsection randomization (page: 7; line 185).

- References section (page: 21; lines: 548-550).

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

19. Sedgwick P. Multistage sampling. BMJ. 2015;351:h4155. Published 2015 Jul 31. doi:10.1136/bmj.h4155.

Please, provide references for the method and software used for sample size calculation.

Reply: We have added the following sentence in the methods section, subsection randomization (page: 8; lines: 198-199) as follows:

“The software used for the sampling procedure were R, package mstage”.

I respectfully suggest the authors to use the same tense throughout the manuscript.

Reply: We apologize this error. We have modified the verbal tense in the following sections:

Abstract – combining present perfect, present continuous, passive and past depending on the chronology of the phases. The introduced modifications are:

- Has recruited (page: 3; line: 87).
- Are being measured (page: 3; line: 92).
- Is measured (page: 3; lines: 92-93).
- Was (page: 3; line: 94).
- Are asked (page: 3; line: 96)

Introduction - combining present and past tense when is considered adequate. The introduced modifications are:

- Underlined (page: 5; line: 122).
- Was a 2012 report (6) because indicated (page: 5; line: 126).
- Underlined (page: 6; line: 146).

Methods – mainly past tense, because the methods definition and the baseline data collection of the PASOS cohort study were performed in 2019. The introduced modifications are:

- Were (page: 7; line: 178).
- Were (page: 7; line: 179).
- Were excluded of the baseline data collection (page: 7: line: 182).
- Was (page: 7; line: 182).
- Were (page: 7; line: 187).
- Was (page: 8; line: 192).
- Were (page: 8; line: 205).
- Baseline data were collected (page: 8; line: 213).
- Were (page: 8; line: 214).
- Completed (page: 9; line: 216).
- Was made (page: 9; line: 217).
- Were (page: 9; line: 218).
- Were (page: 9; line: 220).
- Were (page: 9; line: 221).
- Was (page: 9; line: 223).
- Were (page: 9; line: 225).
- Is being performed (page: 9; line: 230).
- Received (page: 9; line: 232).
- Called (page: 9; line: 237).
- Contacted the (page: 10; line: 240).
- Invited (page: 10; line: 241).
- Were (page: 10; line: 242).

- Received (page: 10; line: 243).
- Received (page: 10; line: 245).
- Were (page: 10; line: 246).
- Was (page: 11; line: 266).
- Was (page: 11; line: 281).
- Wore (page: 11; line: 282).
- Were (page: 11; line: 284).
- Reported (page: 11; line: 284).
- Instructed (page: 11; line: 285).
- Were (page: 11; line: 288).
- Were (page: 11; line: 289).
- Were (page: 12; line: 290).
- Was (page: 12; line: 293).
- Was (page: 12; line: 297).
- Was (page: 12; line: 301).
- Was (page: 12; line: 307).
- Were (page: 12; line: 310).
- Was (page: 13; line: 314).
- Was (page: 13; line: 318).
- Were (page: 13; line: 321).
- Were (page: 13; line: 323).
- Were (page: 13; line: 325).
- Were (page: 13; line: 327).
- Received (page: 14; line: 359).
- Received (page: 14; line: 360).

P.11 line 9: 2 field workers – please explain which field.

Reply: Thank you for the suggestion. We have included the following description:
 “Two visits were carried out in each school by 2 field researchers with a background in physical education, nutrition, or other health sciences.” (page: 8; line: 215).

p.13 – line 54-55. The authors state that “Anthropometrics for each individual will be measured by trained personnel following a standardized protocol”, but no reference is provided.

Reply: We have modified the methods section according to the reviewer’s suggestion as follows (page: 11; lines: 288-289):
 “Anthropometrics for each individual were measured by trained personnel following the WHO standardized protocol (22).”
 Additionally, the following reference has been added in the references section (page: 21; lines: 556-557):
 22. WHO – World Health Organization. Weighing and Measuring a Child. In: Training course and other tools. 2019. <https://www.who.int/childgrowth/training/en/>

Word Count is not reported at the end of the manuscript. Please, consider that the manuscript should not exceed 4,000 words.

Reply: Thank you for the suggestion. The manuscript (from title until contributors’ section), include a total of 3942 words. A word count section has been added in the manuscript just before the references section as follows:
 “Word count
 3942, not exceed the 4000-word allowed.” (page: 18; lines: 439-440).

I discourage the authors to include table describing result of other studies. Moreover, table should be referred in the text. The same tables of results are also reported in the supplementary file2. I personally consider both the supplementary docs uploaded unnecessary.

Reply: We have deleted the supplementary file number 2 and the following sentence in the methods section, subsection study variables (page: 11; lines: 267-269):

“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.”

In order to address major concerns of the study, I suggest the authors:

-to provide a more detailed description of the study procedure (e.g. Lifestyle data of children/adolescents are self-reported online at participating schools). Did data collection happen during school hour? Were the teachers responsible for the students in the room during the administration?

Reply: We understand the reviewers concern, but we are close to the word limit for study protocols. Therefore, we decided to present the validated questionnaires for data collection on parental diet quality, perceived stress, and quality of life in brief with the corresponding reference. The baseline data collection was performed during school hours with the supervision of field researchers and teachers. An online system was used for data reporting derived from questionnaires. The following clarifications have been added to the method section of the manuscript (page: 10; lines: 262-264):
“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.”

-to re-organize the manuscript as follow: the objectives of the study should be specified immediately after the introduction section. Then, the “methods and analysis section” should include: the design (inclusion/exclusion criteria, randomization procedure), participants, measures, procedure, sample size and statistical analysis. The discussion section – instead – is not required from the journal.

Reply: We have followed the proposed structure and we introduced the objectives just after the introduction (page: 6; lines: 158-168).

The reviewer is correct that the journal did not demand a discussion section for study protocols. However, we decided, such as many other authors of study protocols published by the journal, to include this section with the aim to present the reader a deeper discussion of the current knowledge relevant to our project.

-to provide a more meaningful description of all the self-report measures included, that will also include references for each of the validation articles and their Spanish adaptations, as well as the reliability indices of the scale.

Reply: We completely agree with reviewer comment, but as we answered for the previous concern, we are close to the word limit for study protocols. In the original manuscript, we decided to provide a more detailed description of the scientific tools for evaluating the variables related to the main objective of the PASOS study and to include less information for the variables that are more closely related to the secondary objectives of the study. The questionnaires corresponding to references 23, 24, 29, 30 and 31 are originally validated in Spanish. The other questionnaires used in the study have adaptations to Spanish.

. to include the description of the intended statistical analysis.

Reply: According to the reviewer's suggestion we have included a brief statistical analysis section: "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. (page: 14; lines: 342-353).

-to made clear to the reader how the parent's data will be used for the aim of the present study

Reply: Following the reviewer comments, we have added the following sentence in the methods section to better explain how parental variables will be used for the aim of the present study (page: 14; lines: 338-340):

"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."

Moreover, the authors state that the sample size calculation is based on published data of the Spanish Report of Physical Activity – from 2016! I am wondering why they decided not to consider more recent records. Weren't they available?

Reply: We would like to clarify that the sample size calculation of the PASOS study was performed during the summer 2018 when the study planification started. Until the summer 2018, the most recent and robust data about the physical activity level among Spanish children and adolescents were the presented in the Spanish report of physical activity of children and youth published in November 2016.

Notably, authors state that data collection WILL be implemented from March to October 2019 – Please explain. I am afraid this might be a problem for the publication of the protocol in 2020 – but I encourage the authors to submit the results of the study.

Reply: The data collection took longer than we originally assumed. In the originally sent manuscript we detailed the originally agreed data collection and written in the original study protocol. Correct is that we have finished parental data collection at the end of February 2020 because the PASOS research consortium decided to leave open the online link for parents' questionnaires until this date to gather more data. Therefore, the manuscript was submitted to the Journal (5th of December 2019) before the end of data collection. Furthermore, this study was created as a cohort study with follow-up in 2022. We have modified the method section to correct and clarify these points.

The end date for baseline data collection has been modified in the manuscript in the methods section (page: 8; lines: 213-214) as follows:

"Baseline data were collected from March 2019 to February 2020, in 242 primary and secondary schools."

Moreover, as aforementioned in this document, is confirmed that the PASOS study has become a cohort study. This currently reality was only a remote possibility when we submitted the paper to the journal. To correctly reflect this methodological change without introducing excessive modifications to the manuscript, we considered adequate to modify or add the following information:

Title - "Study protocol of a population-based cohort investigating Physical Activity, Sedentarism, lifestyles and Obesity in Spanish youth: The PASOS study." (page: 1; lines: 1-3).

Abstract - "This observational, nationally representative, multi-centre study aims to...". (page: 3; line:

83).

Objectives – “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.”. (page: 7; lines: 169-170).

Study design – “A follow-up of the study participants is planned for 2022 with a repeated collection of all baseline data.”. (page: 7; lines: 174-176).

Data collection – “Baseline data were collected from March 2019 to February 2020, in 242 primary and secondary schools.”. (page: 8; lines: 213-214).

Variables – “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.”. (page: 14; lines: 338-340)

Patient and public involvement – “The baseline results of the PASOS study are being disseminated to the general public, an activity that will continue during the cohort study.”. (page: 14; lines: 360-361).

As a cohort study we consider that is adequate to publish the study protocol because the data collection is still ongoing and follow-up measurement will be performed.