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The effects of physical activity interventions on the body mass index of children and adolescents in Latin America: a protocol for a systematic review and meta-analysis.

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Keywords:	BMI, Latin America, Children, Adolescents, Physical activity

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Manuscripts

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3 1 **Protocol manuscript**
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6 3 **The effects of physical activity interventions on the body mass index of children and**
7 **adolescents in Latin America: a protocol for a systematic review and meta-analysis.**
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11 6 **Authors and affiliations:**

12 7 Andres Godoy-Cumillaf^{1,3*}, Armando Díaz-González², Iván Caverro-Redondo³.
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14 8

15 9 ¹Universidad Autónoma de Chile, Facultad de Educación, Temuco, Chile.

16 10 ²Secretária de Esportes Taubaté, São Paulo, Brasil.

17 11 ³Universidad de Castilla-La Mancha, Health and Social Research Center, Cuenca, Spain.
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24 13 ***Correspondence to:**

25 14 Andrés Godoy-Cumillaf.

26 15 Author's address: Avenida Alemania 01090, Temuco, Chile.

27 16 Telephone number: +56 932259064

28 17 E-mail: andres.godoy@uautonoma.cl
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34 19 **Word counts:** 1937 words.
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3 **1 ABSTRACT.**

4 **2 Introduction:** In Latin America, childhood and adolescent overweight and obesity have
5 become a public health problem; for this reason, intervention programs have been
6 implemented, such as physical activity and food education interventions aimed at
7 preventing and treating these weight issues, using the BMI as a mean to know the impact
8 such interventions have made. Nevertheless, no evidence has been found about the effects
9 of these interventions on the BMI; therefore, this study protocol provides a standardised
10 study methodology with a view to determining the effects of physical activity interventions
11 on the BMI of children and adolescents of Latin America.

12 **10 Methods and analysis:** This systematic review and meta-analysis protocol is based on the
13 Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-
14 P). The literature search will be conducted in MEDLINE, EMBASE, Cochrane Library,
15 Web of Science and Scielo. Randomised controlled trials, non-randomised experimental
16 studies and controlled pre–post studies will be included. The Cochrane Collaboration’s tool
17 and the Quality Assessment Tool for Quantitative Studies will be used to assess the risk of
18 bias for studies included in the systematic review. Standardised pre-intervention mean
19 differences will be calculated as the primary outcome. Subgroup analyses will be
20 performed based on the characteristics of the interventions and population included in the
21 studies.

22 **20 Ethics and dissemination:** This systematic review will provide updated evidence about the
23 effects of physical activity interventions on Latin American population; such evidence may
24 be useful for the institutions responsible for the development of public health policies and
25 for those in charge of the implementation of this type of interventions among children and
26 adolescents in Latin America.

27 Results will be disseminated by publication in a peer-reviewed journal. Since data used for
28 this systematic review will be extracted exclusively from published studies, the approval
29 from an ethical committee will not be required.

30 **28 Prospero registration number:** CRD42019077702.

31 **29 Keywords:** physical activity, BMI, Latin America, children and adolescents.
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STRENGTHS AND LIMITATIONS OF THIS STUDY.

- This study provides a comprehensive methodology to analyse the effect of physical activity interventions on the BMI.
- Two researchers will independently carry out the study selection, data extraction and quality assessment of the studies found.
- This research might be the first evidence of meta-analysis in Latin America providing scientific information about the effect of physical activity interventions on the BMI.
- Differences among the studies design, sample characteristics, type of physical activity interventions and poor methodological quality may restrict the comparison of the selected studies and negatively affect the quality of the evidence of this systematic review and meta-analysis.

1 INTRODUCTION

2 Latin America is a developing region and needs assistance in all aspects; one of the actions
3 to assist development is to promote activities that contribute to address one of the greatest
4 problems affecting the region, such as overweight and obesity, which have significantly
5 increased among children and adolescents in the last decades, becoming a major public
6 health concern. It is estimated that between 20% and 25% of the total Latin American
7 population of children and adolescents are overweight or obese¹. This situation is worrying,
8 since it has been noted that this condition is maintained during adulthood^{2,3}, increasing risk
9 factors for cardiovascular disease, increased blood pressure and some types of cancer^{4,5} and
10 increasing the possibility of premature death in all causes⁶. Therefore, this is a serious
11 situation that must be worked on in order to prevent the future generations of Latin
12 American society to be affected.

13 Body Mass Index (BMI) is a method that allows us to quickly know if a person is
14 overweight or obese and it is a good measure to evaluate general adiposity. A high BMI
15 during childhood and adolescence predispose subjects to develop the aforementioned
16 diseases (high blood pressure, high cholesterol levels and type 2 diabetes) and also has
17 become a quite reliable predictor of mortality⁷ to such a degree that in 2015 more than 4.5
18 million deaths worldwide were associated with high values of BMI⁸.

19 Several interventions, including physical activity interventions, nutritional interventions or
20 a combination of both^{9,10}, have been suggested to mitigate the levels of overweight and
21 obesity. Out of these interventions, physical activity appears to play an important role,
22 contributing to reduce BMI, decrease cardiovascular risk factors and improve
23 cardiorespiratory endurance; all this leading to a reduction of health risk factors¹⁰⁻¹³.

24 Since in Latin America overweight and obesity have become a public health problem,
25 physical activity intervention programs aimed at preventing and treating these negative
26 situations have been implemented. In addition, these interventions have been supplemented
27 by food education, using the BMI as a mean to know the impact these measures have made.
28 Nevertheless, no evidence of meta-analysis addressing this subject in Latin America has
29 been found. However, there are systematic reviews^{1,14,15} which do not address the relation
30 of physical activity interventions and their effects on BMI; therefore, it is necessary to pay
31 closer attention to this matter. Consequently, the objective of this methodological study

1 protocol is to provide Latin America with a procedure which allows us to conduct a
2 systematic review of the effects of physical activity interventions on the BMI, and, at the
3 same time, to collaborate with public health programs related to overweight and obesity.

4 **OBJECTIVE**

5 The purpose of this study protocol is to provide information about a standardised
6 methodology to perform a systematic review and a meta-analysis, with the objective of
7 assessing the effects that physical activity interventions performed in Latin America have
8 on the BMI.

9 **METHODS AND ANALYSIS**

10 This systematic review and meta-analysis protocol is based on the Preferred Reporting
11 Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P)¹⁶ and the
12 Cochrane Collaboration Handbook¹⁷. This protocol has been previously registered in
13 PROSPERO (registration number: CRD42019077702).

14 **Inclusion/exclusion criteria for study selection**

15 In order to be included in the systematic review, studies must report physical activity
16 interventions which meet the following criteria: 1) studies involving population of a Latin
17 American country; 2) studies including participants aged 4-18 years; 3) studies reporting
18 only a type of physical activity or combined health interventions including nutritional or
19 psychological interventions; 4) randomised controlled trials, non-randomised experimental
20 studies and controlled pre-post studies; 5) studies reporting any type of physical activity
21 (physical endurance, sports or alternative exercise (games, dancing, optimised physical
22 education classes)); 6) studies reporting BMI before and after the intervention; 7) studies
23 written in Spanish, English or Portuguese.

24 Studies will be excluded when: 1) include participants younger than 4 and older than 18
25 years old; 2) provide self-reported data; 3) do not report BMI before and/or after the
26 intervention.

27 **Search strategy**

28 The literature search will be conducted in MEDLINE (via PubMed), EMBASE, Cochrane
29 Library, Web of Science and Scielo databases from their inception. Study records will be
30 managed using the Mendeley reference manager. The search strategy will combine boolean
31 operators from the following relevant concepts: physical activity, physical exercise, fitness,

1 physical performance, exercise programs, training programs, prevention programs,
 2 intervention programs, promotion, strategy, childhood obesity, obese children, obesity,
 3 obesity review, obesity prevention (table1). Previous reviews and meta-analyses will be
 4 scanned for additional references. Also, relevant references included in the selected studies
 5 will be screened as supplemental sources.

Table 1. Search strategy for the MEDILINE database.

"physical activity"	"training programs"	"childhood obesity"
OR	OR	OR
"physical exercise"	"prevention programs"	"obese children"
OR	OR	OR
fitness	"intervention programs"	obesity
OR	OR	OR
"physical performance"	promotion	"obesity review"
OR	OR	OR
"exercise programs"	strategy	"obesity prevention"

7 Selection of studies and data extraction

8 All the titles and abstracts of the retrieved articles will be evaluated independently by two
 9 researchers, in order to identify eligible studies for this systematic review, that is, that meet
 10 the inclusion criteria. Studies will be excluded when they do not meet eligibility criteria.
 11 Abstracts not providing enough information related to inclusion/exclusion criteria will be
 12 selected to be evaluated through full-text reading. Two reviewers will examine the included
 13 and excluded studies to verify the reason for each decision. Inconsistencies in data
 14 collection will be resolved by consensus. A third researcher will be asked when consensus
 15 is not reached. The process of identification, selection and inclusion/exclusion of articles
 16 will be shown using the PRISMA¹⁶ flow chart (Figure 1). In addition, full text of the
 17 identified studies will be examined in order to extract the following data: (1) name of the
 18 first author; (2) year of publication; (3) country; (4) study design; (5) age of the
 19 participants; (6) number of participants; (7) characteristics of the population (normal
 20 weight, overweight, obesity); and (8) characteristics of the physical activity interventions.
 21 Any disagreement during data extraction will be solved by discussion to reach a consensus.

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3 1 When necessary, the authors of the potentially eligible studies will be contacted to obtain
4 any missing data.
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6 **Assessment of risk of bias in the included studies**

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8 4 Two researchers will independently conduct a quality assessment according to the
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10 5 Cochrane Collaboration Handbook recommendations¹⁷. Any disagreements will be resolved
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12 6 by discussion and a third reviewer will solve disagreements if consensus is not reached.

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14 7 The methodological quality of the RCTs will be assessed using the Cochrane
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16 8 Collaboration's tool for assessing risk of bias¹⁸. This tool evaluates the risk of bias
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18 9 according to six domains: selection bias, performance bias, detection bias, attrition bias,
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20 10 reporting bias and other bias.

21
22 11 The Quality Assessment Tool for Quantitative Studies¹⁹ assesses the quality of pre-post
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24 12 studies and non-RCTs. This tool evaluates seven domains: selection bias, study design,
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26 13 confounders, blinding, data collection method, withdrawals and drop-outs.

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28 14 In both quality assessment tools, each domain will be considered as strong, moderate or
29
30 15 weak, and studies will be classified as low risk of bias (with no weak ratings), moderate
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32 16 risk of bias (with one weak rating) and high risk of bias (with two or more weak ratings).

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34 17 The agreement rate between reviewers will be reported by calculating kappa statistics.

35 **Statistical analysis**

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37 19 Researchers will summarise the main characteristics of the selected studies, including the
38
39 20 general profile of the study, methods, characteristics of the participants of the study and the
40
41 21 results on Table 2. Reviewers will decide whether a meta-analysis is possible after data
42
43 22 extraction. A minimum of five observations addressing the same specific outcome will be
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45 23 required in order to perform a meta-analysis; when meta-analysis is not feasible,
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47 24 researchers will conduct a narrative synthesis. Studies providing insufficient data to carry
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49 25 out the analyses will be omitted from data synthesis.
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Table 2. Characteristics of studies included in the systematic review and/or meta-analysis.

Reference	Country	Population characteristics			Intervention characteristics		
		Study Design	Age distribution	Sample size	Type of population	Physical activity intervention	Physical activity characteristics
Author information and year of publication	Country	Design of the study	Age (years) of the participants range or means±SD	Number of participants	Population characteristics (low weight, normo weight, overweight, obesity)	Type of physical activity intervention (leisure-time physical activity, physical activity programme or physical activity counseling)	Definition of physical activity intervention (duration of intervention, number of sessions and duration of each session)

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2 If a meta-analysis is possible, STATA V.14 software will be used to combine the pooled
3 mean differences with 95% confidence intervals (CIs). A fixed-effects model will be used if
4 there is no evidence of heterogeneity; otherwise, a random-effects model will be used.
5 Study heterogeneity will be assessed with the I^2 statistic. I^2 values will be considered as:
6 might not be important (0–40%); may represent moderate heterogeneity (30–60%); may
7 represent substantial heterogeneity (50–90%) and considerable heterogeneity (75–100%),
8 the corresponding p values will also be taken into account¹⁷.

9 Data from intention-to-treat analyses will be considered whenever available in RCTs. The
10 BMI pre–post intervention mean difference will be the primary indicator of the intervention
11 outcome. Standardised mean differences will be calculated for BMI levels. Additionally,
12 publication bias will be assessed using a funnel plot, according to the method proposed by
13 Egger²⁰.

14 **Subgroup analysis and meta-regression**

15 Subgroup analyses and meta-regression will be performed considering the main factors
16 which may cause heterogeneity, such as: gender; age (children aged 4–12 years and
17 adolescents aged 12–18 years); country; type of study design; participant population
18 (underweight, normal weight, overweight, obesity); type of intervention (only physical
19 activity or combined with nutritional or psychological interventions); type of physical
20 activity (endurance, sports, games, dancing); length of the intervention (above or below 12

1 weeks); time of physical activity per week (above or below 150 minutes). Moreover,
2 methodological quality of the selected studies will be considered for additional subgroup
3 analyses.

4 **Sensitivity analysis**

5 Sensitivity analyses will be carry out, removing the included studies one by one from the
6 pooled analyses, to assess the robustness of summary estimates and to detect if any singular
7 study accounts for a large proportion of heterogeneity.

8 **ETHICS AND DISSEMINATION**

9 Given that researchers will not collect primary data for this review, ethical approval will
10 not be required. However, once the outcomes of this systematic review and meta-analysis
11 are disseminated in scientific publications, they will be shared through social networks and
12 will be presented in scientific conferences related to the subject, so that our conclusions
13 contribute to improve the health of Latin American population.

14 **DISCUSSION.**

15 Studies carried out among European and United States population have shown that physical
16 activity interventions are associated with reductions of the BMI and are also an effective
17 way of decreasing the percentage of adipose tissue^{10,13}. However, there is no information
18 about the effects of these interventions conducted in Latin America, which geographical,
19 socio-economic and cultural characteristics are inherent to a developing region. Thus, the
20 development of a systematic review and, if possible, a meta-analysis, will enable us to have
21 an overview of the current literature in Latin America about the subject of study, and, at the
22 same time, to contribute to an efficient development of discussions regarding the benefits of
23 physical activity interventions in the region. To this end, the protocol of this systematic
24 review provides a structure for the extraction and synthesis of relevant information.

25 Another situation that is necessary to bear in mind when performing systematic review is to
26 know if physical activity interventions supplemented by other health interventions, such as
27 nutritional or psychological interventions, lead to a greater reduction of BMI, and to
28 appreciate the prominence of physical activity interventions in the prevention and treatment
29 of overweight and obesity among Latin American children and adolescents.

30 Among the potential limitations inherent to systematic reviews and meta-analysis we may
31 find: publication bias, information bias, poor statistical analyses, low methodological

1 quality and inappropriate reporting of methods and findings of the included studies. It is
2 important to keep in mind that these sources of bias will be greater in some countries, due
3 to economic inequalities in the region, which result in an uneven advancement of scientific
4 development in the different countries. Therefore, it is important to properly synthesise the
5 information available in the manuscripts included, so this protocol becomes a necessary
6 text that consolidates methodological structure needed to carry out a systematic review and
7 meta-analysis based on evidence, regarding the effects of physical activity interventions on
8 the BMI of children and adolescents.

9 In summary, this study will provide updated information which may be useful for public
10 health policy makers and for those responsible for the implementation of this type of
11 interventions among Latin American children and adolescents.

13 **Contributors:**

15 AG-C and IC-R designed the study: AG-C was the principal investigator. AG-C and IC-R
16 were the coordinators of the study. AG-C and AD-G conducted the study. AG-C and IC-R
17 gave statistical and epidemiological support. AG-C wrote the article with the support of IC-
18 R and AD-G. All authors reviewed and approved the final version of the manuscript.

20 **Competing interests:**

22 None declared.

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REFERENCES

1. Rivera JÁ, De Cossío TG, Pedraza LS, Aburto TC, Sánchez TG, Martorell R. Childhood and adolescent overweight and obesity in Latin America: A systematic review. *Lancet Diabetes Endocrinol* 2014;2(4):321-332.
2. Wang LY, Chyen D, Lee S, Lowry R. The Association Between Body Mass Index in Adolescence and Obesity in Adulthood. *J Adolesc Heal* 2008;42(5):512-518.
3. Ward ZJ, Cradock AL, Gortmaker SL, Resch SC, Long MW, Giles CM. Simulation of Growth Trajectories of Childhood Obesity into Adulthood. *N Engl J Med*. 2017;377(22):2145-2153.
4. Collaboration PS, Whitlock G, Lewington S, et al. Body-mass index and cause-specific mortality in 900 000 adults: collaborative analyses of 57 prospective studies. *Lancet* 2009;373(9669):1083-1096.
5. Wormser D, Kaptoge S, Di Angelantonio E, et al. Separate and combined associations of body-mass index and abdominal adiposity with cardiovascular disease: Collaborative analysis of 58 prospective studies. *Lancet* 2011;377(9771):1085-1095.
6. Ding EL, Mozaffarian D, Danaei G, et al. The Preventable Causes of Death in the United States: Comparative Risk Assessment of Dietary, Lifestyle, and Metabolic Risk Factors. *PLoS Med* 2009;6(4):e1000058.
7. Lee HJ, Choi EK, Lee SH, Kim YJ, Han K Do, Oh S. Risk of ischemic stroke in metabolically healthy obesity: A nationwide population-based study. *PLoS One* 2018;13(3):1-14.
8. Gakidou E, Afshin A, Abajobir AA, et al. Global, regional, and national comparative risk assessment of 84 behavioural, environmental and occupational, and metabolic risks or clusters of risks, 1990-2016: A systematic analysis for the Global Burden of Disease Study 2016. *Lancet* 2017;390(10100):1345-1422.
9. Hills AP, Andersen LB, Byrne NM. Physical activity and obesity in children. *Br J Sports Med* 2011;45(11):866-870.
10. Kelley GA, Kelley KS, Pate RR. Exercise and BMI in Overweight and Obese Children and Adolescents: A Systematic Review and Trial Sequential Meta-

- 1
2
3 1 Analysis. *Biomed Res Int* 2015;2015:1-17.
4
5 2 11. Jakicic J, Davis K. Obesity and Physical Activity. *Psychiatr Clin N Am.*
6 3 2011;34:829-840.
7
8 4 12. Zolotarjova J, ten Velde G, Vreugdenhil ACE. Effects of multidisciplinary
9 5 interventions on weight loss and health outcomes in children and adolescents with
10 6 morbid obesity. *Obes Rev* 2018;19(7):931-946.
11
12 7 13. Kelley GA, Kelley KS. Effects of Exercise in the Treatment of Overweight and
13 8 Obese Children and Adolescents: A Systematic Review of Meta-Analyses. *J Obes*
14 9 2013;2013:1-10.
15
16 10 14. Legetic BD, Hoehner CM, Brownson RC, et al. Physical Activity Interventions in
17 11 Latin America. *Am J Prev Med* 2008;34(3):224-233.e4.
18
19 12 15. Nagle BJ, Holub CK, Barquera S, et al. Interventions for the treatment of obesity
20 13 among children and adolescents in Latin America: a systematic review TT -
21 14 Intervenciones para el tratamiento de la obesidad en niños y adolescentes en
22 15 Latinoamérica: una revisión sistemática. *Salud Publica Mex* 2013;55:434-440.
23
24 16 16. Moher D, Larissa S, Clarke M, et al. Preferred reporting items for systematic review
25 17 and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev* 2015;4(1).
26
27 18 17. The Cochare Collaboration. In: Higgins JP, Green S, eds. Cochrane handbook for
28 19 systematic review of interventions. 5.1.0. 2011. <http://handbook.cochrane.org>.
29 20 (update March 2011)
30
31 21 18. Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for
32 22 assessing risk of bias in randomised trials. *BMJ* 2011;343(7829):1-9.
33
34 23 19. National Collaborating Centre for Methods and Tool. *Quality assessment tool for*
35 24 *quantitative Studies*. Hamilton ON: McMaster University, 2008. (Updated 13 april,
36 25 2010)
37
38 26 20. Sterne JAC, Egger M, Smith GD. Investigating and dealing with publication and
39 27 other biases in meta-analysis. *Br Med J.* 2001;323:101-105.
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3 **1 TABLES LEGENDS.**
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6 3 **Table 1.** Search strategy for the MEDILINE database.
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10 5 **Table 2.** Characteristics of studies included in the systematic review and/or meta-analysis.
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13 7 **FIGURE LEGENDS.**
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17 9 **FIGURE 1.** PRISMA flow diagram of identification, screening, eligibility and inclusion of
18 studies.
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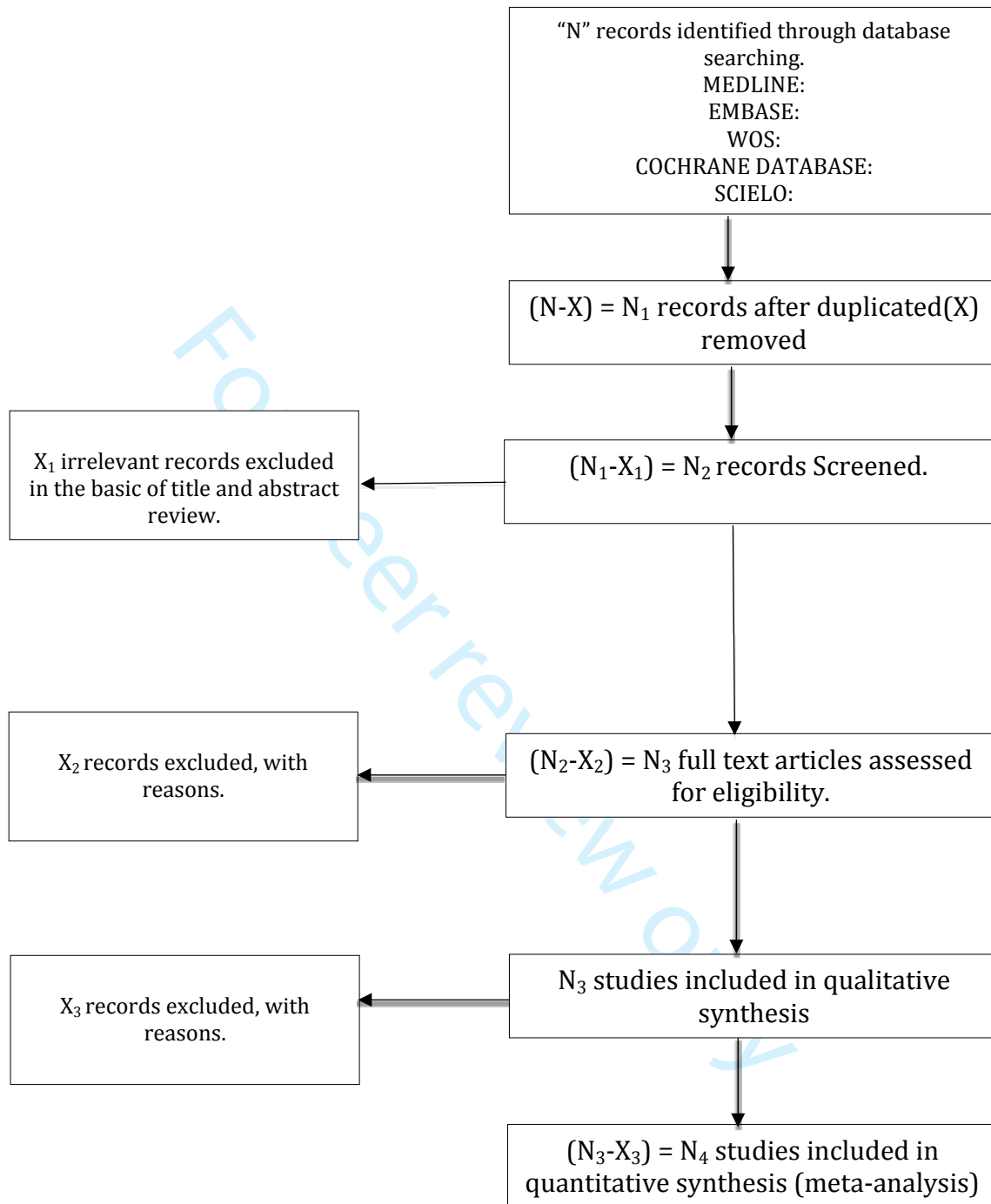


Figure 1. PRISMA flow diagram of identification, screening, eligibility and inclusion of studies.

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification: p. 1	1a	Identify the report as a protocol of a systematic review
Update: NA.	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number
Authors:		
Contact: pp. 1, 10	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author
Contributions: p.10	3b	Describe contributions of protocol authors and identify the guarantor of the review
Amendments: NA	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments
Support:		
Sources: p. 10	5a	Indicate sources of financial or other support for the review
Sponsor: p. 10	5b	Provide name for the review funder and/or sponsor
Role of sponsor or funder: p.10	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
INTRODUCTION		
Rationale: p. 4, 5	6	Describe the rationale for the review in the context of what is already known
Objectives: p. 5	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)
METHODS		
Eligibility criteria: p. 5	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review
Information sources p. 5	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage
Search strategy: pp. 5, 6	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
Study records:		

Data management: pp. 6, 7	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review
Selection process: pp. 6, 7	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process: pp.6,7	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators
Data items: p. 7	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications
Outcomes and prioritization: p. 7	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale
Risk of bias in individual studies: p.7	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis
Data synthesis: pp. 7, 8, 9	15a	Describe criteria under which study data will be quantitatively synthesised
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned
Meta-bias(es): NA	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
Confidence in cumulative evidence: NA	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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Primary Subject Heading:	Public health
Secondary Subject Heading:	Sports and exercise medicine
Keywords:	BMI, Latin America, Children, Adolescents, Physical activity

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3 1 **Protocol manuscript**
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6 3 **The effects of physical activity interventions on the body mass index of children and**
7 **adolescents in Latin America: a protocol for a systematic review and meta-analysis.**
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12 6 **Authors and affiliations:**

13 7 Andrés Godoy-Cumillaf^{1,3}, Armando Díaz², Celia Álvarez-Bueno^{3,4*}; Vicente Martínez-
14 Vizcaíno³, Iván Cavero-Redondo^{3,4}.
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18
19 10 ¹Universidad Autónoma de Chile, Chile. Facultad de Educación, Temuco.

20 11 ²Secretaria de Esportes Taubaté, São Paulo, Brasil.

21 12 ³Universidad de Castilla-La Mancha, Health and Social Research Center, Cuenca, Spain.

22 13 ⁴Universidad Politécnica y Artística del Paraguay, Asunción, Paraguay.
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26

27 15 ***Correspondence to:**

28 16 Celia Álvarez Bueno

29 17 Author's address: C/ Santa Teresa Jornet, s/n, cp: 16071, Cuenca

30 18 Telephone number: +34 969170091. Ext. 4659

31 19 E-mail: celia.alvarezbueno@uclm.es
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3 **1 ABSTRACT.**

4 **2 Introduction:** In Latin America, childhood and adolescent overweight and obesity have
5 become a public health problem; for this reason, intervention programs have been
6 implemented, such as physical activity and nutritional interventions aimed at preventing
7 and treating these weight issues, using the BMI as a mean to know the impact such
8 interventions have made. Although in Latin America some systematic reviews have been
9 performed, any of them have meta-analysed the results of the effect of physical activity
10 interventions on BMI. The objective of this protocol is to present a procedure to carry out a
11 systematic review and a meta-analysis of studies on the effect of physical activity
12 interventions on BMI in Latin American children and adolescents aged 4 to 18 years.

13 **11 Methods and analysis:** This systematic review and meta-analysis protocol is based on the
14 Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-
15 P). The literature search will be conducted in MEDLINE, EMBASE, Cochrane Library,
16 Web of Science and Scielo from their inception until December 2018. Randomised
17 controlled trials (RCTs), non-randomised experimental studies and single-arm pre-post
18 studies will be included. The Cochrane Collaboration's tool for RCTs studies and the
19 Quality Assessment Tool for Quantitative Studies for non-randomised experimental studies
20 and single-arm pre-post studies will be used to assess the risk of bias for studies included in
21 the systematic review. Standardised pre-intervention mean differences will be calculated as
22 the primary outcome. Subgroup analyses will be performed based on the characteristics of
23 the interventions and population included in the studies.

24 **22 Ethics and dissemination:** This systematic review will provide updated evidence about the
25 effects of physical activity interventions on Latin American population; such evidence may
26 be useful for the institutions responsible for the development of public health policies and
27 for those in charge of the implementation of this type of interventions among children and
28 adolescents in Latin America.

29 Results will be disseminated by publication in a peer-reviewed journal. Since data used for
30 this systematic review will be extracted exclusively from published studies, the approval
31 from an ethical committee will not be required.

32 **30 Prospero registration number:** CRD42019077702.

33 **31 Keywords:** physical activity, BMI, Latin America, children and adolescents.

STRENGTHS AND LIMITATIONS OF THIS STUDY.

- This study provides a comprehensive methodology to analyse the effect of physical activity interventions on the BMI.
- Two researchers will independently carry out the study selection, data extraction and quality assessment of the studies found.
- This research might be the first evidence of meta-analysis in Latin America providing scientific information about the effect of physical activity interventions on the BMI.
- Differences among the studies design, sample characteristics, type of physical activity interventions and poor methodological quality may restrict the comparison of the selected studies and negatively affect the quality of the evidence of this systematic review and meta-analysis.

1 INTRODUCTION

2 Latin America is a developing region and needs assistance in all aspects; one of the actions
3 to assist development is to promote activities that contribute to address one of the greatest
4 problems affecting the region, such as overweight and obesity, which have significantly
5 increased among children and adolescents in the last decades, becoming a major public
6 health concern. It is estimated that between 20% and 25% of the total Latin American
7 population of children and adolescents are overweight or obese¹. This situation is worrying,
8 since it has been noted that this condition is maintained during adulthood^{2,3}, increasing risk
9 factors for cardiovascular disease, increased blood pressure and some types of cancer^{4,5} and
10 increasing the possibility of premature all cause mortality⁶. Therefore, this is a serious
11 situation that must be worked on in order to prevent the future generations of Latin
12 American society to be affected.

13 Body Mass Index (BMI) is a method that allows us to quickly know if a person is
14 overweight or obese and it is a measure to evaluate general adiposity⁷⁻⁹. There is evidence
15 that reflects that in low-income countries (most of in Latin America countries) in the last 3
16 decades there has been an increase in BMI values in children and adults, a situation that
17 mainly affects women¹⁰. A high BMI during childhood and adolescence predispose subjects
18 to develop the aforementioned diseases (high blood pressure, high cholesterol levels and
19 type 2 diabetes) and also has become a quite reliable predictor of mortality¹¹ to such a
20 degree that in 2015 more than 4.5 million deaths worldwide were associated with high
21 values of BMI¹².

22 Several interventions, including physical activity interventions, nutritional interventions or
23 a combination of both^{13,14}, have been suggested to mitigate the levels of overweight and
24 obesity. Out of these interventions, physical activity appears to play an important role,
25 contributing to reduce BMI, decrease cardiovascular risk factors and improve
26 cardiorespiratory endurance; all this leading to a reduction of health risk factors¹⁴⁻¹⁷.

27 Since in Latin America overweight and obesity have become a public health problem,
28 physical activity intervention programs aimed at preventing and treating these negative
29 situations have been implemented. In addition, these interventions have been supplemented
30 by nutritional interventions, using the BMI as a mean to know the impact these measures
31 have made. Although in Latin America some systematic reviews have been performed^{1,18,19},

1 any of them have meta-analyzed the results of the effect of physical activity interventions
2 on BMI. Therefore, the purpose of this protocol is to provide the methodology for a meta-
3 analysis in order to synthesize the effect of physical activity interventions on BMI in Latin
4 American children and adolescents.

5 Therefore, it is necessary to pay closer attention to this matter. Consequently, this study
6 protocol can be collaborate with public health programs related to overweight and obesity.

7 8 **OBJECTIVE**

9 The objective of this protocol is to present a procedure to carry out a systematic review and
10 a meta-analysis of studies on the effect of physical activity interventions on BMI in Latin
11 American children and adolescents aged 4 to 18 years.

12 13 **METHODS AND ANALYSIS**

14 This systematic review and meta-analysis protocol is based on the Preferred Reporting
15 Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P)²⁰ and the
16 Cochrane Collaboration Handbook²¹. This protocol has been previously registered in
17 PROSPERO (registration number: CRD42019077702).

18 19 **Patient and Public Involvement**

20 No patient involved.

21 22 **Search strategy**

23 The literature search will be conducted in MEDLINE (via PubMed), EMBASE, Cochrane
24 Library, Web of Science and Scielo databases from their inception until December 2018.

25 Searches for unpublished studies will be conducted at: OPEN GRAY, ProQuest
26 dissertations & Thesis Global, Theseo, Networked digital library of theses and dissertations
27 (NDLTD), and Google Scholar. A search of ClinicalTrials.gov and EudraCT clinical trial
28 records will also be conducted. The literature search will be complemented by screening
29 references included in the articles considered eligible for the systematic review. Study
30 records will be managed using the Mendeley reference manager. The search strategy will
31 include the following free text terms combining Boolean operators from the following

1 relevant concepts (Table 1): physical activity, physical exercise, fitness, physical
 2 performance, exercise program, exercise programme, exercise, training program, training
 3 programme, prevention program, prevention programme, intervention program,
 4 intervention programme, promotion, strategy, childhood obesity, obese children, obesity,
 5 obesity review, obesity prevention, BMI, underweight, normal weight, overweight, obesity,
 6 studies, randomised controlled trials, RCT, non-randomised experimental, single-arm pre-
 7 post (Table1). Previous reviews and meta-analyses will be scanned for additional
 8 references. Also, relevant references included in the selected studies will be screened as
 9 supplemental sources.

Table 1. Search strategy for the MEDILINE database.

"physical activity"	"training program"	"childhood obesity"	BMI	studies
OR	OR	OR	OR	OR
"physical exercise"	"training programme"	"obese children"	underweight	"randomised controlled trials"
OR	OR	OR	OR	OR
fitness	"prevention program"	obesity	"normal weight"	RCT
OR	OR	OR	OR	OR
"physical performance"	"prevention programme"	"obesity review"	overweight	"non-randomised experimental"
AND	AND	AND	AND	AND
OR	OR	OR	OR	OR
"exercise programs"	"intervention program"	"obesity prevention"	obesity	"single-arm pre-post"
OR	OR			
exercise	"intervention programme"			
	OR			
	promotion			
	OR			
	strategy			

Inclusion/exclusion criteria for study selection

In order to be included in the systematic review, studies must report physical activity interventions which meet the following criteria: 1) studies involving population of a Latin American country; 2) studies including participants aged 4-18 years; 3) studies reporting only one type of physical activity (physical endurance, sports or alternative exercise (games, dancing, optimised physical education classes), which may or may not have included nutritional health interventions; 4) randomised controlled trials (RCTs), non-randomised experimental studies and single-arm pre-post studies; 5) studies reporting BMI before and after the intervention; 6) studies written in Spanish, English or Portuguese.

Studies will be excluded when: 1) include participants younger than 4 and older than 18 years old; 2) provide self-reported data; 3) do not report BMI before and/or after the intervention.

In case of finding studies with another age range, but in which population data between 4 and 18 years are available, they will be included in the analysis.

Selection of studies

All the titles and abstracts of the retrieved articles will be evaluated independently by two researchers, in order to identify eligible studies for this systematic review, that is, that meet the inclusion criteria. Also, this first review will be done to identify and exclude duplicate documents. Abstracts not providing enough information related to inclusion/exclusion criteria will be selected to be evaluated through full-text reading. Each author will extract the data of the same five studies, and then they will compare the extraction and will agree which data they will include in the Table of Characteristics of studies included. Two reviewers will examine the included and excluded studies to verify the reason for each decision. The inconsistencies in the selection will be resolved with a third researcher.

Data extraction

The process of identification, selection and inclusion/exclusion of articles will be shown using the PRISMA²⁰ flow chart (Figure 1). In addition, full text of the identified studies

1 will be examined in order to extract the following data: (1) name of the first author; (2) year
2 of publication; (3) country; (4) study design; (5) age of the participants; (6) number of
3 participants; (7) characteristics of the population (normal weight, overweight, obesity); (8)
4 Type of physical activity intervention (leisure-time physical activity, physical activity
5 programs or physical activity counseling); (9) characteristics of the physical activity (length
6 of intervention, number of sessions, duration of each session, type of physical measurement
7 [ie. Physical activity scale, accelerometer or pedometer]); (10) type of nutritional
8 intervention (food education, nutritional counseling, diet intervention); and (11) Nutritional
9 intervention characteristics (length of intervention). When necessary, the authors of the
10 potentially eligible studies will be contacted to obtain any missing data.

11 12 **Assessment of risk of bias in the included studies**

13 Two researchers will independently conduct a quality assessment according to the
14 Cochrane Collaboration Handbook recommendations²¹. Any disagreements will be resolved
15 by discussion and a third reviewer will solve disagreements if consensus is not reached.

16 The methodological quality of the RCTs will be assessed using the Cochrane
17 Collaboration's tool for assessing risk of bias²². This tool evaluates the risk of bias
18 according to six domains: selection bias, performance bias, detection bias, attrition bias,
19 reporting bias and other bias.

20 The Quality Assessment Tool for Quantitative Studies²³ assesses the quality of pre-post
21 studies and non-RCTs. This tool evaluates seven domains: selection bias, study design,
22 confounders, blinding, data collection method, withdrawals and drop-outs.

23 In both quality assessment tools, each domain will be considered as strong, moderate or
24 weak, and studies will be classified as low risk of bias (with no weak ratings), moderate
25 risk of bias (with one weak rating) and high risk of bias (with two or more weak ratings).

26 The agreement rate between reviewers will be reported by calculating kappa statistics.

27 28 **Statistical analysis**

29 Researchers will summarise the main characteristics of the selected studies, including the
30 general profile of the study, methods, characteristics of the participants of the study and the
31 results on Table 2. A narrative synthesis of the data extracted in Table of characteristics of

1 the studies included will be conducted, then a meta-analysis will be performed based on
 2 studies that show BMI pre-post intervention. Separating studies that included physical
 3 activity interventions from those in which physical activity and nutritional health are
 4 combined. Studies providing insufficient data to carry out the analyses will be included in
 5 the systematic review but omitted from meta-analysis.
 6 If a meta-analysis is possible, STATA V.14 software will be used to combine the pooled
 7 mean differences with 95% confidence intervals (CIs). A fixed-effects model will be used if
 8 there is no evidence of heterogeneity; otherwise, a random-effects model will be used.
 9 Study heterogeneity will be assessed with the I^2 statistic. I^2 values will be considered as:
 10 might not be important (0–40%); may represent moderate heterogeneity (30–60%); may
 11 represent substantial heterogeneity (50–90%) and considerable heterogeneity (75–100%),
 12 the corresponding p -values will also be taken into account²¹.
 13 Data from intention-to-treat analyses will be considered whenever available in RCTs. Two
 14 analysis will be performed: 1) BMI mean difference pre–post intervention from Physical
 15 activity intervention versus control, and 2) BMI mean difference pre-post Physical activity
 16 intervention. Standardised mean differences will be calculated for BMI levels.
 17 Additionally, publication bias will be assessed using a funnel plot, according to the method
 18 proposed by Egger²⁴.

Table 2. Characteristics of studies included in the systematic review and/or meta-analysis.

Reference	Population characteristics					Intervention characteristics			
	Country	Study Design	Age distribution	Sample size	Type of population	Physical activity intervention	Physical activity characteristics	Nutritional intervention	Nutritional characteristics
Author information and year of publication	Country	Design of the study	Age (years) of the participants range or means±SD	Number of participants	Population characteristics (low weight, normal weight, overweight, obesity)	Type of physical activity intervention (leisure-time physical activity, physical activity programs or physical activity counseling)	Definition of physical activity intervention (length of intervention, number of sessions, duration of each session, type of physical activity measurement [ie. Physical activity scale,	Type of nutritional intervention (food education, nutritional counseling, diet intervention)	Definition of nutritional intervention (length of intervention).

accelerometer
or pedometer]

1 Subgroup analysis and meta-regression

2 Subgroup analyses and meta-regression will be performed considering the main factors
3 which may cause heterogeneity, such as: gender; age (children aged 4-12 years and
4 adolescents aged 12-18 years); type of population (general population or native
5 population); country; type of study design; participant population (underweight, normal
6 weight, overweight, obesity); type of intervention (only physical activity or combined with
7 nutritional interventions); type of physical activity (endurance, sports, games, dancing,
8 lifestyle physical activity interventions); length of the intervention (above or below 12
9 weeks); duration of physical activity per week (above or below 150 minutes). Moreover,
10 methodological quality of the selected studies will be considered for additional subgroup
11 analyses.

13 Sensitivity analysis

14 Sensitivity analyses will be carry out, removing the included studies one by one from the
15 pooled analyses, to assess the robustness of summary estimates and to detect if any singular
16 study accounts for a large proportion of heterogeneity.

18 ETHICS AND DISSEMINATION

19 Given that researchers will not collect primary data for this review, ethical approval will
20 not be required. However, once the outcomes of this systematic review and meta-analysis
21 are disseminated in scientific publications, they will be shared through social networks and
22 will be presented in scientific conferences related to the subject, so that our conclusions
23 contribute to improve the health of Latin American population.

25 DISCUSSION.

26 Studies carried out among European and United States population have shown that physical
27 activity interventions are associated with reductions of the BMI and are also an effective
28 way of decreasing the percentage of adipose tissue^{14,17}. However, there is no information
29 about the effects of these interventions conducted in Latin America, which geographical,

1 socio-economic and cultural characteristics are inherent to a developing region. Thus, the
2 development of a systematic review and, if possible, a meta-analysis, will enable us to have
3 an overview of the current literature in Latin America about the subject of study, and, at the
4 same time, to contribute to an efficient development of discussions regarding the benefits of
5 physical activity interventions in the region. To this end, the protocol of this systematic
6 review provides a structure for the extraction and synthesis of relevant information. This
7 could allow knowing which type of interventions bring the best benefits to reduce the
8 values of BMI, considering the setting (schools, health care centres or others), type of
9 population (according to their nutritional status), intensity, duration and number of
10 sessions.

11 Other issues that should be highlighted when performing this systematic review are whether
12 the study design (RCTs, non-randomised experimental studies and single-arm pre-post
13 studies) could affect the results as it has been reported in previous studies^{25,26} as well as
14 physical activity interventions supplemented by other health interventions, such as
15 nutritional interventions, lead to a greater reduction of BMI. These considerations will
16 allow us to check the prominence of physical activity interventions in the prevention and
17 treatment of overweight and obesity among Latin American children and adolescents.

18 Among the potential limitations inherent to systematic reviews and meta-analysis we may
19 find: publication bias, information bias, poor statistical analyses, low methodological
20 quality and inappropriate reporting of methods and findings of the included studies. It is
21 important to keep in mind that these sources of bias will be greater in some countries, due
22 to economic inequalities in the region, which result in an uneven advancement of scientific
23 development in the different countries. Therefore, it is important to properly synthesise the
24 information available in the manuscripts included, so this protocol becomes a necessary
25 text that consolidates methodological structure needed to carry out a systematic review and
26 meta-analysis based on evidence, regarding the effects of physical activity interventions on
27 the BMI of children and adolescents.

28 As a conclusion, this study will provide updated information which may be useful for
29 public health policy makers and for those responsible for the implementation of this type of
30 interventions among Latin American children and adolescents.

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8 **Contributors:**
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12 6 AG-C and IC-R designed the study: AG-C was the principal investigator. AG-C and IC-R
13 7 were the coordinators of the study. AG-C and AD-G conducted the study. AG-C, CA-B,
14 8 VM-V and IC-R gave statistical and epidemiological support. AG-C wrote the article with
15 9 the support of IC-R, CA-B, VM-V and AD-G. All authors reviewed and approved the final
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REFERENCES

1. Rivera JÁ, De Cossío TG, Pedraza LS, Aburto TC, Sánchez TG, Martorell R. Childhood and adolescent overweight and obesity in Latin America: A systematic review. *Lancet Diabetes Endocrinol* 2014;2(4):321-332.
2. Wang LY, Chyen D, Lee S, Lowry R. The Association Between Body Mass Index in Adolescence and Obesity in Adulthood. *J Adolesc Heal* 2008;42(5):512-518.
3. Ward ZJ, Cradock AL, Gortmaker SL, Resch SC, Long MW, Giles CM. Simulation of Growth Trajectories of Childhood Obesity into Adulthood. *N Engl J Med*. 2017;377(22):2145-2153.
4. Collaboration PS, Whitlock G, Lewington S, et al. Body-mass index and cause-specific mortality in 900 000 adults: collaborative analyses of 57 prospective studies. *Lancet* 2009;373(9669):1083-1096.
5. Wormser D, Kaptoge S, Di Angelantonio E, et al. Separate and combined associations of body-mass index and abdominal adiposity with cardiovascular disease: Collaborative analysis of 58 prospective studies. *Lancet* 2011;377(9771):1085-1095.
6. Ding EL, Mozaffarian D, Danaei G, et al. The Preventable Causes of Death in the United States: Comparative Risk Assessment of Dietary, Lifestyle, and Metabolic Risk Factors. *PLoS Med* 2009;6(4):e1000058.
7. Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for child overweight and obesity worldwide: international survey. *BMJ* 2000; 320(7244):1240-3.
8. Dietz WH, Robinson TN. Use of the body mass index (BMI) as a measure of overweight in children and adolescents. *J Pediatr* 1998;132(2):191-3.
9. Poskitt EM. Body mass index and child obesity: are we nearing a definition? *Acta Paediatr* 2000;89(5):507-509.

10. Swinburn GA, Sacks G, Hall KD, McPherson K, Finegood DT, Moodie ML, Gortmaker SL. The global obesity pandemic: shaped by global drivers and local environments. *Lancet* 2011;378(9793):804-14.
11. Lee HJ, Choi EK, Lee SH, Kim YJ, Han K Do, Oh S. Risk of ischemic stroke in metabolically healthy obesity: A nationwide population-based study. *PLoS One* 2018;13(3):1-14.
12. Gakidou E, Afshin A, Abajobir AA, et al. Global, regional, and national comparative risk assessment of 84 behavioural, environmental and occupational, and metabolic risks or clusters of risks, 1990-2016: A systematic analysis for the Global Burden of Disease Study 2016. *Lancet* 2017;390(10100):1345-1422.
13. Hills AP, Andersen LB, Byrne NM. Physical activity and obesity in children. *Br J Sports Med* 2011;45(11):866-870.
14. Kelley GA, Kelley KS, Pate RR. Exercise and BMI in Overweight and Obese Children and Adolescents: A Systematic Review and Trial Sequential Meta-Analysis. *Biomed Res Int* 2015;2015:1-17.
15. Jakicic J, Davis K. Obesity and Physical Activity. *Psychiatr Clin N Am.* 2011;34:829-840.
16. Zolotarjova J, ten Velde G, Vreugdenhil ACE. Effects of multidisciplinary interventions on weight loss and health outcomes in children and adolescents with morbid obesity. *Obes Rev* 2018;19(7):931-946.
17. Kelley GA, Kelley KS. Effects of Exercise in the Treatment of Overweight and Obese Children and Adolescents: A Systematic Review of Meta-Analyses. *J Obes* 2013;2013:1-10.
18. Legetic BD, Hoehner CM, Brownson RC, et al. Physical Activity Interventions in Latin America. *Am J Prev Med* 2008;34(3):224-233.e4.
19. Nagle BJ, Holub CK, Barquera S, et al. Interventions for the treatment of obesity among children and adolescents in Latin America: a systematic review TT - Intervenciones para el tratamiento de la obesidad en niños y adolescentes en Latinoamérica: una revisión sistemática. *Salud Publica Mex* 2013;55:434-440.
20. Moher D, Larissa S, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev* 2015;4(1).

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3 1 21. The Cochare Collaboration. In: Higgins JP, Green S, eds. Cochrane handbook for
4 systematic review of interventions. 5.1.0. 2011. <http://handbook.cochrane.org>.
5 2
6 3
7 (update March 2011)
8 4 22. Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for
9 assessing risk of bias in randomised trials. *BMJ* 2011;343(7829):1-9.
10 5
11 6 23. National Collaborating Centre for Methods and Tool. *Quality assessment tool for*
12 *quantitative Studies*. Hamilton ON: McMaster University, 2008. (Updated 13 april,
13 7
14 2010)
15 8
16 9 24. Sterne JAC, Egger M, Smith GD. Investigating and dealing with publication and
17 other biases in meta-analysis. *Br Med J*. 2001;323:101-105.
18 10
19 11
20 12 25. Brown T, Summerbell C. Systematic review of school-based interventions that focus
21 on changing dietary intake and physical activity levels to prevent childhood obesity:
22 an update to the obesity guidance produced by the National Institute for Health and
23 13
24 Clinical Excellence. *Obes Rev* 2009;10(1):110-41.
25 14
26 15
27 16 26. Katz DL. School-based interventions for health promotion and weight control: not
28 just waiting on the world to change. *Annu Rev Public Health* 2009;30:253-72.
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TABLES LEGENDS.

Table 1. Search strategy for the MEDILINE database.

Table 2. Characteristics of studies included in the systematic review and/or meta-analysis.

FIGURE LEGENDS.

FIGURE 1. PRISMA flow diagram of identification, screening, eligibility and inclusion of studies.

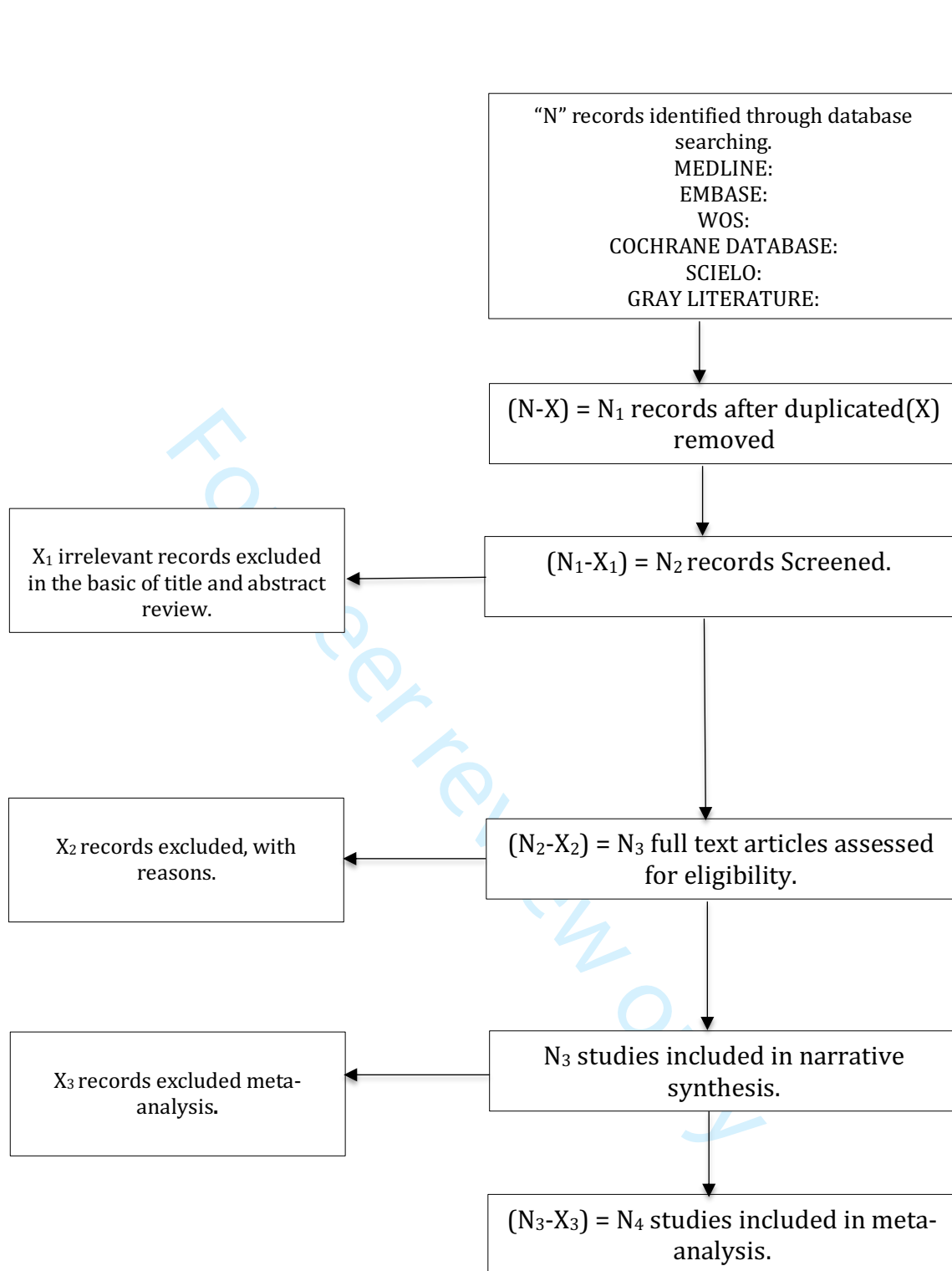


Figure 1. PRISMA flow diagram of identification, screening, eligibility and inclusion of studies.

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification: p. 1	1a	Identify the report as a protocol of a systematic review
Update: NA.	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number
Authors:		
Contact: pp. 1, 10	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author
Contributions: p.10	3b	Describe contributions of protocol authors and identify the guarantor of the review
Amendments: NA	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments
Support:		
Sources: p. 10	5a	Indicate sources of financial or other support for the review
Sponsor: p. 10	5b	Provide name for the review funder and/or sponsor
Role of sponsor or funder: p.10	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
INTRODUCTION		
Rationale: p. 4, 5	6	Describe the rationale for the review in the context of what is already known
Objectives: p. 5	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)
METHODS		
Eligibility criteria: p. 5	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review
Information sources p. 5	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage
Search strategy: pp. 5, 6	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
Study records:		

Data management: pp. 6, 7	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review
Selection process: pp. 6, 7	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process: pp.6,7	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators
Data items: p. 7	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications
Outcomes and prioritization: p. 7	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale
Risk of bias in individual studies: p.7	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis
Data synthesis: pp. 7, 8, 9	15a	Describe criteria under which study data will be quantitatively synthesised
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned
Meta-bias(es): NA	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
Confidence in cumulative evidence: NA	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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Effects of physical-activity interventions on the body mass index of children and adolescents in Latin America: A protocol for systematic reviews and meta-analyses

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6 3 **Effects of physical-activity interventions on the body mass index of children and**
7 **adolescents in Latin America: A protocol for systematic reviews and meta-analyses**
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10 5
11 6 **Authors and affiliations:**

12 7 Andrés Godoy-Cumillaf^{1,3}, Armando Díaz², Celia Álvarez-Bueno^{3,4*}; Vicente Martínez-
13 Vizcaíno³, Iván Cavero-Redondo^{3,4}.
14
15 8

16 9
17 10 ¹Universidad Autónoma de Chile, Chile. Facultad de Educación, Pedagogía en Educación
18 Física, Temuco.
19 11

20 12 ²Secretaria de Esportes Taubaté, São Paulo, Brazil.
21 13

22 14 ³Universidad de Castilla-La Mancha, Health and Social Research Centre, Cuenca, Spain.
23 15

24 16 ⁴Universidad Politécnica y Artística del Paraguay, Asunción, Paraguay.
25 17
26 18

27 19
28 20
29 21 ***Correspondence:**

30 22 Celia Álvarez Bueno
31 23

32 24 C/ Santa Teresa Jornet, s/n, cp: 16071, Cuenca, Spain
33 25

34 26 Telephone: +34 969170091. Ext. 4659
35 27

36 28 E-mail: celia.alvarezbueno@uclm.es
37 29
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3 **1 ABSTRACT.**

4 **2 Introduction:** In Latin America, the number of children and adolescents who are
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3 overweight or obese has significantly increased in recent decades, and this situation has
4 become a major public-health concern. To address this problem, several intervention
5 programmes, based on factors such as physical activity and nutrition, have been
6 implemented, and body mass index (BMI) has been widely used as a means of measuring
7 the impact of such interventions. Although some Latin-America-based systematic reviews
8 have been performed, there have been no previous meta-analyses of findings regarding the
9 effect of physical-activity interventions on BMI. Considering this, the objective of this
10 study protocol is to provide a standardised and transparent methodology for performing
11 systematic reviews and meta-analyses of study findings regarding the effect physical-
12 activity interventions have on BMI of Latin American children and adolescents aged four to
13 18 years.

14 **Methods and analysis:** This systematic review and meta-analysis protocol is based on the
15 Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-
16 P) statement. The literature search will involve MEDLINE, EMBASE, Cochrane Library,
17 Web of Science and Scielo for articles published up to July 2019. This search will include
18 randomised controlled trials (RCTs), non-randomised experimental studies, and single-arm
19 pre-post studies. Further, the Cochrane Collaboration's tool for RCT studies and the
20 Quality Assessment Tool for Quantitative Studies for non-randomised experimental and
21 single-arm pre-post studies will be used to assess the risk of bias among the studies
22 included in the systematic review. For the meta-analysis, the statistical program STATA
23 V.14 will be used, and standardised mean differences are calculated as the primary
24 outcomes. Subgroup analyses will then be performed based on the characteristics of the
25 interventions and populations included in the studies examined.

26 **Ethics and dissemination:** This systematic review protocol is designed to provide updated
27 evidence regarding the effects of physical-activity interventions on the Latin American
28 population; such evidence may be useful for institutions responsible for the development of
29 public-health policies and for those tasked with implementing such interventions among
30 children and adolescents in Latin America.

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3 1 The results should be disseminated through publication in a peer-reviewed journal. Since
4 2 the data used in systematic reviews of this type will be extracted exclusively from
5 3 published studies, approval from an ethics committee will not be required.
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10 5 **Prospero registration number:** CRD42019077702.
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13 7 **Keywords:** physical activity, BMI, Latin America, children and adolescents.
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STRENGTHS AND LIMITATIONS OF THIS STUDY.

- This study provides a comprehensive methodology for analysing the effect of physical-activity interventions on BMI.
- In the protocol, two researchers will independently perform the study selection, data extraction, and quality assessments.
- This research may produce the first Latin-America-based meta-analysis that provides scientific information regarding the effect of physical-activity interventions on BMI.
- Differences among the study designs, sample characteristics, types of physical-activity interventions, and poor methodological quality may restrict comparison of the selected studies and negatively affect the quality of the evidence obtained through associated systematic reviews and meta-analyses.

1 INTRODUCTION

2 In Latin America, levels of overweight and obesity among children and adolescents have
3 significantly increased in recent decades, and this issue has now become a major public-
4 health concern^{1,2}. A tool that facilitates a quick assessment of whether a person is
5 overweight or obese, as well as their level of general adiposity, is body mass index (BMI)<sup>3-
6 5</sup>. As a result of BMI-based assessments, it is now estimated that between 20% and 25% of
7 the total Latin-American population of children and adolescents are overweight or obese⁵.
8 This is a worrying situation, as studies have suggested that these conditions are maintained
9 into and during adulthood^{6,7}, and that they increase risk factors for cardiovascular disease,
10 high blood pressure, some types of cancer^{8,9}, and all causes of premature mortality¹⁰. In
11 fact, BMI has become such a reliable predictor of mortality¹¹ that in 2015 over 4.5 million
12 deaths worldwide were associated with high BMI values¹².

13 However, in children and adolescents BMI values should be used and interpreted
14 cautiously, as there is evidence that, although such values are useful for classifying
15 adiposity¹³, they can be a poor measure of changes in adiposity¹⁴. Moreover, childhood
16 weight gain can generally be attributed to fat-free mass rather than fat mass, and this means
17 that BMI is unable to precisely reflect changes that occur over time¹⁵, particularly in
18 adolescent males and children with low BMI¹⁶.

19 Physical activity plays an important role in reducing BMI, along with lowering risk factors
20 for cardiovascular disease and improving cardiorespiratory fitness; this, in turn, leads to a
21 reduction in risk factors for overall health¹⁷⁻²⁰. As a result of these benefits, researchers
22 have implemented physical-activity-focussed interventions, nutritional-focussed
23 interventions, or a combination of both^{20,21}, and have used BMI to measure their effect.
24 Underlining this approach, previous systematic reviews performed in Latin America have
25 shown that, while few studies have implemented physical-activity interventions to treat
26 overweight and obesity, the implementation of physical-education policies and programmes
27 is necessary to promote children's and adolescents' health, because these interventions can
28 effectively create positive changes among this population^{1,22,23}. However, there have been
29 no previous Latin-America-based meta-analyses of the effects physical-activity
30 interventions have on BMI. Considering this, the present study aims to attract more

1 attention to the necessity of such interventions, and to generate evidence that can encourage
2 changes in public policy that can contribute to addressing this public-health crisis.

3 4 **OBJECTIVE**

5 This study protocol seeks to provide a standardised and transparent methodology for
6 performing systematic reviews and meta-analyses of findings concerning the effect
7 physical-activity interventions have on BMI of Latin American children and adolescents
8 aged four to 18 years.

9 10 **METHODS AND ANALYSIS**

11 This systematic review and meta-analysis protocol is based on the Preferred Reporting
12 Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) statement²⁴ and
13 the Cochrane Collaboration Handbook²⁵. This protocol has previously been registered in
14 PROSPERO (registration number: CRD42019077702).

15 16 **Inclusion/exclusion criteria for study selection**

17 For this protocol, in order to be included in associated systematic reviews studies must have
18 reported physical-activity interventions that meet the following criteria: 1) involving the
19 population of a Latin American country; 2) including participants aged 4–18 years; 3)
20 reporting any type of physical activity (physical endurance, sports, or alternative exercise
21 [e.g. games, dancing, optimised physical education classes], which may or may not have
22 included nutritional interventions); 4) being a randomised controlled trial (RCT), non-
23 randomised experimental study, or single-arm pre-post study; 5) reporting BMI both before
24 and after the intervention; 6) written in Spanish, English, or Portuguese; and 7) published
25 before July 2019.

26 Meanwhile, the following exclusion criteria will be set: 1) only including participants
27 younger than four or older than 18 years old; 2) providing self-reported data for BMI.

28 Studies that feature different age ranges, but that nevertheless include population data for
29 the ages of four to 18 years, will be included in the analysis.

1 **Search strategy**

2 Literature searches will be conducted through the MEDLINE (via PubMed), EMBASE,
3 Cochrane Library, Web of Science, and Scielo databases.

4 Meanwhile, searches for unpublished studies will be conducted using OPEN GRAY,
5 ProQuest Dissertations & Thesis Global, Theseo, Networked Digital Library of Theses and
6 Dissertations, and Google Scholar. Further, a search of ClinicalTrials.gov and EudraCT
7 clinical trial records will also be conducted. The literature search will be complemented by
8 screening references included in articles that are considered eligible for systematic review.
9 Study records will then be managed using the Mendeley reference manager. The search
10 strategy will include free text terms, combining Boolean operators from the relevant
11 concepts presented in Table 1. Previous reviews and meta-analyses will also be scanned for
12 additional references. Finally, relevant references included in the selected studies will be
13 screened as supplemental sources.

14

Table 1. Search strategy for the MEDILINE database.

physical activity [tw]		training program* [tiab]		childhood obesity [tiab]		underweight [tw]		studies [tiab]
OR		OR		OR		OR		OR
physical exercise [tw]		prevention program* [tiab]		obese children [tiab]		normal weight [tw]		randomised controlled trials [tiab]
OR		OR		OR		OR		OR
physical performance [tw]		intervention program* [tiab]		obesity prevention [tiab]		overweight [tw]		RCT [tiab]
OR		OR		OR		OR		OR
exercise program* [tiab]	AND	promotion [tw]	AND	obesity review [tiab]	AND	BMI [tiab]	AND	non-randomised experimental [tiab]
OR		OR		OR		OR		OR
physical fitness [mh]		strategy [tw]		paediatric obesity [mh]		obesity [tiab]		single-arm pre-post [tiab]
OR						OR		
exercise [mh]						body mass index [mh]		

1 mh: MeSH terms; tiab: title/abstract; tw: text word. * is used to search for or all terms that begin with a word
 2 (e.g. 'training program*' would return results such as 'training programs' and 'training programme')

4 Study selection

5 After excluding duplicated records, two researchers will independently evaluate the titles
 6 and abstracts of the retrieved articles in order to identify eligible studies for the systematic
 7 review. Abstracts that do not provide sufficient information regarding inclusion/exclusion
 8 criteria will then be evaluated through a full-text reading. Then, two researchers will
 9 examine the included and excluded studies to verify the reason for each decision.
 10 Inconsistencies between these two researchers regarding selection will be resolved by a
 11 third researcher, who will make the final decision, always based on the inclusion/exclusion
 12 criteria.

1 **Data extraction**

2 The process of identification, selection, and the inclusion/exclusion of articles will follow
3 the PRISMA²⁴ flow chart (shown in Figure 1). For the first five studies, the extraction tool
4 will be operated by all researchers; this is performed to ensure that the data extraction is
5 consistent and to create a ‘Table of Characteristics’ (Table 2). In addition, the full texts of
6 the identified studies will be examined to extract the following data: (1) name of the first
7 author; (2) year of publication; (3) country; (4) study design; (5) participants’ ages; (6)
8 number of participants; (7) population characteristics (normal weight, overweight, obesity);
9 (8) type of physical-activity intervention (leisure-time physical activity, lifestyle physical
10 activity, physical-activity programme, or physical activity counselling); (9) characteristics
11 of the physical activity in question (length of intervention, intervention setting, number of
12 sessions, duration of each session, type of physical measurement applied [i.e. physical-
13 activity scale, accelerometer, or pedometer]); (10) type of nutritional intervention (food
14 education, nutritional counselling, diet intervention); and (11) characteristics of this
15 nutritional intervention (length of intervention). When necessary, the authors of potentially
16 eligible studies will be contacted to obtain any missing data.

18 **Assessment of risk of bias in the included studies**

19 Two researchers will independently conduct a quality assessment, following the Cochrane
20 Collaboration Handbook recommendations²⁵. Any disagreements will be resolved through
21 discussion and, if a consensus cannot be reached, a third reviewer will intervene to resolve
22 the disagreement.

23 The methodological quality of the RCTs will be assessed using the Cochrane
24 Collaboration’s tool for assessing risk of bias²⁶. This tool evaluates risk of bias in terms of
25 six domains: selection bias, performance bias, detection bias, attrition bias, reporting bias,
26 and other bias.

27 Meanwhile, the Quality Assessment Tool for Quantitative Studies²⁷ will be used to assess
28 the quality of pre-post studies and non-RCTs. This tool evaluates seven domains: selection
29 bias, study design, confounders, blinding, data-collection method, withdrawals, and drop-
30 outs.

1 In both quality-assessment tools, each domain is considered ‘strong’, ‘moderate’, or ‘weak’
2 and, based on this, studies will be classified as having a low risk of bias (with no weak
3 ratings), a moderate risk of bias (with one weak rating), or a high risk of bias (with two or
4 more weak ratings). The agreement rate between reviewers will be reported by calculating
5 kappa statistics.

6 7 **Statistical analysis**

8 Researchers will summarise the main characteristics of each selected study, including the
9 general profile of the study, the methods, the characteristics of the study participants, and
10 the results (as shown in Table 2). A narrative synthesis of the data extracted in the Table of
11 Characteristics for the included studies will be conducted, and then a meta-analysis will be
12 performed on studies that featured BMI pre-post interventions (separating studies that
13 included physical-activity interventions from those in which physical activity and
14 nutritional health were combined). Studies providing insufficient data to perform such
15 analyses will be included in the systematic review, but will be omitted from the meta-
16 analysis.

17 For studies for which a meta-analysis is appropriate, STATA V.14 software will be used to
18 combine the pooled mean differences with 95% confidence intervals. If there is no evidence
19 of heterogeneity, a fixed-effects model will be used; otherwise, a random-effects model will
20 be used. Study heterogeneity will be assessed using the I^2 statistic. Specifically, I^2 values
21 will be stratified as follows: ‘might not be important’ (0–40%); ‘may represent moderate
22 heterogeneity’ (30–60%); ‘may represent substantial heterogeneity’ (50–90%) and
23 ‘considerable heterogeneity’ (75–100%); the corresponding p -values will also be taken into
24 account²⁴.

25 For RCTs, data from intention-to-treat analyses will be considered, whenever available.
26 Specifically, two analysis will be performed: 1) mean difference in BMI pre-post physical-
27 activity-based intervention (with or without nutritional intervention) versus a control group,
28 and 2) mean difference in BMI pre-post physical-activity-based intervention (with or
29 without nutritional intervention), without a control group. Standardised mean differences
30 will be calculated for BMI levels. Additionally, publication bias will be assessed using a
31 funnel plot, following the method proposed by Egger²⁸.

1 **Subgroup analysis and meta-regression**

2 Next, subgroup analyses and meta-regression will be performed, considering the main
3 factors that may cause heterogeneity, such as gender; age (children aged 4–12 years and/or
4 adolescents aged 12–18 years); type of population (general population, indigenous
5 population, or a mix of both); country; type of study design; participant population
6 (underweight, normal weight, overweight, and/or obese); type of intervention (only
7 physical activity or combined with nutritional intervention); type of physical activity
8 (endurance, sports, games, dancing, and/or lifestyle physical-activity intervention); length
9 of the intervention (above or below 12 weeks); the setting in which the intervention occurs;
10 and duration of physical activity per week (above or below 150 minutes). Moreover, the
11 methodological quality of the selected studies will be considered for additional subgroup
12 analyses.

14 **Sensitivity analysis**

15 Finally, to assess the robustness of summary estimates and to detect whether any singular
16 study accounts for a large proportion of heterogeneity, sensitivity analyses will be
17 performed, removing the included studies one-by-one from the pooled analyses.

19 **ETHICS AND DISSEMINATION**

20 Given that, in this protocol, researchers will not collect primary data for their reviews,
21 ethical approval will not be required. Once the outcomes of the associated systematic
22 reviews and meta-analyses are disseminated in scientific publications, they may be shared
23 through social networks and presented in scientific conferences related to the subject; thus,
24 the conclusions may contribute to improving the health of the Latin American population.

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Table 2. Characteristics of studies included in the systematic review and/or meta-analyses.

Population characteristics						Intervention characteristics			
Reference	Country	Study Design	Age distribution	Sample size	Type of population	Physical-activity intervention	Physical activity characteristics	Nutritional intervention	Nutritional characteristics
Author information and year of publication	Country	Design of the study	Age (years) of the participants range or means \pm SD	Number of participants	Population characteristics (low weight, normal weight, overweight, obese)	Type of physical-activity intervention (leisure-time physical activity, physical activity programme, and/or physical activity counselling)	Definition of physical-activity intervention (length of intervention, number of sessions, duration of each session, type of physical measurement [i.e. Physical activity scale, accelerometer or pedometer])	Type of nutritional intervention (food education, nutritional counselling, diet intervention)	Definition of nutritional intervention (length of intervention).

1 DISCUSSION

2 Studies conducted among populations in Europe and the United States have shown that
3 physical-activity interventions are associated with reductions of BMI, and are also an
4 effective method of decreasing the percentage of adipose tissue^{17,20}. However, there have
5 been no previous meta-analyses of the effects of these interventions in the context of Latin
6 America, which has geographical, socio-economic, and cultural characteristics that are
7 inherent to a developing region. Thus, a suitable systematic review and, if appropriate, a
8 meta-analysis, will enable us to gain an overview of the current Latin-America-based
9 literature regarding the study subject and, concurrently, could contribute to the efficient
10 development of discussions regarding the benefits of physical-activity interventions in the
11 region. To this end, the systematic review protocol provides a structure for the extraction
12 and synthesis of relevant information. This could provide us with evidence regarding the
13 types of interventions that are most beneficial for reducing BMI values, particularly in
14 regard to setting (school, health-care centre, or other), population type (as nutritional effects
15 can vary between population types), intensity, duration, and number of sessions.

16 Other issues that should be highlighted when performing systematic reviews based on this
17 protocol are whether the study design (RCTs, non-randomised experimental studies, and
18 single-arm pre-post studies) could affect the results (as has been reported in previous
19 studies^{29,30}), as well as whether physical-activity interventions supplemented by other
20 health interventions, such as nutritional interventions, can lead to a greater reduction in
21 BMI. Such considerations would allow us to measure the effect of physical-activity
22 interventions in regard to the prevention and treatment of overweight and obesity among
23 Latin American children and adolescents.

24 Among the potential limitations inherent to systematic reviews and meta-analyses, the
25 following (as elements of the studies examined) are particularly notable: publication bias,
26 information bias, poor statistical analyses, low methodological quality, and inappropriate
27 reporting of methods and findings. It is important to remember that, as a result of economic
28 inequalities, these biases may be greater in some countries, which can result in an uneven
29 advancement of scientific development across the region as a whole. Therefore, it is
30 important to properly synthesise the information available in examined manuscripts; thus,
31 this protocol represents a necessary text that consolidates the methodological structure

1 needed to perform appropriate, evidence-based systematic reviews and meta-analyses
2 regarding the effects of physical-activity interventions on BMI of children and adolescents.
3 In conclusion, application of this study protocol can provide updated information regarding
4 the effects of physical-activity interventions on BMI of Latin American children and
5 adolescents. Such information may assist the roles of public-health policy makers and those
6 responsible for the implementation of such interventions.

7 8 **Patient and Public Involvement**

9 No patients or members of the public were involved in the design of this protocol.

10 11 **Contributors:**

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13 AG-C and IC-R designed the study: AG-C was the principal investigator. AG-C and IC-R
14 coordinated the study. AG-C and AD conducted the study. AG-C, CA-B, VM-V, and IC-R
15 provided statistical and epidemiological support. AG-C wrote the article with the support of
16 IC-R, CA-B, VM-V, and AD. All authors reviewed and approved the final version of the
17 manuscript.

18 19 **Competing interests:**

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1 REFERENCES

- 1 1. Rivera JÁ, De Cossío TG, Pedraza LS, Aburto TC, Sánchez TG, Martorell R.
2 Childhood and adolescent overweight and obesity in Latin America: A systematic
3 review. *Lancet Diabetes Endocrinol* 2014;2(4):321-332.
- 4 2. Swinburn BA, Sacks G, Hall KD, McPherson K, Finegood DT, Moodie ML,
5 Gortmaker SL. The global obesity pandemic: Shaped by global drivers and local
6 environments. *Lancet* 2011;378(9793):804-814.
- 7 3. Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for
8 child overweight and obesity worldwide: International survey. *BMJ*
9 2000;320(7244):1240-1243.
- 10 4. Dietz WH, Robinson TN. Use of the body mass index (BMI) as a measure of
11 overweight in children and adolescents. *J Pediatr* 1998;132(2):191-193.
- 12 5. Poskitt EM. Body mass index and child obesity: Are we nearing a definition? *Acta*
13 *Paediatr* 2000;89(5):507-509.
- 14 6. Wang LY, Chyen D, Lee S, Lowry R. The association between body mass index in
15 adolescence and obesity in adulthood. *J Adolesc Heal* 2008;42(5):512-518.
- 16 7. Ward ZJ, Long MW, Resch SC, Giles CM, Cradock AL, Gortmaker SL. Simulation
17 of growth trajectories of childhood obesity into adulthood. *N Engl J Med*
18 2017;377(22):2145-2153.
- 19 8. Prospective Studies Collaboration, Whitlock G, Lewington S, et al. Body-mass index
20 and cause-specific mortality in 900,000 adults: Collaborative analyses of 57
21 prospective studies. *Lancet* 2009;373(9669):1083-1096.
- 22 9. Emerging Risk Factors Collaboration, Wormser D, Kaptoge S, et al. Separate and
23 combined associations of body-mass index and abdominal adiposity with
24 cardiovascular disease: Collaborative analysis of 58 prospective studies. *Lancet*
25 2011;377(9771):1085-1095.
- 26 10. Danaei G, Ding EL, Mozaffarian D, Taylor B, Rehm J, Murray CJ, Ezzati M. The
27 preventable causes of death in the United States: Comparative risk assessment of
28 dietary, lifestyle, and metabolic risk factors. *PLoS Med* 2009;6(4):e1000058.

- 1 11. Lee HJ, Choi EK, Lee SH, Kim YJ, Do Han K, Oh S. Risk of ischemic stroke in
2 metabolically healthy obesity: A nationwide population-based study. *PLoS One*
3 2018;13(3):1-14.
- 4 12. GBD 2016 Risk Factors Collaborators. Global, regional, and national comparative
5 risk assessment of 84 behavioural, environmental and occupational, and metabolic
6 risks or clusters of risks, 1990-2016: A systematic analysis for the Global Burden of
7 Disease Study 2016. *Lancet* 2017;390(10100):1345-1422.
- 8 13. Pietrobelli A, Faith MS, Allison DB, Gallagher D, Chiumello G, Heymsfield SB.
9 Body mass index as a measure of adiposity among children and adolescents: A
10 validation study. *J Pediatr* 1998;132(2):204-210.
- 11 14. Cole TJ, Faith MS, Pietrobelli A, Heo M. What is the best measure of adiposity
12 change in growing children: BMI, BMI %, BMI z-score or BMI centile? *Eur J Clin*
13 *Nutr* 2005;59(3):419-425.
- 14 15. Maynard LM, Wisemandle W, Roche AF, Chumlea WC, Guo SS, Siervogel RM.
15 Childhood body composition in relation to body mass index. *Pediatrics*
16 2001;107(2):344-350.
- 17 16. Demerath EW, Schubert CM, Maynard LM, et al. Do changes in body mass index
18 percentile reflect changes in body composition in children? Data from the Fels
19 Longitudinal Study. *Pediatrics* 2006;117(3):e487-e495.
- 20 17. Kelley GA, Kelley KS. Effects of exercise in the treatment of overweight and obese
21 children and adolescents: A systematic review of meta-analyses. *J Obes*
22 2013;2013:783103.
- 23 18. Jakicic JM, Davis KK. Obesity and physical activity. *Psychiatr Clin N Am*
24 2011;34(4):829-840.
- 25 19. Zolotarjova J, ten Velde G, Vreugdenhil ACE. Effects of multidisciplinary
26 interventions on weight loss and health outcomes in children and adolescents with
27 morbid obesity. *Obes Rev* 2018;19(7):931-946.
- 28 20. Kelley GA, Kelley KS, Pate RR. Exercise and BMI in overweight and obese children
29 and adolescents: A systematic review and trial sequential meta-analysis. *BioMed Res*
30 *Int* 2015;2015:704539.

- 1
2
3 1 21. Hills AP, Andersen LB, Byrne NM. Physical activity and obesity in children. *Br J*
4 *Sports Med* 2011;45(11):866-870.
5 2
6 3 22. Legetic BD, Hoehner CM, Brownson RC, et al. Physical activity interventions in
7 Latin America. *Am J Prev Med* 2008;34(3):224-233.e4.
8 4
9 5 23. Nagle BJ, Holub CK, Barquera S, et al. Interventions for the treatment of obesity
10 among children and adolescents in Latin America: A systematic review. *Salud Publ*
11 *Mex* 2013;55:434-440.
12 6
13 7
14 8 24. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic
15 review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev*
16 9
17 2015;4(1):1.
18 10
19 11 25. Higgins JPT, Green S, editors. Cochrane handbook for systematic reviews of
20 interventions. Version 5.1.0 [updated March 2011]. The Cochrane Collaboration;
21 2011 [cited 2019 Aug 27]. Available from:www.handbook.cochrane.org.
22 12
23 13
24 14 26. Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for
25 assessing risk of bias in randomised trials. *BMJ* 2011;343(7829):1-9.
26 15
27 16 27. National Collaborating Centre for Methods and Tools. Quality assessment tool for
28 quantitative studies: Hamilton ON: McMaster University; 2008.
29 17
30 18 28. Sterne JAC, Egger M, Smith GD. Systematic reviews in health care: Investigating
31 and dealing with publication and other biases in meta-analysis. *BMJ*
32 2001;323(7304):101-105.
33 19
34 20 29. Brown T, Summerbell C. Systematic review of school-based interventions that focus
35 on changing dietary intake and physical activity levels to prevent childhood obesity:
36 An update to the obesity guidance produced by the National Institute for Health and
37 Clinical Excellence. *Obes Rev* 2009;10(1):110-141.
38 21
39 22
40 23
41 24
42 25 30. Katz DL. School-based interventions for health promotion and weight control: Not
43 just waiting on the world to change. *Annu Rev Public Health* 2009;30:253-272.
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3 **1 TABLE LEGENDS.**
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6 **2 Table 1.** Search strategy for the MEDLINE database.
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8 **3 Table 2.** Characteristics of studies included in the systematic review and/or meta-analysis.
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13 **5 FIGURE LEGENDS.**

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15 **6 FIGURE 1.** PRISMA flow diagram for identifying, screening, and determining the
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17 eligibility of and whether to include studies.
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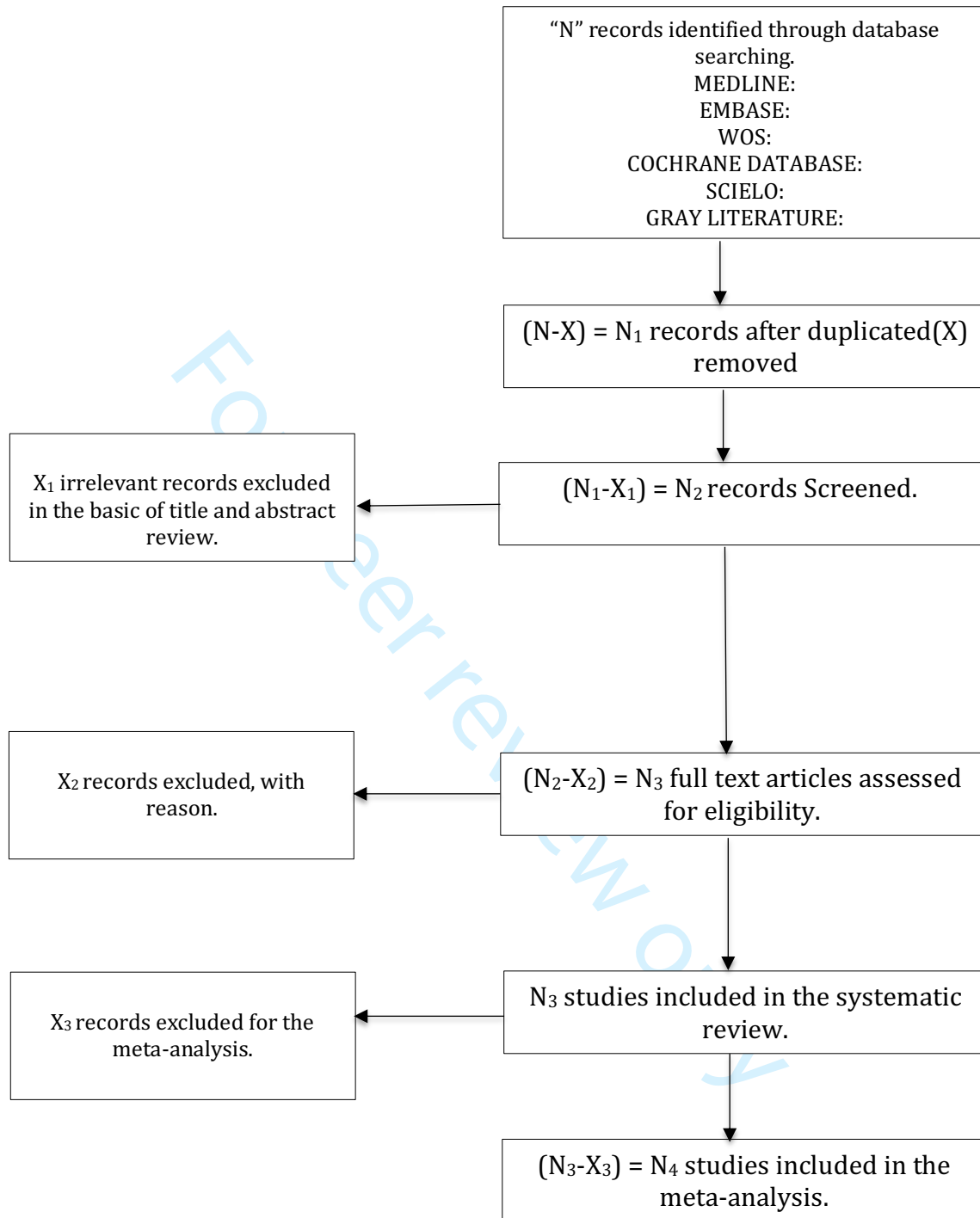


Figure 1. PRISMA flow diagram of identification, screening, eligibility and inclusion of studies.

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification: p. 1	1a	Identify the report as a protocol of a systematic review
Update: NA.	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number
Authors:		
Contact: pp. 1, 10	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author
Contributions: p.10	3b	Describe contributions of protocol authors and identify the guarantor of the review
Amendments: NA	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments
Support:		
Sources: p. 10	5a	Indicate sources of financial or other support for the review
Sponsor: p. 10	5b	Provide name for the review funder and/or sponsor
Role of sponsor or funder: p.10	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
INTRODUCTION		
Rationale: p. 4, 5	6	Describe the rationale for the review in the context of what is already known
Objectives: p. 5	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)
METHODS		
Eligibility criteria: p. 5	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review
Information sources p. 5	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage
Search strategy: pp. 5, 6	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
Study records:		

Data management: pp. 6, 7	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review
Selection process: pp. 6, 7	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process: pp.6,7	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators
Data items: p. 7	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications
Outcomes and prioritization: p. 7	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale
Risk of bias in individual studies: p.7	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis
Data synthesis: pp. 7, 8, 9	15a	Describe criteria under which study data will be quantitatively synthesised
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned
Meta-bias(es): NA	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
Confidence in cumulative evidence: NA	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

BMJ Open

Effects of physical-activity interventions on the body mass index of children and adolescents in Latin America: A protocol for a systematic review and meta-analysis

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Primary Subject Heading:	Public health
Secondary Subject Heading:	Sports and exercise medicine
Keywords:	BMI, Latin America, Children, Adolescents, Physical activity

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6 3 **Effects of physical-activity interventions on the body mass index of children and**
7 **adolescents in Latin America: A protocol for a systematic review and meta-analysis**
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11 6 **Authors and affiliations:**

12 7 Andrés Godoy-Cumillaf^{1,3}, Armando Díaz², Celia Álvarez-Bueno^{3,4*}; Vicente Martínez-
13 Vizcaíno³, Iván Cavero-Redondo^{3,4}.
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16 9
17 10 ¹Universidad Autónoma de Chile, Chile. Facultad de Educación, Pedagogía en Educación
18 Física, Temuco.
19 11

20 12 ²Secretaria de Esportes Taubaté, São Paulo, Brazil.
21 13

22 14 ³Universidad de Castilla-La Mancha, Health and Social Research Centre, Cuenca, Spain.
23 15

24 16 ⁴Universidad Politécnica y Artística del Paraguay, Asunción, Paraguay.
25 17
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27 19
28 20
29 21 ***Correspondence:**

30 22 Celia Álvarez Bueno
31 23

32 24 C/ Santa Teresa Jornet, s/n, cp: 16071, Cuenca, Spain
33 25

34 26 Telephone: +34 969170091. Ext. 4659
35 27

36 28 E-mail: celia.alvarezbueno@uclm.es
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3 **1 ABSTRACT.**

4 **2 Introduction:** In Latin America, the number of children and adolescents who are overweight
5 or obese has significantly increased in recent decades, and this situation has become a major
6 public-health concern. To address this problem, several intervention programmes, based on
7 factors such as physical activity and nutrition, have been implemented, and body mass index
8 (BMI) has been widely used as a means of measuring the impact of such interventions.
9 Although some Latin-America-based systematic reviews have been performed, there have
10 been no previous meta-analyses of findings regarding the effect of physical-activity
11 interventions on BMI. Thus, the objective of the systematic review and meta-analysis will be
12 to provide an up-to-date synthesis of the effects of physical-activity interventions on BMI of
13 Latin American children and adolescents aged four to 18 years.

14 **12 Methods and analysis:** This systematic review and meta-analysis protocol is based on the
15 Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-
16 P) statement. The literature search will involve MEDLINE, EMBASE, Cochrane Library,
17 Web of Science and Scielo for articles published up to July 2019. This search will include
18 randomised controlled trials (RCTs), non-randomised experimental studies, and single-arm
19 pre-post studies. Further, the Cochrane Collaboration's tool for RCT studies and the Quality
20 Assessment Tool for Quantitative Studies for non-randomised experimental and single-arm
21 pre-post studies will be used to assess the risk of bias among the studies included in the
22 systematic review. For the meta-analysis, the statistical program STATA V.14 will be used,
23 and standardised mean differences are calculated as the primary outcomes. Subgroup
24 analyses will then be performed based on the characteristics of the interventions and
25 populations included in the studies examined.

26 **24 Ethics and dissemination:** This systematic review protocol is designed to provide updated
27 evidence regarding the effects of physical-activity interventions on the Latin American
28 population; such evidence may be useful for institutions responsible for the development of
29 public-health policies and for those tasked with implementing such interventions among
30 children and adolescents in Latin America.

31 The results should be disseminated through publication in a peer-reviewed journal. Since the
data used in systematic reviews of this type will be extracted exclusively from published
studies, approval from an ethics committee will not be required.

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Prospero registration number: CRD42019077702.

Keywords: physical activity, BMI, Latin America, children and adolescents.

For peer review only

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- In the protocol, two reviewers will independently perform the study selection, data extraction, and quality assessments.
- This review may produce the first Latin-America-based meta-analysis that provides scientific information regarding the effect of physical-activity interventions on BMI.
- Differences among the study designs, sample characteristics, types of physical-activity interventions, and poor methodological quality may restrict comparison of the selected studies and negatively affect the quality of the evidence obtained through associated systematic reviews and meta-analyses.

1 INTRODUCTION

2 In Latin America, levels of overweight and obesity among children and adolescents have
3 significantly increased in recent decades, and this issue has now become a major public-
4 health concern^{1,2}. A tool that facilitates a quick assessment of whether a person is overweight
5 or obese, as well as their level of general adiposity, is body mass index (BMI)³⁻⁵. As a result
6 of BMI-based assessments, it is now estimated that between 20% and 25% of the total Latin-
7 American population of children and adolescents are overweight or obese⁵. This is a worrying
8 situation, as studies have suggested that these conditions are maintained into and during
9 adulthood^{6,7}, and that they increase risk factors for cardiovascular disease, high blood
10 pressure, some types of cancer^{8,9}, and all causes of premature mortality¹⁰. In fact, BMI has
11 become such a reliable predictor of mortality¹¹ that in 2015 over 4.5 million deaths worldwide
12 were associated with high BMI values¹².

13 However, in children and adolescents BMI values should be used and interpreted cautiously,
14 as there is evidence that, although such values are useful for classifying adiposity¹³, they can
15 be a poor measure of changes in adiposity¹⁴. Moreover, childhood weight gain can generally
16 be attributed to fat-free mass rather than fat mass, and this means that BMI is unable to
17 precisely reflect changes that occur over time¹⁵, particularly in adolescent males and children
18 with low BMI¹⁶. Despite these problems, BMI will be used because it is one of the most
19 practical methods to evaluate the changes in adiposity in children and adolescents¹⁴.
20 Furthermore, it is widely used to measure the prevalence of overweight, obesity, and
21 underweight in childhood¹⁷.

22 Physical activity plays an important role in reducing BMI, along with lowering risk factors
23 for cardiovascular disease and improving cardiorespiratory fitness; this, in turn, leads to a
24 reduction in risk factors for overall health¹⁸⁻²¹. As a result of these benefits, researchers have
25 implemented physical-activity-focused interventions, nutritional-focussed interventions, or a
26 combination of both^{21,22}, and have used BMI to measure their effect. Underlining this
27 approach, previous systematic reviews performed in Latin America have shown that, while
28 few studies have implemented physical-activity interventions to treat overweight and obesity,
29 the implementation of physical-education policies and programmes is necessary to promote
30 children's and adolescents' health, because these interventions can effectively create positive
31 changes among this population^{1,23,24}, such as having a significant positive effect on BMI, as

1 well as some anthropometric variables in children and youth with overweight and obesity,
2 all through the promotion of physical activity and healthy diet. However, there have been no
3 previous Latin-America-based meta-analyses of the effects physical-activity interventions
4 have on BMI. Considering this, the present study aims to attract more attention to the
5 necessity of such interventions, and to generate evidence that can encourage changes in
6 public policy that can contribute to addressing this public-health crisis.

7

8 **OBJECTIVE**

9 The systematic review and meta-analysis will provide an up-to-date synthesis of the effects
10 of physical-activity interventions on BMI of Latin American children and adolescents aged
11 four to 18 years.

12

13 **METHODS AND ANALYSIS**

14 This systematic review and meta-analysis protocol is based on the Preferred Reporting Items
15 for Systematic Review and Meta-Analysis Protocols (PRISMA-P) statement²⁵ and the
16 Cochrane Collaboration Handbook²⁶. This protocol has previously been registered in
17 PROSPERO (registration number: CRD42019077702).

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19 **Inclusion/exclusion criteria for study selection**

20 For this protocol, in order to be included in associated systematic reviews studies must have
21 reported physical-activity interventions that meet the following criteria: 1) involving the
22 population of a Latin American country; 2) including participants aged 4–18 years; 3)
23 reporting any type of physical activity (physical endurance, sports, or alternative exercise
24 [e.g. games, dancing, optimised physical education classes], which may or may not have
25 included nutritional interventions); 4) being a randomised controlled trial (RCT), non-
26 randomised experimental study, or single-arm pre-post study; 5) reporting BMI both before
27 and after the intervention; 6) written in Spanish, English, or Portuguese; and 7) published
28 before October 2019.

29 Meanwhile, the following exclusion criteria will be set: 1) only including participants
30 younger than four or older than 18 years old; 2) providing self-reported data for BMI.

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3 1 Studies that feature different age ranges, but that nevertheless include population data for the
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5 2 ages of four to 18 years, will be included in the analysis.
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8 4 **Search strategy**

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10 5 Literature searches will be conducted through the MEDLINE (via PubMed), EMBASE,
11
12 6 Cochrane Library, Web of Science, and Scielo databases.

13 7 Meanwhile, searches for unpublished studies will be conducted using OPEN GRAY,
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15 8 ProQuest Dissertations & Thesis Global, Theseo, Networked Digital Library of Theses and
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17 9 Dissertations, and Google Scholar. Further, a search of ClinicalTrials.gov and EudraCT
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19 10 clinical trial records will also be conducted. The literature search will be complemented by
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21 11 screening references included in articles that are considered eligible for systematic review.
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23 12 Study records will then be managed using the Mendeley reference manager. The search
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25 13 strategy will include free text terms, combining Boolean operators from the relevant concepts
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27 14 presented in Table 1. Previous reviews and meta-analyses will also be scanned for additional
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29 15 references. Finally, reference lists of included papers will be hand-searched.
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Table 1. Search strategy for the MEDILINE database.

Search set	Medline	Search set	Medline
#1	physical activity [tw]	#18	paediatric obesity [mh]
#2	physical exercise [tw]	#19	14 OR 15 OR 16 OR 17 OR 18
#3	physical performance [tw]	#20	underweight [tw]
#4	exercise program* [tiab]	#21	normal weight [tw]
#5	physical fitness [mh]	#22	overweight [tw]
#6	exercise [mh]	#23	BMI [tiab]
#7	1 OR 2 OR 3 OR 4 OR 5 OR 6 OR	#24	obesity [tiab]
#8	training program* [tiab]	#25	body mass index [mh]
#9	prevention program* [tiab]	#26	20 OR 21 OR 22 OR 23 OR 24 OR 25
#10	intervention program* [tiab]	#27	studies [tiab]
#11	promotion [tw]	#28	randomised controlled trials [tiab]
#12	strategy [tw]	#29	RCT [tiab]
#13	8 OR 9 OR 10 OR 11 OR 12	#30	non-randomised experimental [tiab]
#14	childhood obesity [tiab]	#31	single-arm pre-post [tiab]
#15	obese children [tiab]	#32	27 OR 28 OR 29 OR 30 OR 31
#16	obesity prevention [tiab]	#33	7 AND 13 AND 19 AND 26 AND 32
#17	obesity review [tiab]		

mh: MeSH terms; tiab: title/abstract; tw: text word. * is used to search for or all terms that begin with a word (e.g. 'training program*' would return results such as 'training programs' and 'training programme')

Study selection

After excluding duplicated records, two researchers will independently evaluate the titles and abstracts of the retrieved articles in order to identify eligible studies for the systematic review. Abstracts that do not provide sufficient information regarding inclusion/exclusion criteria will then be evaluated through a full-text reading. Then, two researchers will examine the included and excluded studies to verify the reason for each decision. Inconsistencies between these two researchers regarding selection will be resolved by a third researcher, who will make the final decision, always based on the inclusion/exclusion criteria.

1 **Data extraction**

2 The process of identification, selection, and the inclusion/exclusion of articles will follow the
3 PRISMA²⁵ flow chart (shown in Figure 1). Once the included studies will be identified, the
4 information will be summarized in the ‘Table of Characteristics’ (Table 2), being the data
5 independently extracted by two reviewers. For the first five studies, the extraction process
6 will be performed by these two reviewers; this is performed to ensure that the data extraction
7 is consistent. In addition, the full texts of the identified studies will be examined to extract
8 the following data: (1) name of the first author; (2) year of publication; (3) country; (4) study
9 design; (5) participants’ ages; (6) number of participants; (7) population characteristics
10 (normal weight, overweight, obesity); (8) type of physical-activity intervention (leisure-time
11 physical activity, lifestyle physical activity, physical-activity programme, or physical activity
12 counselling); (9) characteristics of the physical activity in question (length of intervention,
13 intervention setting, number of sessions, duration of each session, type of physical
14 measurement applied [i.e. physical-activity scale, accelerometer, or pedometer]); (10) type
15 of nutritional intervention (food education, nutritional counselling, diet intervention); and
16 (11) characteristics of this nutritional intervention (length of intervention). When necessary,
17 the authors of potentially eligible studies will be contacted to obtain any missing data.

19 **Assessment of risk of bias in the included studies**

20 Two researchers will independently conduct a quality assessment, following the Cochrane
21 Collaboration Handbook recommendations²⁶. Any disagreements will be resolved through
22 discussion and, if a consensus cannot be reached, a third reviewer will intervene to resolve
23 the disagreement.

24 The methodological quality of the RCTs will be assessed using the Cochrane Collaboration’s
25 tool for assessing risk of bias²⁷. This tool evaluates risk of bias in terms of six domains:
26 selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias.
27 Meanwhile, the Quality Assessment Tool for Quantitative Studies²⁸ will be used to assess the
28 quality of pre-post studies and non-RCTs. This tool evaluates seven domains: selection bias,
29 study design, confounders, blinding, data-collection method, withdrawals, and drop-outs.

30 In both quality-assessment tools, each domain is considered ‘strong’, ‘moderate’, or ‘weak’
31 and, based on this, studies will be classified as having a low risk of bias (with no weak

1 ratings), a moderate risk of bias (with one weak rating), or a high risk of bias (with two or
2 more weak ratings). The agreement rate between reviewers will be reported by calculating
3 kappa statistics.

4 5 **Statistical analysis**

6 Researchers will summarize the main characteristics of each included study, including the
7 general profile of the study, the methods, the characteristics of the study participants, and the
8 results (as shown in Table 2). A meta-analysis will be performed on studies that showed BMI
9 pre-post interventions (separating studies that included physical-activity interventions from
10 those in which physical activity and nutritional health were combined). Studies providing
11 insufficient data to perform such analyses will be included in the systematic review but will
12 be omitted from the meta-analysis.

13 For studies for which a meta-analysis is appropriate, STATA V.14 software will be used to
14 combine the pooled mean differences with 95% confidence intervals. If there is no evidence
15 of heterogeneity, a fixed-effects model will be used; otherwise, a random-effects model will
16 be used. Study heterogeneity will be assessed using the I^2 statistic. Specifically, I^2 values will
17 be stratified as follows: ‘might not be important’ (0–40%); ‘may represent moderate
18 heterogeneity’ (30–60%); ‘may represent substantial heterogeneity’ (50–90%) and
19 ‘considerable heterogeneity’ (75–100%); the corresponding p -values will also be taken into
20 account²⁵.

21 For RCTs, data from intention-to-treat analyses will be considered, whenever available.
22 Specifically, two analyses will be performed: 1) mean difference in BMI pre-post physical-
23 activity-based intervention (with or without nutritional intervention) versus a control group,
24 and 2) mean difference in BMI pre-post physical-activity-based intervention (with or without
25 nutritional intervention), without a control group. Standardised mean differences will be
26 calculated for BMI levels. Additionally, publication bias will be assessed using a funnel plot,
27 following the method proposed by Egger²⁹.

28 **Subgroup analysis and meta-regression**

29 Next, subgroup analyses and meta-regression will be performed, considering the main factors
30 that may cause heterogeneity, such as gender; age (children aged 4–12 years and/or
31 adolescents aged 12–18 years); type of population (general population, indigenous

1 population, or a mix of both); country; type of study design; participant population
2 (underweight, normal weight, overweight, and/or obese); type of intervention (only physical
3 activity or combined with nutritional intervention); type of physical activity (endurance,
4 sports, games, dancing, and/or lifestyle physical-activity intervention); length of the
5 intervention (above or below 12 weeks); the setting in which the intervention occurs; and
6 duration of physical activity per week (above or below 150 minutes). Moreover, the
7 methodological quality of the selected studies will be considered for additional subgroup
8 analyses.

10 **Sensitivity analysis**

11 Finally, to assess the robustness of summary estimates and to detect whether any singular
12 study accounts for a large proportion of heterogeneity, sensitivity analyses will be performed,
13 removing the included studies one-by-one from the pooled analyses.

15 **ETHICS AND DISSEMINATION**

16 Given that, in this protocol, researchers will not collect primary data for their reviews, ethical
17 approval will not be required. Once the outcomes of the associated systematic reviews and
18 meta-analyses are disseminated in scientific publications, they may be shared through social
19 networks and presented in scientific conferences related to the subject; thus, the conclusions
20 may contribute to improving the health of the Latin American population.

1

Table 2. Characteristics of studies included in the systematic review and/or meta-analysis.

Population characteristics					Intervention characteristics				
Reference	Country	Study Design	Age distribution	Sample size	Type of population	Physical-activity intervention	Physical activity characteristics	Nutritional intervention	Nutritional characteristics
Author information and year of publication	Country	Design of the study	Age (years) of the participants range or means \pm SD	Number of participants	Population characteristics (low weight, normal weight, overweight, obese)	Type of physical-activity intervention (leisure-time physical activity, physical activity programme, and/or physical activity counselling)	Definition of physical-activity intervention (length of intervention, number of sessions, duration of each session, type of physical measurement [i.e. Physical activity scale, accelerometer or pedometer])	Type of nutritional intervention (food education, nutritional counselling, diet intervention)	Definition of nutritional intervention (length of intervention).

1 DISCUSSION

2 Studies conducted among populations in Europe and the United States have shown that
3 physical-activity interventions are associated with reductions of BMI, and are also an
4 effective method of decreasing the percentage of adipose tissue^{18,21}. However, there have
5 been no previous meta-analyses of the effects of these interventions in the context of Latin
6 America, which has geographical, socio-economic, and cultural characteristics that are
7 inherent to a developing region. Thus, a suitable systematic review and, if appropriate, a
8 meta-analysis, will enable us to gain an overview of the current Latin-America-based
9 literature regarding the study subject and, concurrently, could contribute to the efficient
10 development of discussions regarding the benefits of physical-activity interventions in the
11 region. To this end, the systematic review protocol provides a structure for the extraction and
12 synthesis of relevant information. This could provide us with evidence regarding the types
13 of interventions that are most beneficial for reducing BMI values, particularly in regard to
14 setting (school, health-care centre, or other), population type (as nutritional effects can vary
15 between population types), intensity, duration, and number of sessions.

16 Other issues that should be highlighted when performing systematic reviews based on this
17 protocol are whether the study design (RCTs, non-randomised experimental studies, and
18 single-arm pre-post studies) could affect the results (as has been reported in previous
19 studies^{30,31}), as well as whether physical-activity interventions supplemented by other health
20 interventions, such as nutritional interventions, can lead to a greater reduction in BMI. Such
21 considerations would allow us to measure the effect of physical-activity interventions in
22 regard to the prevention and treatment of overweight and obesity among Latin American
23 children and adolescents.

24 Among the potential limitations inherent to systematic reviews and meta-analyses, the
25 following (as elements of the studies examined) are particularly notable: publication bias,
26 information bias, poor statistical analyses, low methodological quality, and inappropriate
27 reporting of methods and findings. It is important to remember that, as a result of economic
28 inequalities, these biases may be greater in some countries, which can result in an uneven
29 advancement of scientific development across the region as a whole. Therefore, it is
30 important to properly synthesise the information available in examined manuscripts; thus,
31 this protocol represents a necessary text that consolidates the methodological structure

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3 1 needed to perform appropriate, evidence-based systematic reviews and meta-analyses
4 regarding the effects of physical-activity interventions on BMI of children and adolescents.
5 2
6 3 In conclusion, the systematic review and meta-analysis will provide an up-to-date synthesis
7 of the effects of physical-activity interventions on BMI of Latin American children and
8 4
9 adolescents aged four to 18 years. Such information may assist the roles of public-health
10 5
11 policy makers and those responsible for the implementation of such interventions.
12 6
13 7

8 **Patient and Public Involvement**

9 No patients or members of the public were involved in the design of this protocol.
10

11 **Contributors:**

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13 AG-C and IC-R designed the study: AG-C was the principal investigator. AG-C and IC-R
14 coordinated the study. AG-C and AD conducted the study. AG-C, CA-B, VM-V, and IC-R
15 provided statistical and epidemiological support. AG-C wrote the article with the support of
16 IC-R, CA-B, VM-V, and AD. All authors reviewed and approved the final version of the
17 manuscript.
18

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20 None declared.
21

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1 REFERENCES

- 1 1. Rivera JÁ, De Cossío TG, Pedraza LS, Aburto TC, Sánchez TG, Martorell R.
2 Childhood and adolescent overweight and obesity in Latin America: A systematic
3 review. *Lancet Diabetes Endocrinol* 2014;2(4):321-332.
- 4 2. Swinburn BA, Sacks G, Hall KD, McPherson K, Finegood DT, Moodie ML,
5 Gortmaker SL. The global obesity pandemic: Shaped by global drivers and local
6 environments. *Lancet* 2011;378(9793):804-814.
- 7 3. Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for
8 child overweight and obesity worldwide: International survey. *BMJ*
9 2000;320(7244):1240-1243.
- 10 4. Dietz WH, Robinson TN. Use of the body mass index (BMI) as a measure of
11 overweight in children and adolescents. *J Pediatr* 1998;132(2):191-193.
- 12 5. Poskitt EM. Body mass index and child obesity: Are we nearing a definition? *Acta*
13 *Paediatr* 2000;89(5):507-509.
- 14 6. Wang LY, Chyen D, Lee S, Lowry R. The association between body mass index in
15 adolescence and obesity in adulthood. *J Adolesc Heal* 2008;42(5):512-518.
- 16 7. Ward ZJ, Long MW, Resch SC, Giles CM, Cradock AL, Gortmaker SL. Simulation
17 of growth trajectories of childhood obesity into adulthood. *N Engl J Med*
18 2017;377(22):2145-2153.
- 19 8. Prospective Studies Collaboration, Whitlock G, Lewington S, et al. Body-mass index
20 and cause-specific mortality in 900,000 adults: Collaborative analyses of 57
21 prospective studies. *Lancet* 2009;373(9669):1083-1096.
- 22 9. Emerging Risk Factors Collaboration, Wormser D, Kaptoge S, et al. Separate and
23 combined associations of body-mass index and abdominal adiposity with
24 cardiovascular disease: Collaborative analysis of 58 prospective studies. *Lancet*
25 2011;377(9771):1085-1095.
- 26 10. Danaei G, Ding EL, Mozaffarian D, Taylor B, Rehm J, Murray CJ, Ezzati M. The
27 preventable causes of death in the United States: Comparative risk assessment of
28 dietary, lifestyle, and metabolic risk factors. *PLoS Med* 2009;6(4):e1000058.

- 1 11. Lee HJ, Choi EK, Lee SH, Kim YJ, Do Han K, Oh S. Risk of ischemic stroke in
2 metabolically healthy obesity: A nationwide population-based study. *PLoS One*
3 2018;13(3):1-14.
- 4 12. GBD 2016 Risk Factors Collaborators. Global, regional, and national comparative risk
5 assessment of 84 behavioural, environmental and occupational, and metabolic risks or
6 clusters of risks, 1990-2016: A systematic analysis for the Global Burden of Disease
7 Study 2016. *Lancet* 2017;390(10100):1345-1422.
- 8 13. Pietrobelli A, Faith MS, Allison DB, Gallagher D, Chiumello G, Heymsfield SB. Body
9 mass index as a measure of adiposity among children and adolescents: A validation
10 study. *J Pediatr* 1998;132(2):204-210.
- 11 14. Cole TJ, Faith MS, Pietrobelli A, Heo M. What is the best measure of adiposity change
12 in growing children: BMI, BMI %, BMI z-score or BMI centile? *Eur J Clin Nutr*
13 2005;59(3):419-425.
- 14 15. Maynard LM, Wisemandle W, Roche AF, Chumlea WC, Guo SS, Siervogel RM.
15 Childhood body composition in relation to body mass index. *Pediatrics*
16 2001;107(2):344-350.
- 17 16. Demerath EW, Schubert CM, Maynard LM, et al. Do changes in body mass index
18 percentile reflect changes in body composition in children? Data from the Fels
19 Longitudinal Study. *Pediatrics* 2006;117(3):e487-e495.
- 20 17. Cole TJ, Lobstein T. Extended international (IOTF) body mass index cut-offs for
21 thinness, overweight and obesity. *Pediatr Obes* 2012;7(4):284-94.
- 22 18. Kelley GA, Kelley KS. Effects of exercise in the treatment of overweight and obese
23 children and adolescents: A systematic review of meta-analyses. *J Obes*
24 2013;2013:783103.
- 25 19. Jakicic JM, Davis KK. Obesity and physical activity. *Psychiatr Clin N Am*
26 2011;34(4):829-840.
- 27 20. Zolotarjova J, ten Velde G, Vreugdenhil ACE. Effects of multidisciplinary
28 interventions on weight loss and health outcomes in children and adolescents with
29 morbid obesity. *Obes Rev* 2018;19(7):931-946.

- 1 21. Kelley GA, Kelley KS, Pate RR. Exercise and BMI in overweight and obese children
2 and adolescents: A systematic review and trial sequential meta-analysis. *BioMed Res*
3 *Int* 2015;2015:704539.
- 4 22. Hills AP, Andersen LB, Byrne NM. Physical activity and obesity in children. *Br J*
5 *Sports Med* 2011;45(11):866-870.
- 6 23. Legetic BD, Hoehner CM, Brownson RC, et al. Physical activity interventions in Latin
7 America. *Am J Prev Med* 2008;34(3):224-233.e4.
- 8 24. Nagle BJ, Holub CK, Barquera S, et al. Interventions for the treatment of obesity
9 among children and adolescents in Latin America: A systematic review. *Salud Publ*
10 *Mex* 2013;55:434-440.
- 11 25. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review
12 and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev* 2015;4(1):1.
- 13 26. Higgins JPT, Green S, editors. Cochrane handbook for systematic reviews of
14 interventions. Version 5.1.0 [updated March 2011]. The Cochrane Collaboration;
15 2011 [cited 2019 Aug 27]. Available from:www.handbook.cochrane.org.
- 16 27. Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for
17 assessing risk of bias in randomised trials. *BMJ* 2011;343(7829):1-9.
- 18 28. National Collaborating Centre for Methods and Tools. Quality assessment tool for
19 quantitative studies: Hamilton ON: McMaster University; 2008.
- 20 29. Sterne JAC, Egger M, Smith GD. Systematic reviews in health care: Investigating and
21 dealing with publication and other biases in meta-analysis. *BMJ* 2001;323(7304):101-
22 105.
- 23 30. Brown T, Summerbell C. Systematic review of school-based interventions that focus
24 on changing dietary intake and physical activity levels to prevent childhood obesity:
25 An update to the obesity guidance produced by the National Institute for Health and
26 Clinical Excellence. *Obes Rev* 2009;10(1):110-141.
- 27 31. Katz DL. School-based interventions for health promotion and weight control: Not
28 just waiting on the world to change. *Annu Rev Public Health* 2009;30:253-272.

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3 **1 TABLE LEGENDS.**
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5 **2 Table 1.** Search strategy for the MEDLINE database.
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7 **3 Table 2.** Characteristics of studies included in the systematic review and/or meta-analysis.
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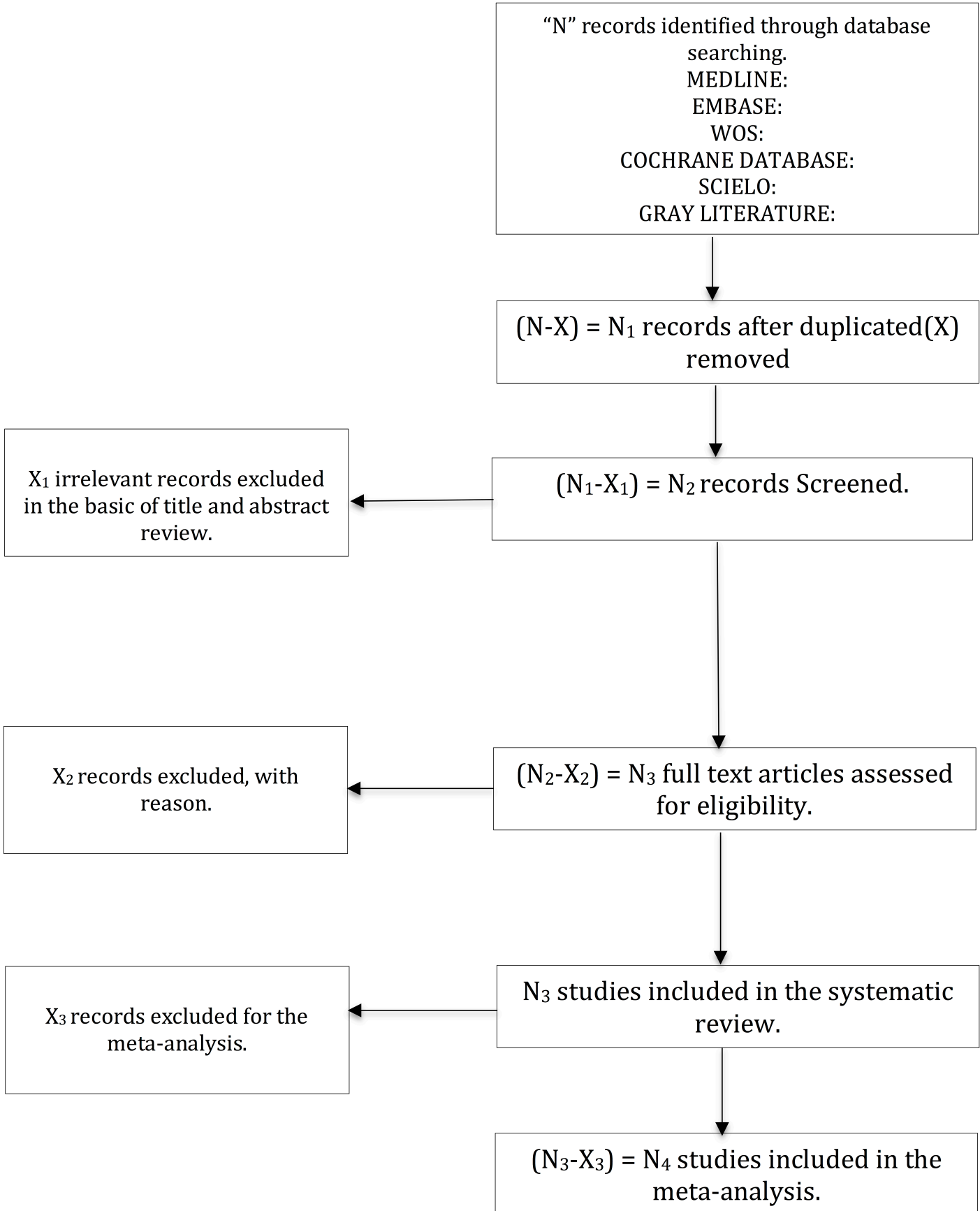
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12 **5 FIGURE LEGENDS.**
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14 **6 FIGURE 1.** PRISMA flow diagram for identifying, screening, and determining the eligibility
15 of and whether to include studies.
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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification: p. 1	1a	Identify the report as a protocol of a systematic review
Update: NA.	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number
Authors:		
Contact: pp. 1, 10	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author
Contributions: p.10	3b	Describe contributions of protocol authors and identify the guarantor of the review
Amendments: NA	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments
Support:		
Sources: p. 10	5a	Indicate sources of financial or other support for the review
Sponsor: p. 10	5b	Provide name for the review funder and/or sponsor
Role of sponsor or funder: p.10	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
INTRODUCTION		
Rationale: p. 4, 5	6	Describe the rationale for the review in the context of what is already known
Objectives: p. 5	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)
METHODS		
Eligibility criteria: p. 5	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review
Information sources p. 5	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage
Search strategy: pp. 5, 6	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
Study records:		

Data management: pp. 6, 7	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review
Selection process: pp. 6, 7	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process: pp.6,7	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators
Data items: p. 7	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications
Outcomes and prioritization: p. 7	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale
Risk of bias in individual studies: p.7	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis
Data synthesis: pp. 7, 8, 9	15a	Describe criteria under which study data will be quantitatively synthesised
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned
Meta-bias(es): NA	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
Confidence in cumulative evidence: NA	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

BMJ Open

Effects of physical-activity interventions on the body mass index of children and adolescents in Latin America: A protocol for a systematic review and meta-analysis

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Primary Subject Heading:	Public health
Secondary Subject Heading:	Sports and exercise medicine
Keywords:	BMI, Latin America, Children, Adolescents, Physical activity

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Manuscripts

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6 3 **Effects of physical-activity interventions on the body mass index of children and**
7 **adolescents in Latin America: A protocol for a systematic review and meta-analysis**
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11 6 **Authors and affiliations:**

12 7 Andrés Godoy-Cumillaf^{1,3}, Armando Díaz², Celia Álvarez-Bueno^{3,4*}; Vicente Martínez-
13 8 Vizcaíno³, Iván Cavero-Redondo^{3,4}.
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15 9

16 10 ¹Universidad Autónoma de Chile, Chile. Facultad de Educación, Pedagogía en Educación
17 11 Física, Temuco.

18 12 ²Secretaria de Esportes Taubaté, São Paulo, Brazil.

19 13 ³Universidad de Castilla-La Mancha, Health and Social Research Centre, Cuenca, Spain.

20 14 ⁴Universidad Politécnica y Artística del Paraguay, Asunción, Paraguay.
21
22 15

23 16 ***Correspondence:**

24 17 Celia Álvarez Bueno

25 18 C/ Santa Teresa Jornet, s/n, cp: 16071, Cuenca, Spain

26 19 Telephone: +34 969170091. Ext. 4659

27 20 E-mail: celia.alvarezbueno@uclm.es
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3 **1 ABSTRACT.**

4 **2 Introduction:** In Latin America, the number of children and adolescents who are overweight
5 or obese has significantly increased in recent decades, and this situation has become a major
6 public-health concern. To address this problem, several intervention programmes, based on
7 factors such as physical activity and nutrition, have been implemented, and body mass index
8 (BMI) has been widely used as a means of measuring the impact of such interventions.
9 Although some Latin-America-based systematic reviews have been performed, there have
10 been no previous meta-analyses of findings regarding the effect of physical-activity
11 interventions on BMI. Thus, the objective of the systematic review and meta-analysis will be
12 to provide an up-to-date synthesis of the effects of physical-activity interventions on BMI of
13 Latin American children and adolescents aged four to 18 years.

14 **12 Methods and analysis:** This systematic review and meta-analysis protocol is based on the
15 Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-
16 P) statement. The literature search will involve MEDLINE, EMBASE, Cochrane Library,
17 Web of Science and Scielo for articles published up to July 2019. This search will include
18 randomised controlled trials (RCTs), non-randomised experimental studies, and single-arm
19 pre-post studies. Further, the Cochrane Collaboration's tool for RCT studies and the Quality
20 Assessment Tool for Quantitative Studies for non-randomised experimental and single-arm
21 pre-post studies will be used to assess the risk of bias among the studies included in the
22 systematic review. For the meta-analysis, the statistical program STATA V.14 will be used,
23 and standardised mean differences are calculated as the primary outcomes. Subgroup
24 analyses will then be performed based on the characteristics of the interventions and
25 populations included in the studies examined.

26 **24 Ethics and dissemination:** This systematic review protocol is designed to provide updated
27 evidence regarding the effects of physical-activity interventions on the Latin American
28 population; such evidence may be useful for institutions responsible for the development of
29 public-health policies and for those tasked with implementing such interventions among
30 children and adolescents in Latin America.

31 The results should be disseminated through publication in a peer-reviewed journal. Since the
data used in systematic reviews of this type will be extracted exclusively from published
studies, approval from an ethics committee will not be required.

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Prospero registration number: CRD42019077702.

Keywords: physical activity, BMI, Latin America, children and adolescents.

For peer review only

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- In the protocol, two reviewers will independently perform the study selection, data extraction, and quality assessments.
- This review may produce the first Latin-America-based meta-analysis that provides scientific information regarding the effect of physical-activity interventions on BMI.
- Differences among the study designs, sample characteristics, types of physical-activity interventions, and poor methodological quality may restrict comparison of the selected studies and negatively affect the quality of the evidence obtained through associated systematic reviews and meta-analyses.

1 INTRODUCTION

2 In Latin America, levels of overweight and obesity among children and adolescents have
3 significantly increased in recent decades, and this issue has now become a major public-
4 health concern^{1,2}. A tool that facilitates a quick assessment of whether a person is overweight
5 or obese, as well as their level of general adiposity, is body mass index (BMI)³⁻⁵. As a result
6 of BMI-based assessments, it is now estimated that between 20% and 25% of the total Latin-
7 American population of children and adolescents are overweight or obese⁵. This is a worrying
8 situation, as studies have suggested that these conditions are maintained into and during
9 adulthood^{6,7}, and that they increase risk factors for cardiovascular disease, high blood
10 pressure, some types of cancer^{8,9}, and all causes of premature mortality¹⁰. In fact, BMI has
11 become such a reliable predictor of mortality¹¹ that in 2015 over 4.5 million deaths worldwide
12 were associated with high BMI values¹².

13 However, in children and adolescents BMI values should be used and interpreted cautiously,
14 as there is evidence that, although such values are useful for classifying adiposity¹³, they can
15 be a poor measure of changes in adiposity¹⁴. Moreover, childhood weight gain can generally
16 be attributed to fat-free mass rather than fat mass, and this means that BMI is unable to
17 precisely reflect changes that occur over time¹⁵, particularly in adolescent males and children
18 with low BMI¹⁶. Despite these problems, BMI will be used because it is one of the most
19 practical methods to evaluate the changes in adiposity in children and adolescents¹⁴.
20 Furthermore, it is widely used to measure the prevalence of overweight, obesity, and
21 underweight in childhood¹⁷.

22 Physical activity plays an important role in reducing BMI, along with lowering risk factors
23 for cardiovascular disease and improving cardiorespiratory fitness; this, in turn, leads to a
24 reduction in risk factors for overall health¹⁸⁻²¹. As a result of these benefits, researchers have
25 implemented physical-activity-focused interventions, nutritional-focussed interventions, or a
26 combination of both^{21,22}, and have used BMI to measure their effect. Underlining this
27 approach, previous systematic reviews performed in Latin America have shown that, while
28 few studies have implemented physical-activity interventions to treat overweight and obesity,
29 the implementation of physical-education policies and programmes is necessary to promote
30 children's and adolescents' health, because these interventions can effectively create positive
31 changes among this population^{1,23,24}, such as having a significant positive effect on BMI, as

1 well as some anthropometric variables in children and youth with overweight and obesity,
2 all through the promotion of physical activity and healthy diet. However, there have been no
3 previous Latin-America-based meta-analyses of the effects physical-activity interventions
4 have on BMI. Considering this, the present study aims to attract more attention to the
5 necessity of such interventions, and to generate evidence that can encourage changes in
6 public policy that can contribute to addressing this public-health crisis.

7

8 **OBJECTIVE**

9 The systematic review and meta-analysis will provide an up-to-date synthesis of the effects
10 of physical-activity interventions on BMI of Latin American children and adolescents aged
11 four to 18 years.

12

13 **METHODS AND ANALYSIS**

14 This systematic review and meta-analysis protocol is based on the Preferred Reporting Items
15 for Systematic Review and Meta-Analysis Protocols (PRISMA-P) statement²⁵ and the
16 Cochrane Collaboration Handbook²⁶. This protocol has previously been registered in
17 PROSPERO (registration number: CRD42019077702).

18

19 **Inclusion/exclusion criteria for study selection**

20 For this protocol, in order to be included in associated systematic reviews studies must have
21 reported physical-activity interventions that meet the following criteria: 1) involving the
22 population of a Latin American country; 2) including participants aged 4–18 years; 3)
23 reporting any type of physical activity (physical endurance, sports, or alternative exercise
24 [e.g. games, dancing, optimised physical education classes], which may or may not have
25 included nutritional interventions); 4) being a randomised controlled trial (RCT), non-
26 randomised experimental study, or single-arm pre-post study; 5) reporting BMI both before
27 and after the intervention; 6) written in Spanish, English, or Portuguese; and 7) published
28 before October 2019.

29 Meanwhile, the following exclusion criteria will be set: 1) only including participants
30 younger than four or older than 18 years old; 2) providing self-reported data for BMI.

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3 1 Studies that feature different age ranges, but that nevertheless include population data for the
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5 2 ages of four to 18 years, will be included in the analysis.
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8 4 **Search strategy**

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10 5 Literature searches will be conducted through the MEDLINE (via PubMed), EMBASE,
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12 6 Cochrane Library, Web of Science, and Scielo databases.

13 7 Meanwhile, searches for unpublished studies will be conducted using OPEN GRAY,
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15 8 ProQuest Dissertations & Thesis Global, Theseo, Networked Digital Library of Theses and
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17 9 Dissertations, and Google Scholar. Further, a search of ClinicalTrials.gov and EudraCT
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19 10 clinical trial records will also be conducted. The literature search will be complemented by
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21 11 screening references included in articles that are considered eligible for systematic review.
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23 12 Study records will then be managed using the Mendeley reference manager. The search
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25 13 strategy will include free text terms, combining Boolean operators from the relevant concepts
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27 14 presented in Table 1. Previous reviews and meta-analyses will also be scanned for additional
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29 15 references. Finally, reference lists of included papers will be hand-searched.
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Table 1. Search strategy for the MEDILINE database.

Search set	Medline	Search set	Medline
#1	physical activity [tw]	#18	paediatric obesity [mh]
#2	physical exercise [tw]	#19	14 OR 15 OR 16 OR 17 OR 18
#3	physical performance [tw]	#20	underweight [tw]
#4	exercise program* [tiab]	#21	normal weight [tw]
#5	physical fitness [mh]	#22	overweight [tw]
#6	exercise [mh]	#23	BMI [tiab]
#7	1 OR 2 OR 3 OR 4 OR 5 OR 6 OR	#24	obesity [tiab]
#8	training program* [tiab]	#25	body mass index [mh]
#9	prevention program* [tiab]	#26	20 OR 21 OR 22 OR 23 OR 24 OR 25
#10	intervention program* [tiab]	#27	studies [tiab]
#11	promotion [tw]	#28	randomised controlled trials [tiab]
#12	strategy [tw]	#29	RCT [tiab]
#13	8 OR 9 OR 10 OR 11 OR 12	#30	non-randomised experimental [tiab]
#14	childhood obesity [tiab]	#31	single-arm pre-post [tiab]
#15	obese children [tiab]	#32	27 OR 28 OR 29 OR 30 OR 31
#16	obesity prevention [tiab]	#33	7 AND 13 AND 19 AND 26 AND 32
#17	obesity review [tiab]		

mh: MeSH terms; tiab: title/abstract; tw: text word. * is used to search for or all terms that begin with a word (e.g. 'training program*' would return results such as 'training programs' and 'training programme')

Study selection

After excluding duplicated records, two researchers will independently evaluate the titles and abstracts of the retrieved articles in order to identify eligible studies for the systematic review. Abstracts that meet inclusion criteria or that do not provide sufficient information regarding the inclusion/exclusion criteria will then be evaluated through a full-text reading. Then, two researchers will examine the included and excluded studies to verify the reason for each decision. Inconsistencies between these two researchers regarding selection will be resolved by a third researcher, who will make the final decision, always based on the inclusion/exclusion criteria.

1 **Data extraction**

2 The process of identification, selection, and the inclusion/exclusion of articles will follow the
3 PRISMA²⁵ flow chart (shown in Figure 1). The full texts of the identified studies will be
4 examined to extract the following data: (1) name of the first author; (2) year of publication;
5 (3) country; (4) study design; (5) participants' ages; (6) number of participants; (7) population
6 characteristics (normal weight, overweight, obesity); (8) type of physical-activity
7 intervention (leisure-time physical activity, lifestyle physical activity, physical-activity
8 programme, or physical activity counselling); (9) characteristics of the physical activity in
9 question (length of intervention, intervention setting, number of sessions, duration of each
10 session, type of physical measurement applied [i.e. physical-activity scale, accelerometer, or
11 pedometer]); (10) type of nutritional intervention (food education, nutritional counselling,
12 diet intervention); and (11) characteristics of this nutritional intervention (length of
13 intervention). When necessary, the authors of potentially eligible studies will be contacted to
14 obtain any missing data. The information will be summarized in the 'Table of Characteristics'
15 (Table 2), being the data independently extracted by two reviewers. For the first five studies,
16 the extraction process will be performed by these two reviewers; this is performed to ensure
17 that the data extraction is consistent.

19 **Assessment of risk of bias in the included studies**

20 Two researchers will independently conduct a quality assessment, following the Cochrane
21 Collaboration Handbook recommendations²⁶. Any disagreements will be resolved through
22 discussion and, if a consensus cannot be reached, a third reviewer will intervene to resolve
23 the disagreement.

24 The methodological quality of the RCTs will be assessed using the Cochrane Collaboration's
25 tool for assessing risk of bias²⁷. This tool evaluates risk of bias in terms of six domains:
26 selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias.
27 Meanwhile, the Quality Assessment Tool for Quantitative Studies²⁸ will be used to assess the
28 quality of pre-post studies and non-RCTs. This tool evaluates seven domains: selection bias,
29 study design, confounders, blinding, data-collection method, withdrawals, and drop-outs.

30 In both quality-assessment tools, each domain is considered 'strong', 'moderate', or 'weak'
31 and, based on this, studies will be classified as having a low risk of bias (with no weak

1 ratings), a moderate risk of bias (with one weak rating), or a high risk of bias (with two or
2 more weak ratings). The agreement rate between reviewers will be reported by calculating
3 kappa statistics.

4 5 **Statistical analysis**

6 Researchers will summarize the main characteristics of each included study, including the
7 general profile of the study, the methods, the characteristics of the study participants, and the
8 results (as shown in Table 2). A meta-analysis will be performed on studies that showed BMI
9 pre-post interventions (separating studies that included physical-activity interventions from
10 those in which physical activity and nutritional health were combined). Studies providing
11 insufficient data to perform such analyses will be included in the systematic review but will
12 be omitted from the meta-analysis.

13 For studies for which a meta-analysis is appropriate, STATA V.14 software will be used to
14 combine the pooled mean differences with 95% confidence intervals. If there is no evidence
15 of heterogeneity, a fixed-effects model will be used; otherwise, a random-effects model will
16 be used. Study heterogeneity will be assessed using the I^2 statistic. Specifically, I^2 values will
17 be stratified as follows: ‘might not be important’ (0–40%); ‘may represent moderate
18 heterogeneity’ (30–60%); ‘may represent substantial heterogeneity’ (50–90%) and
19 ‘considerable heterogeneity’ (75–100%); the corresponding p -values will also be taken into
20 account²⁵.

21 For RCTs, data from intention-to-treat analyses will be considered, whenever available.
22 Specifically, two analyses will be performed: 1) mean difference in BMI pre-post physical-
23 activity-based intervention (with or without nutritional intervention) versus a control group,
24 and 2) mean difference in BMI pre-post physical-activity-based intervention (with or without
25 nutritional intervention), without a control group. Standardised mean differences will be
26 calculated for BMI levels. Additionally, publication bias will be assessed using a funnel plot,
27 following the method proposed by Egger²⁹.

28 **Subgroup analysis and meta-regression**

29 Next, subgroup analyses and meta-regression will be performed, considering the main factors
30 that may cause heterogeneity, such as gender; age (children aged 4–12 years and/or
31 adolescents aged 12–18 years); type of population (general population, indigenous

1 population, or a mix of both); country; type of study design; participant population
2 (underweight, normal weight, overweight, and/or obese); type of intervention (only physical
3 activity or combined with nutritional intervention); type of physical activity (endurance,
4 sports, games, dancing, and/or lifestyle physical-activity intervention); length of the
5 intervention (above or below 12 weeks); the setting in which the intervention occurs; and
6 duration of physical activity per week (above or below 150 minutes). Moreover, the
7 methodological quality of the selected studies will be considered for additional subgroup
8 analyses.

10 **Sensitivity analysis**

11 Finally, to assess the robustness of summary estimates and to detect whether any singular
12 study accounts for a large proportion of heterogeneity, sensitivity analyses will be performed,
13 removing the included studies one-by-one from the pooled analyses.

15 **ETHICS AND DISSEMINATION**

16 Given that, in this protocol, researchers will not collect primary data for their reviews, ethical
17 approval will not be required. Once the outcomes of the associated systematic reviews and
18 meta-analyses are disseminated in scientific publications, they may be shared through social
19 networks and presented in scientific conferences related to the subject; thus, the conclusions
20 may contribute to improving the health of the Latin American population.

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Table 2. Characteristics of studies included in the systematic review and/or meta-analysis.

Population characteristics					Intervention characteristics				
Reference	Country	Study Design	Age distribution	Sample size	Type of population	Physical-activity intervention	Physical activity characteristics	Nutritional intervention	Nutritional characteristics
Author information and year of publication	Country	Design of the study	Age (years) of the participants range or means \pm SD	Number of participants	Population characteristics (low weight, normal weight, overweight, obese)	Type of physical-activity intervention (leisure-time physical activity, physical activity programme, and/or physical activity counselling)	Definition of physical-activity intervention (length of intervention, number of sessions, duration of each session, type of physical measurement [i.e. Physical activity scale, accelerometer or pedometer])	Type of nutritional intervention (food education, nutritional counselling, diet intervention)	Definition of nutritional intervention (length of intervention).

1 DISCUSSION

2 Studies conducted among populations in Europe and the United States have shown that
3 physical-activity interventions are associated with reductions of BMI, and are also an
4 effective method of decreasing the percentage of adipose tissue^{18,21}. However, there have
5 been no previous meta-analyses of the effects of these interventions in the context of Latin
6 America, which has geographical, socio-economic, and cultural characteristics that are
7 inherent to a developing region. Thus, a suitable systematic review and, if appropriate, a
8 meta-analysis, will enable us to gain an overview of the current Latin-America-based
9 literature regarding the study subject and, concurrently, could contribute to the efficient
10 development of discussions regarding the benefits of physical-activity interventions in the
11 region. To this end, the systematic review protocol provides a structure for the extraction and
12 synthesis of relevant information. This could provide us with evidence regarding the types
13 of interventions that are most beneficial for reducing BMI values, particularly in regard to
14 setting (school, health-care centre, or other), population type (as nutritional effects can vary
15 between population types), intensity, duration, and number of sessions.

16 Other issues that should be highlighted when performing systematic reviews based on this
17 protocol are whether the study design (RCTs, non-randomised experimental studies, and
18 single-arm pre-post studies) could affect the results (as has been reported in previous
19 studies^{30,31}), as well as whether physical-activity interventions supplemented by other health
20 interventions, such as nutritional interventions, can lead to a greater reduction in BMI. Such
21 considerations would allow us to measure the effect of physical-activity interventions in
22 regard to the prevention and treatment of overweight and obesity among Latin American
23 children and adolescents.

24 Among the potential limitations inherent to systematic reviews and meta-analyses, the
25 following (as elements of the studies examined) are particularly notable: publication bias,
26 information bias, poor statistical analyses, low methodological quality, and inappropriate
27 reporting of methods and findings. It is important to remember that, as a result of economic
28 inequalities, these biases may be greater in some countries, which can result in an uneven
29 advancement of scientific development across the region as a whole. Therefore, it is
30 important to properly synthesise the information available in examined manuscripts; thus,
31 this protocol represents a necessary text that consolidates the methodological structure

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3 1 needed to perform appropriate, evidence-based systematic reviews and meta-analyses
4 regarding the effects of physical-activity interventions on BMI of children and adolescents.
5 2
6 3 In conclusion, the systematic review and meta-analysis will provide an up-to-date synthesis
7 of the effects of physical-activity interventions on BMI of Latin American children and
8 4
9 adolescents aged four to 18 years. Such information may assist the roles of public-health
10 5
11 policy makers and those responsible for the implementation of such interventions.
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8 **Patient and Public Involvement**

9 No patients or members of the public were involved in the design of this protocol.
10

11 **Contributors:**

12
13 AG-C and IC-R designed the study: AG-C was the principal investigator. AG-C and IC-R
14 coordinated the study. AG-C and AD conducted the study. AG-C, CA-B, VM-V, and IC-R
15 provided statistical and epidemiological support. AG-C wrote the article with the support of
16 IC-R, CA-B, VM-V, and AD. All authors reviewed and approved the final version of the
17 manuscript.
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20 None declared.
21

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24 or not-for-profit sectors.
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3 **REFERENCES**
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1. Rivera JÁ, De Cossío TG, Pedraza LS, Aburto TC, Sánchez TG, Martorell R. Childhood and adolescent overweight and obesity in Latin America: A systematic review. *Lancet Diabetes Endocrinol* 2014;2(4):321-332.
2. Swinburn BA, Sacks G, Hall KD, McPherson K, Finegood DT, Moodie ML, Gortmaker SL. The global obesity pandemic: Shaped by global drivers and local environments. *Lancet* 2011;378(9793):804-814.
3. Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for child overweight and obesity worldwide: International survey. *BMJ* 2000;320(7244):1240-1243.
4. Dietz WH, Robinson TN. Use of the body mass index (BMI) as a measure of overweight in children and adolescents. *J Pediatr* 1998;132(2):191-193.
5. Poskitt EM. Body mass index and child obesity: Are we nearing a definition? *Acta Paediatr* 2000;89(5):507-509.
6. Wang LY, Chyen D, Lee S, Lowry R. The association between body mass index in adolescence and obesity in adulthood. *J Adolesc Heal* 2008;42(5):512-518.
7. Ward ZJ, Long MW, Resch SC, Giles CM, Cradock AL, Gortmaker SL. Simulation of growth trajectories of childhood obesity into adulthood. *N Engl J Med* 2017;377(22):2145-2153.
8. Prospective Studies Collaboration, Whitlock G, Lewington S, et al. Body-mass index and cause-specific mortality in 900,000 adults: Collaborative analyses of 57 prospective studies. *Lancet* 2009;373(9669):1083-1096.
9. Emerging Risk Factors Collaboration, Wormser D, Kaptoge S, et al. Separate and combined associations of body-mass index and abdominal adiposity with cardiovascular disease: Collaborative analysis of 58 prospective studies. *Lancet* 2011;377(9771):1085-1095.
10. Danaei G, Ding EL, Mozaffarian D, Taylor B, Rehm J, Murray CJ, Ezzati M. The preventable causes of death in the United States: Comparative risk assessment of dietary, lifestyle, and metabolic risk factors. *PLoS Med* 2009;6(4):e1000058.

- 1 11. Lee HJ, Choi EK, Lee SH, Kim YJ, Do Han K, Oh S. Risk of ischemic stroke in
2 metabolically healthy obesity: A nationwide population-based study. *PLoS One*
3 2018;13(3):1-14.
- 4 12. GBD 2016 Risk Factors Collaborators. Global, regional, and national comparative risk
5 assessment of 84 behavioural, environmental and occupational, and metabolic risks or
6 clusters of risks, 1990-2016: A systematic analysis for the Global Burden of Disease
7 Study 2016. *Lancet* 2017;390(10100):1345-1422.
- 8 13. Pietrobelli A, Faith MS, Allison DB, Gallagher D, Chiumello G, Heymsfield SB. Body
9 mass index as a measure of adiposity among children and adolescents: A validation
10 study. *J Pediatr* 1998;132(2):204-210.
- 11 14. Cole TJ, Faith MS, Pietrobelli A, Heo M. What is the best measure of adiposity change
12 in growing children: BMI, BMI %, BMI z-score or BMI centile? *Eur J Clin Nutr*
13 2005;59(3):419-425.
- 14 15. Maynard LM, Wisemandle W, Roche AF, Chumlea WC, Guo SS, Siervogel RM.
15 Childhood body composition in relation to body mass index. *Pediatrics*
16 2001;107(2):344-350.
- 17 16. Demerath EW, Schubert CM, Maynard LM, et al. Do changes in body mass index
18 percentile reflect changes in body composition in children? Data from the Fels
19 Longitudinal Study. *Pediatrics* 2006;117(3):e487-e495.
- 20 17. Cole TJ, Lobstein T. Extended international (IOTF) body mass index cut-offs for
21 thinness, overweight and obesity. *Pediatr Obes* 2012;7(4):284-94.
- 22 18. Kelley GA, Kelley KS. Effects of exercise in the treatment of overweight and obese
23 children and adolescents: A systematic review of meta-analyses. *J Obes*
24 2013;2013:783103.
- 25 19. Jakicic JM, Davis KK. Obesity and physical activity. *Psychiatr Clin N Am*
26 2011;34(4):829-840.
- 27 20. Zolotarjova J, ten Velde G, Vreugdenhil ACE. Effects of multidisciplinary
28 interventions on weight loss and health outcomes in children and adolescents with
29 morbid obesity. *Obes Rev* 2018;19(7):931-946.

- 1
2
3 1 21. Kelley GA, Kelley KS, Pate RR. Exercise and BMI in overweight and obese children
4 and adolescents: A systematic review and trial sequential meta-analysis. *BioMed Res*
5 2 *Int* 2015;2015:704539.
6 3
7 4 22. Hills AP, Andersen LB, Byrne NM. Physical activity and obesity in children. *Br J*
8 4 *Sports Med* 2011;45(11):866-870.
9 5
10 6 23. Legetic BD, Hoehner CM, Brownson RC, et al. Physical activity interventions in Latin
11 6 *America. Am J Prev Med* 2008;34(3):224-233.e4.
12 7
13 8 24. Nagle BJ, Holub CK, Barquera S, et al. Interventions for the treatment of obesity
14 8 among children and adolescents in Latin America: A systematic review. *Salud Publ*
15 9 *Mex* 2013;55:434-440.
16 10
17 11 25. Moher D, Shamseer L, Clarke M, et al. Preferred reporting items for systematic review
18 11 and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev* 2015;4(1):1.
19 12
20 13 26. Higgins JPT, Green S, editors. Cochrane handbook for systematic reviews of
21 13 interventions. Version 5.1.0 [updated March 2011]. The Cochrane Collaboration;
22 14 2011 [cited 2019 Aug 27]. Available from:www.handbook.cochrane.org.
23 15
24 16 27. Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for
25 16 assessing risk of bias in randomised trials. *BMJ* 2011;343(7829):1-9.
26 17
27 18 28. National Collaborating Centre for Methods and Tools. Quality assessment tool for
28 18 quantitative studies: Hamilton ON: McMaster University; 2008.
29 19
30 20 29. Sterne JAC, Egger M, Smith GD. Systematic reviews in health care: Investigating and
31 20 dealing with publication and other biases in meta-analysis. *BMJ* 2001;323(7304):101-
32 21 105.
33 22
34 23 30. Brown T, Summerbell C. Systematic review of school-based interventions that focus
35 23 on changing dietary intake and physical activity levels to prevent childhood obesity:
36 24 An update to the obesity guidance produced by the National Institute for Health and
37 25 Clinical Excellence. *Obes Rev* 2009;10(1):110-141.
38 26
39 27 31. Katz DL. School-based interventions for health promotion and weight control: Not
40 27 just waiting on the world to change. *Annu Rev Public Health* 2009;30:253-272.
41 28
42 29
43 30
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3 **1 TABLE LEGENDS.**
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5 **2 Table 1.** Search strategy for the MEDLINE database.
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7 **3 Table 2.** Characteristics of studies included in the systematic review and/or meta-analysis.
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13 **5 FIGURE LEGENDS.**

14 **6 FIGURE 1.** PRISMA flow diagram for identifying, screening, and determining the eligibility
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17 of and whether to include studies.
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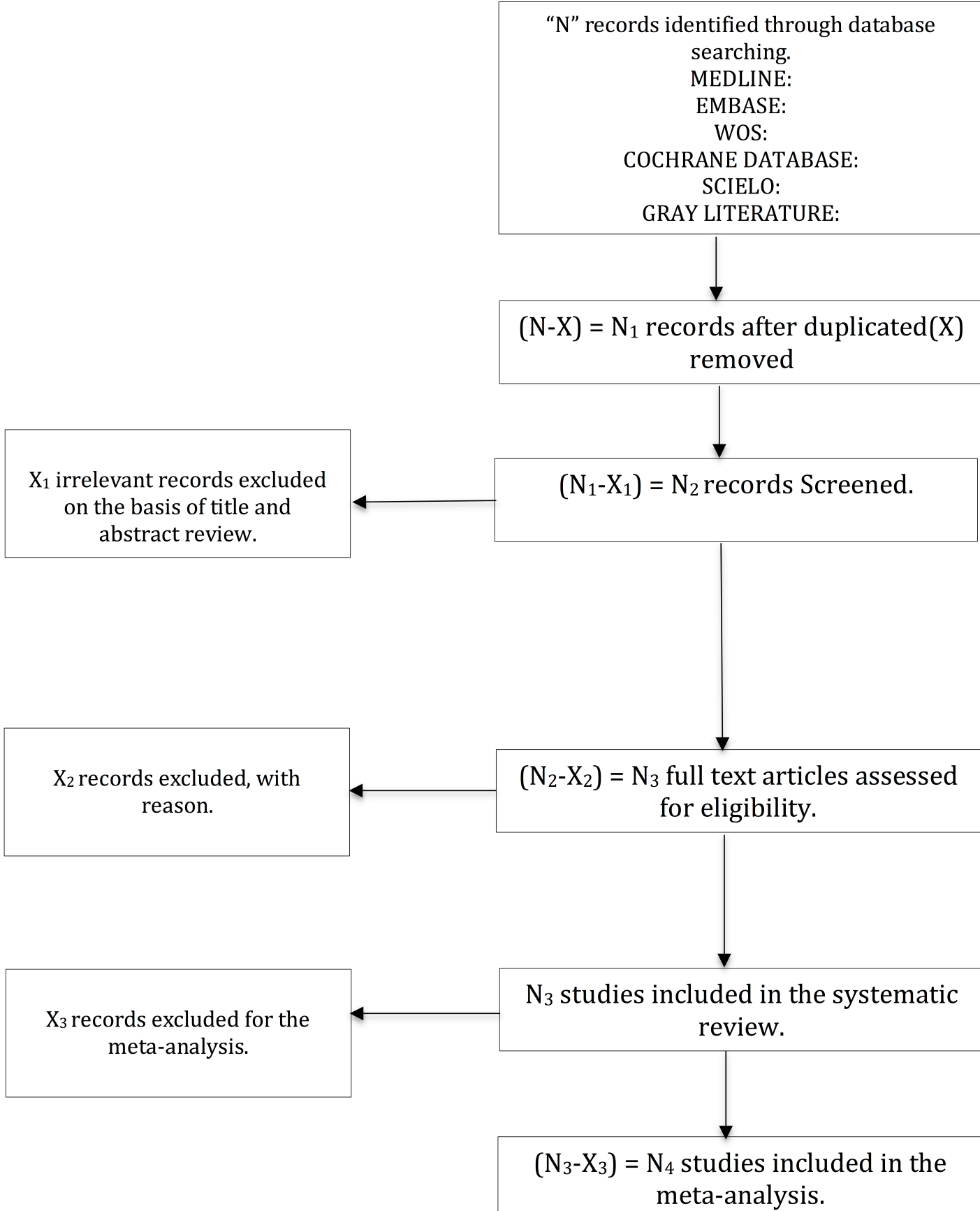
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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification: p. 1	1a	Identify the report as a protocol of a systematic review
Update: NA.	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number
Authors:		
Contact: pp. 1, 10	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author
Contributions: p.10	3b	Describe contributions of protocol authors and identify the guarantor of the review
Amendments: NA	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments
Support:		
Sources: p. 10	5a	Indicate sources of financial or other support for the review
Sponsor: p. 10	5b	Provide name for the review funder and/or sponsor
Role of sponsor or funder: p.10	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
INTRODUCTION		
Rationale: p. 4, 5	6	Describe the rationale for the review in the context of what is already known
Objectives: p. 5	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)
METHODS		
Eligibility criteria: p. 5	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review
Information sources p. 5	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage
Search strategy: pp. 5, 6	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
Study records:		

Data management: pp. 6, 7	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review
Selection process: pp. 6, 7	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process: pp.6,7	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators
Data items: p. 7	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications
Outcomes and prioritization: p. 7	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale
Risk of bias in individual studies: p.7	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis
Data synthesis: pp. 7, 8, 9	15a	Describe criteria under which study data will be quantitatively synthesised
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I ² , Kendall's τ)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned
Meta-bias(es): NA	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
Confidence in cumulative evidence: NA	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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