

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

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| TITLE (PROVISIONAL) | 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 |
| AUTHORS | Godoy-Cumillaf, Andrés; Diaz, Armando; Álvarez-Bueno, Celia; Martinez-Vizcaino, Vicente; Caverro-Redondo, Iván |

VERSION 1 – REVIEW

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| REVIEWER | Louise Hayes Institute of Health & Society Newcastle University, UK |
| REVIEW RETURNED | 17-Apr-2019 |

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| GENERAL COMMENTS | <p>Thank you for the opportunity to review this systematic review protocol.</p> <p>I have a few minor comments that I suggest the authors address.</p> <ol style="list-style-type: none">1. There are a few minor linguistic errors. I think the protocol would benefit from a thorough proof read.2. The population that is the focus of the review should be made clear in the objective (i.e. specify children and adolescents aged 4-18 years).3. It is stated that the focus is on physical activity interventions, but that interventions including diet/nutrition components will also be included. How will studies that are not evaluating physical activity interventions alone be handled in the meta-analysis? Perhaps the authors should consider having a separate meta-analysis for combined activity and diet interventions, or at least including in the sub-group analysis?4. Studies including participants aged <4 and >18 years are to be excluded. What strategy will be used if a paper includes, for example, participants aged 12-20 years? Would this be excluded? Might there be potential for including the data for those aged <18 years only, if available either in the published manuscript or from the authors?5. I found table 1 (search terms) a little confusing. I assume that the terms are combined with 'OR' going down the columns and with 'AND' going across the columns. This could be made clear in the table heading. I did also wonder if 'exercise' should be included as a search term in its own right? Perhaps some scoping work using different combinations of terms is warranted, if it hasn't already been done.6. I don't think it's mentioned, but presumably de-duplication of the papers identified from the search will be conducted before the titles and abstracts are screened.7. In the Statistical analysis section 'researchers' and 'reviewers' are referred to. Are these the same individuals? If so use one term consistently to describe them. |
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| REVIEWER | Asgeir Mamen Department of Health Sciences, Kristiania University College, Norway |
| REVIEW RETURNED | 27-Apr-2019 |

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| GENERAL COMMENTS | <p>The background for the study and the methods used are well described, and seems adequate. My main concern is about using BMI for obesity checking. This topic should receive more attention in Your upcoming articles, but also now the issue should be given more focus. One reference for its us is not sufficient. You should also make a point of adjusting the BMI to age and sex when evaluating the results (Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for child overweight and obesity worldwide: International survey. British Medical Journal 2000;320:1240-1243.).</p> <p>In Table 2 I miss some information on the interventions. As I have understood, some interventions will included also nutritional guidance, if so, this should be reported in the table.</p> <p>The text may need a rewrite to adhere to high quality English. Some examples: line10, page 5 "...premature all cause mortality," line18 page 6: "...reporting only one type of physical...", line 4, page 9 "the corresponding p-values..." with p in italics.</p> <p>I wish You luck with the research on this very important subject!</p> |
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| REVIEWER | Natalie Pearson Loughborough University |
| REVIEW RETURNED | 28-May-2019 |

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| GENERAL COMMENTS | <p>This manuscript describes a protocol for a systematic review and meta-analysis of studies examining the effects of physical activity interventions on the body mass index of children and adolescents in Latin America. I have focused only on the methodology section of this manuscript and my comments are below:</p> <ol style="list-style-type: none"> 1. line 15/16 (page 6) it is stated that 'studies must report physical activity interventions which meet the following criteria...' However, one of the criteria is that studies report on a type of physical activity intervention. consider rephrasing this for clarity. for example, for inclusion studies were required to: 3) report on a type of physical activity or ... 2. consider moving the search strategy before the inclusion criteria 3. in your inclusion criteria (5), do studies need to report on a physical activity outcome or is it that the intervention can be any type of physical activity? this is currently unclear 4. also re-iterate whether you are only including studies that have a control group? again, this isn't clear 5. add a date that the search will go up to. for example, studies published up to and including... 6. consider the use of the AND boolean operator in your searches, given that the focus is on physical activity interventions and BMI |
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| | <p>not OR BMI you are likely to miss studies or gather far too many irrelevant studies.</p> <p>7. Further more given that BMI is an outcome, why isn't this included in the search terms?</p> <p>8. Given that you are searching for interventions or RCT's, these should also be considered in your searches again using operators such as AND</p> <p>9. I think the selection of studies should be in a separate paragraph/sub heading to data extraction. At present the selection of studies paragraph is a bit messy and not east to read/follow.</p> <p>10. How will you deal with duplicates? this should be detailed in the selection of studies paragraph along with full text screening.</p> <p>11. will you extract details on the measurement of physical activity or how it was intervened on?</p> <p>12. page 8 lines 21-23. it is unclear why the prospect of a meta-analysis is being left open given that the outcome of interest in BMI (i.e. all studies will have the same specific outcome because it is part of your inclusion criteria). Are you unsure that there will be enough studies (as you stated that a minimum of 5 studies are required)? Needs clarification</p> |
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| REVIEWER | Emma Hock University of Sheffield United Kingdom |
| REVIEW RETURNED | 30-May-2019 |

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| GENERAL COMMENTS | <p>This manuscript reports on a protocol for a systematic review and meta-analysis of physical activity interventions on BMI among children and adolescents in Latin America. Strengths include the use of PRISMA-P, registration on PROSPERO, study selection, data extraction and quality assessment independently undertaken by two reviewers, and a novel review question. The main limitations are a lack of clarity around some elements of the review question, searches, data extraction and meta-analysis, and the proposal that only pre-post mean differences in BMI will be examined to indicate effectiveness.</p> <p>In my opinion, the main point that needs to be addressed is that comparative pre-post data (intervention versus control from pre- to post-intervention) should be examined in the meta-analysis. If the aim is to examine the effectiveness of physical activity interventions on BMI, then there should be at least one analysis that uses comparative data, where given, to attempt to address extraneous factors that may impact on BMI. This is not to say that there can't also be a meta-analysis of pre-post changes in BMI, however it would be remiss not to do a comparative analysis. Without this, I am not sure the meta-analysis could be considered to examine the effectiveness of the interventions.</p> <p>There are some other improvements and points of clarification that could be made to this manuscript, in my opinion, summarised as follows:</p> <p>Abstract</p> |
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Reword the phrase “no evidence has been found about the effects of these interventions on the BMI” (p.3, lines 6-7) to clarify this point. I think essentially this is meant to be saying that some studies have examined the effectiveness of physical activity interventions on BMI in this population, however there has been no attempt to synthesise these findings?

The objective needs re-wording for clarity (p.3, lines 7-9) - see below.

Also, clarify that the two quality assessment measures are for different study types (p.3, lines 14-16).

Introduction

I think the description of BMI as a “good measure to evaluate general adiposity” (p.5, line 14) needs to be revised/attenuated, and a reference added, as it is relatively well known that BMI, whilst a reasonable proxy to adiposity and other more sensitive measures, can be problematic, particularly in children and young people, and this requires consideration when discussing the use of BMI as a measure.

The objective at the end of this section is not needed as it repeats the content of the subsequent section, although I can see that it is part of the logical thread. Instead, you could say something more general about the need for synthesis of available evidence.

Objective

At the moment, this seems to relate to the protocol and is a little confusing - it gives the reader the impression that the review is going to be about developing methods (or methodology? Although I think the two have been confused here) when it is really about examining effectiveness. So this section needs to be clarified to focus on the objective of the review, which is to examine the effectiveness of physical activity interventions on BMI among children and adolescents in Latin America. This also needs to be rectified in the abstract (see above).

Methods and analysis

It would be useful to specify why you are including non-randomised studies and controlled pre-post studies (and what the difference between these is) (p.6, lines 19-20), and also consider the impact of including these study types in the Discussion section. Are you also planning to include single-arm studies (and again, why or why not)? A little more clarity on this would be helpful.

Also, in terms of inclusion criteria, it would be useful to clarify whether the studies would need to be examining a native population (and perhaps what the cutoff is for a proportion of non-natives in a study population), and whether lifestyle physical activity interventions are also going to be examined in addition to the ones listed? Or is there a reason to believe that there won't be any?

In terms of the search strategy, will you seek to identify grey literature (and if not, what is the reason)? Will citation searching be undertaken? It would also be useful to clarify a few things in terms of the phrasing of the searches. Ideally, I think both spellings for “program/programme” should be used, in case there is any literature in an international journal that uses UK English - at the

moment, that would be missed. Will MeSH headings be used? If so, which ones, and how will they be combined with the other search strategy? What search limits will be used? Will any terms be truncated? Also, with regard to the terms in the MEDLINE example strategy, it would be useful to specify that the three types of terms will be combined with the "AND" boolean operator (presumably they will) - at the moment, this example looks incomplete and difficult to replicate. It may be helpful to take a look at the paper by Aromataris and Riitano (2014) of the Joanna Briggs Institute or other similar literature.

Please can you clarify the meaning of "Inconsistencies in data collection will be resolved by consensus" (p.7, lines 13-14) in the part on study selection.

Regarding data extraction and data items, it would be useful to clarify here that two reviewers will independently extract data (as per in the highlights), and also say how the extracted data will be combined. In terms of data items, it would be useful to also extract/state that you are going to extract the control condition (what it involves), setting (e.g. school, community, family) and effectiveness data. Will there be any piloting of the data extraction process? If not, why not?

I have already mentioned the need to do a meta-analysis of comparative data (intervention versus control from pre- to post-intervention). Regarding the subgroup analyses, could lifestyle physical activity interventions be added (p.9, line 20) (see above)? Also, for "time", do you mean "duration" (p.10, line 1)? A bit more clarity and detail on the role of narrative synthesis in the review would also help. For instance, will narrative synthesis be conducted for any studies not eligible for inclusion in the meta-analysis, but eligible for inclusion in the review (p.8, lines 23-25)?

Discussion

It is useful that you have highlighted the policy and intervention implications (p.11, lines 9-11). I wonder if it might be possible, from your review findings (when conducted), to tease apart a little bit some of the things that policymakers and intervention developers might be able to use? For example, which types of intervention are more effective in children of which age and gender? I realise that a realist synthesis is well beyond the scope of the current review, however looking at the data extraction and synthesis, it looks like you should be able to say something along these lines - in which case, it might be useful to mention that here too.

Figure 1

Please could you clarify what the last excluded records box (X3 records excluded, with reasons) is for? Is this studies excluded at the point of narrative synthesis? Or is it for records that are excluded from the quantitative synthesis? If the latter, it would be clearer I think to rephrase this as "records included in the narrative synthesis but not the meta-analysis" or similar, or leave out altogether, since these are still included in the review. Also, I think it would be useful to keep terms consistent with the main text, so use "narrative synthesis" and "meta-analysis" instead of qualitative and quantitative synthesis, for clarity.

Lastly, I have noticed a few (minor) grammatical errors/typos, and addressing these would also improve the clarity of the manuscript.

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| | <p>A further proofread may be beneficial. If you are struggling to spot these, I am happy to make comments on the manuscript to highlight these if needed.</p> <p>References</p> <p>Aromataris, E. & Riitano, D. (2014). Constructing a search strategy and searching for evidence. A guide to the literature search for a systematic review. <i>American Journal of Nursing</i>, 114(5), 49-56. doi: 10.1097/01.NAJ.0000446779.99522.f6.</p> |
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VERSION 1 – AUTHOR RESPONSE

Reviewer #1:

1. Comments: There are a few minor linguistic errors. I think the protocol would benefit from a thorough proof read.

Authors: Thank you for the reviewer’s comment. The manuscript has been reviewed by a proof-reading service.

2. Comments: The population that is the focus of the review should be made clear in the objective (i.e. specify children and adolescents aged 4-18 years).

Authors: We really appreciate the reviewer’s thoughtful comment. Thus, we have included in the objective the focused population.

Page 2, line 8 to 10 and page 5, line 8 to 10:

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

3. Comments: It is stated that the focus is on physical activity interventions, but that interventions including diet/nutrition components will also be included. How will studies that are not evaluating physical activity interventions alone be handled in the meta-analysis? Perhaps the authors should consider having a separate meta-analysis for combined activity and diet interventions, or at least including in the sub-group analysis?.

Authors: The reviewer comments seem judicious. Thus, we have included, in the “statistical analysis” section, information to mention the separate meta-analysis for physical activity and nutritional interventions.

Page 8, lines 29 and 30, and page 9, line 1:

“Separating studies that included physical activity interventions from those in which physical activity and nutritional health are combined”.

4. Comments: Studies including participants aged <4 and >18 years are to be excluded. What strategy will be used if a paper includes, for example, participants aged 12-20 years? Would this be excluded? Might there be potential for including the data for those aged <18 years only, if available either in the published manuscript or from the authors?.

Authors: We really appreciate the reviewer’s thoughtful comment. We have included information on the strategy that will be used in the case that studies have information of participants aged <4 and >18 years.

Page 7, lines 12 and 13:

“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”.

5. Comments: I found table 1 (search terms) a little confusing. I assume that the terms are combined with 'OR' going down the columns and with 'AND' going across the columns. This could be made clear in the table heading. I did also wonder if 'exercise' should be included as a search term in its own right? Perhaps some scoping work using different combinations of terms is warranted, if it hasn't already been done.

Authors: Thank you for the reviewer's comment. The terms "AND" and "exercise" were added in Table 1.

6. Comments: I don't think it's mentioned, but presumably de-duplication of the papers identified from the search will be conducted before the titles and abstracts are screened.

Authors: Thank you for the reviewer's comment. We have included this information in the "selection of studies" section.

Page 7, lines 18 and 19:

"Also, this first review will be done to identify and exclude duplicate documents".

7. Comments: In the Statistical analysis section 'researchers' and 'reviewers' are referred to. Are these the same individuals? If so use one term consistently to describe them.

Authors: Thank you for the reviewer's comment. As suggested, both are the same individuals, thus we have modified both as 'researchers'.

Reviewer #2:

1. Comments: The background for the study and the methods used are well described, and seems adequate. My main concern is about using BMI for obesity checking. This topic should receive more attention in Your upcoming articles, but also now the issue should be given more focus. One reference for its use is not sufficient.

Authors: We really appreciate the reviewer's thoughtful comment. References were added, and the main concern about using BMI was reformulated.

Page 4, lines 13 to 17:

"Body Mass Index (BMI) is a method that allows us to quickly know if a person is overweight or obese and it is a measure to evaluate general adiposity⁷⁻⁹. There is evidence that reflects that in low-income countries (most of Latin America countries) since 3 decades ago there has been an increase in BMI values in children and adults, a situation that mainly affects women¹⁰".

New References included:

- ⁷Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for child overweight and obesity worldwide: International survey. *BMJ* 2000;320:1240-1243.
- ⁸Dietz 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.
- ⁹Poskitt M. Body mass index and child obesity: are we nearing a definition? *Acta Paediatr* 2000;89(5):507-509.
- ¹⁰Swinburn 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.

2. Comments: In Table 2 I miss some information on the interventions. As I have understood, some interventions will include also nutritional guidance, if so, this should be reported in the table.

Authors: Thank you for reviewer comment. As suggested, we have added in Table 2 information on nutritional interventions.

Table 2:

- Nutritional intervention: Type of nutritional intervention (food education, nutritional counseling, diet intervention).
- Nutritional characteristics: Definition of nutritional intervention (length of intervention).

3. Comments: The text may need a rewrite to adhere to high quality English. Some examples: line10, page 5 "...premature all cause mortality," line18 page 6: "...reporting only one type of physical...", line 4, page 9 "the corresponding p-values..." with p in italics.

Authors: Thank you for the reviewer's comment. The manuscript has been reviewed by a proof-reading service.

Page 4, line 10:

"[...] premature all cause [...].

Page 7, lines 4 and 5:

"[...] studies reporting only one type of physical activity [...].

Page 9, line 9:

"[...] p-values [...].

Reviewer #3:

This manuscript describes a protocol for a systematic review and meta-analysis of studies examining the effects of physical activity interventions on the body mass index of children and adolescents in Latin America. I have focused only on the methodology section of this manuscript and my comments are below:

1. Comments: line 15/16 (page 6) it is stated that 'studies must report physical activity interventions which meet the following criteria...' However, one of the criteria is that studies report on a type of physical activity intervention. consider rephrasing this for clarity. for example, for inclusion studies were required to: 3) report on a type of physical activity or ...

Authors: Thank you for the reviewer's comment. As suggested, we have rephrased the inclusion criteria as follows:

Page 7, lines 4 to 7:

"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".

2. Comments: consider moving the search strategy before the inclusion criteria

Authors: Thank you. Done.

3. Comments: in your inclusion criteria (5), do studies need to report on a physical activity outcome or is it that the intervention can be any type of physical activity? this is currently unclear.

Authors: We really appreciate the reviewer's thoughtful comment. We have rephrased into the third inclusion criteria as follows:

Page 7, lines 4 to 7:

"[...], 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. Comments: also re-iterate whether you are only including studies that have a control group? again, this isn't clear

Authors: We really appreciate the reviewer's thoughtful comment. Apologize for the misunderstanding, we have modified the inclusion criteria as follows:

Page 7, lines 7 and 8:

"[...], 4) randomized controlled trials, non-randomized experimental studies and single-arm pre-post studies. [...]"

5. Comments: add a date that the search will go up to. for example, studies published up to and including...

Authors: Thank you for the reviewer's comment. As suggested, we have included this information.

Page 5, line 23:

"[...] studies published until December 2018. [...]"

6. Comments: consider the use of the AND boolean operator in your searches, given that the focus is on physical activity interventions and BMI not OR BMI you are likely to miss studies or gather far too many irrelevant studies.

Authors: Thank you for the reviewer's comment. As suggested, we have included the Boolean operator AND and the following terms in Table 1 and in the "search strategy" section.

Page 6 lines 3 and 4:

"BMI, underweight, normal weight, overweight, obesity".

7. Comments: Furthermore given that BMI is an outcome, why isn't this included in the search terms?

Authors: We really appreciate the reviewer's thoughtful comment. As suggested, we have included search terms and in the Table 1.

Page 6 lines 3 and 4:

"BMI, underweight, normal weight, overweight, obesity".

8. Comments: Given that you are searching for interventions or RCT's, these should also be considered in your searches again using operators such as AND

Authors: Thank you for the reviewer's comment. As suggested, we have included search terms and in the Table 1.

Page 6, lines 4 and 5:

"randomised controlled trials, RCTs, non-randomised experimental, single-arm pre-post".

9. Comments: I think the selection of studies should be in a separate paragraph/sub heading to data extraction. At present the selection of studies paragraph is a bit messy and not easy to read/follow.

Authors: The reviewer's comment seems judicious. As suggested, paragraphs were separated. Also, the study selection paragraph has been rephrased.

Page 7, lines 16 to 24:

"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."

10. Comments: How will you deal with duplicates? this should be detailed in the selection of studies paragraph along with full text screening.

Authors: Thank you for the reviewer's comment. We have included this information in the "selection of studies" section.

Page 7, lines 18 and 19:

"[...]. Also, this first review will be done to identify and exclude duplicate documents. [...]"

11. Comments: will you extract details on the measurement of physical activity or how it was intervened on?

Authors: The reviewer's comment seems judicious. As suggested, we have included in the characteristics of the intervention the details on the measurement of physical activity as follows:

Page 8, lines 1 to 4:

"[...]; (8) Type of physical activity intervention (leisure-time physical activity, physical activity programs or physical activity counseling); (9) characteristics of the physical activity (length of intervention, number of sessions, duration of each session, type of physical measurement [ie. Physical activity scale, accelerometer or pedometer]);(10) [...]"

12. Comments: page 8 lines 21-23. it is unclear why the prospect of a meta-analysis is being left open given that the outcome of interest in BMI (i.e. all studies will have the same specific outcome because it is part of your inclusion criteria). Are you unsure that there will be enough studies (as you stated that a minimum of 5 studies are required)? Needs clarification.

Authors:

We really appreciate the reviewer's thoughtful comment. As reviewer suggested one inclusion criteria will be studies reporting BMI before and after the intervention. Thus, we have modified the sentence as follows (Page 8, lines 27 to 30 and page 9, lines 1 and 2.)

"[...]. A narrative synthesis of the data extracted in Table of characteristics of the studies included will be conducted, then a meta-analysis will be performed based on studies that show BMI pre-post intervention. Studies providing insufficient data to carry out the analyses will be included in the systematic review but omitted from meta-analysis."

Reviewer #4

Comments: This manuscript reports on a protocol for a systematic review and meta-analysis of physical activity interventions on BMI among children and adolescents in Latin America. Strengths include the use of PRISMA-P, registration on PROSPERO, study selection, data extraction and quality assessment independently undertaken by two reviewers, and a novel review question. The main limitations are a lack of clarity around some elements of the review question, searches, data extraction and meta-analysis, and the proposal that only pre-post mean differences in BMI will be examined to indicate effectiveness.

Authors: We really appreciate the reviewer's thoughtful comments.

2. Comments: In my opinion, the main point that needs to be addressed is that comparative pre-post data (intervention versus control from pre- to post-intervention) should be examined in the meta-analysis. If the aim is to examine the effectiveness of physical activity interventions on BMI, then there should be at least one analysis that uses comparative data, where given, to attempt to address extraneous factors that may impact on BMI. This is not to say that there can't also be a meta-analysis of pre-post changes in BMI, however it would be remiss not to do a comparative analysis. Without this, I am not sure the meta-analysis could be considered to examine the effectiveness of the interventions.

Authors: The reviewer's comment seems judicious. We have rephrased last paragraph from Statistical analysis section in order to cope the reviewer suggestion as follows

Page 9, lines 10 to 15:

"Data from intention-to-treat analyses will be considered whenever available in RCTs. Two analysis will be performed: 1) BMI mean difference pre-post intervention from Physical activity intervention versus control, and 2) BMI mean difference pre-post Physical activity intervention. Standardised mean differences will be calculated for BMI levels. Additionally, publication bias will be assessed using a funnel plot, according to the method proposed by Egger."

There are some other improvements and points of clarification that could be made to this manuscript, in my opinion, summarized as follows:

Abstract

3. Comments:

Reword the phrase “no evidence has been found about the effects of these interventions on the BMI” (p.3, lines 6-7) to clarify this point. I think essentially this is meant to be saying that some studies have examined the effectiveness of physical activity interventions on BMI in this population, however there has been no attempt to synthesize these findings?

Authors: We really appreciate the reviewer’s thoughtful comment. The phrase was reworded as follows:

Page 2, lines 6 to 8:

“Although, in Latin America some systematic reviews have been performed, any of them have meta-analyzed the results of the effect of physical activity interventions on BMI”.

4. Comments: The objective needs re-wording for clarity (p.3, lines 7-9) - see below.

Authors: Thank you for the reviewer’s comment. The objective was rephrased and clarified.

Page 2, lines 8 to 10:

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

5. Comments: Also, clarify that the two quality assessment measures are for different study types (p.3, lines 14-16).

Authors: Thank you for the reviewer’s comment. As suggested, we have included this information as follows:

Page 2, lines 16 to 19.

“The Cochrane Collaboration’s tool for RCTs studies and the Quality Assessment Tool for Quantitative Studies for non-randomised experimental studies and single-arm pre-post studies will be used to assess the risk of bias for studies included in the systematic review”.

Introduction

6. Comments:

I think the description of BMI as a “good measure to evaluate general adiposity” (p.5, line 14) needs to be revised/attenuated, and a reference added, as it is relatively well known that BMI, whilst a reasonable proxy to adiposity and other more sensitive measures, can be problematic, particularly in children and young people, and this requires consideration when discussing the use of BMI as a measure.

Authors: We really appreciate the reviewer’s thoughtful comment. As suggested, we have modified the paragraph as follows:

Page 4, lines 13 to 17:

“Body Mass Index (BMI) is a method that allows us to quickly know if a person is overweight or obese and it is a measure to evaluate general adiposity⁷⁻⁹. There is evidence that reflects that in low-income countries (most of in Latin America countries) in the last 3 decades there has been an increase in BMI values in children and adults, a situation that mainly affects women¹⁰”.

New References included:

- ⁷Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for child overweight and obesity worldwide: International survey. *BMJ* 2000;320:1240-1243.
- ⁸Dietz 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.
- ⁹Poskitt M. Body mass index and child obesity: are we nearing a definition? *Acta Paediatr* 2000;89(5):507-509.
- ¹⁰Swinburn 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.

7. Comments: The objective at the end of this section is not needed as it repeats the content of the subsequent section, although I can see that it is part of the logical thread. Instead, you could say something more general about the need for synthesis of available evidence.

Authors: Thank you for the reviewer's comment. As suggested, we have modified the end of the "introduction" section as follows:

Page 5, lines 1 to 3:

"Therefore, the purpose of this protocol is to provide the methodology for a meta-analysis in order to synthesize the effect of physical activity interventions on BMI in Latin American children and adolescents".

Objective

8. Comments:

At the moment, this seems to relate to the protocol and is a little confusing - it gives the reader the impression that the review is going to be about developing methods (or methodology? Although I think the two have been confused here) when it is really about examining effectiveness. So this section needs to be clarified to focus on the objective of the review, which is to examine the effectiveness of physical activity interventions on BMI among children and adolescents in Latin America. This also needs to be rectified in the abstract (see above).

Authors: We really appreciate the reviewer's thoughtful comment. We have rephrased the objective as follows:

Page 5, lines 8 to 10:

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

Methods and analysis

9. Comments:

It would be useful to specify why you are including non-randomised studies and controlled pre-post studies (and what the difference between these is) (p.6, lines 19-20), and also consider the impact of including these study types in the Discussion section. Are you also planning to include single-arm studies (and again, why or why not)? A little more clarity on this would be helpful.

Authors: Thank you for the reviewer's comment. Apologize for the misunderstanding, we have modified the inclusion as follows:

Page 7, lines 7 and 8:

"[...], 4) randomised controlled trials (RCTs), non-randomised experimental studies and single-arm pre-post studies. [...]"

Additionally, we have included a paragraph in Discussion section to support the inclusion of different design.

Page 11, lines 8 to 10:

"Other issue that should be highlighted when performing this systematic review are whether the study design (RCTs, non-randomised experimental studies and single-arm pre-post studies) could affect the results as it has been reported in previous studies^{25,26}".

New References included:

- 25Brown T, Summerbell C. Systematic review of school-based interventions that focus on changing dietary intake and physical activity levels to prevent childhood obesity: an update to the obesity guidance produced by the National Institute for Health and Clinical Excellence. *Obes Rev* 2009;10(1):110-41.
- 26Katz DL. School-based interventions for health promotion and weight control: not just waiting on the world to change. *Annu Rev Public Health* 2009;30:253-72.

10. Comments: Also, in terms of inclusion criteria, it would be useful to clarify whether the studies would need to be examining a native population (and perhaps what the cutoff is for a proportion of non-natives in a study population), and whether lifestyle physical activity interventions are also going to be examined in addition to the ones listed? Or is there a reason to believe that there won't be any? Authors: The reviewer's comment seems judicious. We would like to include all type of population in our review, but as reviewer suggested the inclusion of native population could be a cofounder of our review. Thus, we have included in Subgroup analyses and meta-regression section this concern as follows:

Page 10, lines 1 to 4:

"Subgroup analyses and meta-regression will be performed considering the main factors which may cause heterogeneity, such as: gender; age (children aged 4-12 years and adolescents aged 12-18 years); type of population (general population or native population); [...]"

Furthermore, we have included in type physical activity as inclusion criteria lifestyle physical activity interventions (Page 9, line 13). And in consequence as a subgroup analysis.

11. Comments: In terms of the search strategy, will you seek to identify grey literature (and if not, what is the reason)? Will citation searching be undertaken? It would also be useful to clarify a few things in terms of the phrasing of the searches. Ideally, I think both spellings for "program/programme" should be used, in case there is any literature in an international journal that uses UK English - at the moment, that would be missed. Will MeSH headings be used? If so, which ones, and how will they be combined with the other search strategy? What search limits will be used? Will any terms be truncated? Also, with regard to the terms in the MEDLINE example strategy, it would be useful to specify that the three types of terms will be combined with the "AND" boolean operator (presumably they will) - at the moment, this example looks incomplete and difficult to replicate. It may be helpful to take a look at the paper by Aromataris and Riitano (2014) of the Joanna Briggs Institute or other similar literature.

Authors: We really appreciate the thoughtful reviewer's comment. We have included the search in the most relevant gray literature databases, as well as clinical trial records ClinicalTrials.gov and EudraCT.

Page 5, lines 24 to 27:

"Searches for unpublished studies will be conducted at: OPEN GRAY, ProQuest dissertations & Thesis Global, Theseo, Networked digital library of theses and dissertations (NDLTD), and Google Scholar. A search of ClinicalTrials.gov and EudraCT clinical trial records will also be conducted."

Also, regarding citation searching a new sentence have been included

Page 5, lines 27 and 28:

"The literature search will be complemented by screening references included in the articles considered eligible for the systematic review."

Regarding spellings for "program/programme" concern, we have considered reviewer suggestion and we have included programme in the search strategy.

Furthermore, apologize for misunderstanding in search strategy, as reviewer suggested we have included the AND boolean operator in the Table 1. Also, we didn't include any truncated and/or MeSH terms. Thus, we have modified the following sentence: "The search strategy will combine Boolean operators from the following relevant concepts" as follows Page 5, lines 29 to 31.

"[...]. The search strategy will include the following free text terms combining Boolean operators from the following relevant concepts (Table 1):[...]"

12. Comments: Please can you clarify the meaning of "Inconsistencies in data collection will be resolved by consensus" (p.7, lines 13-14) in the part on study selection.

Authors: Thank you for the reviewer's comment. As suggested, we have modified the sentence in order to clarify the meaning:

Page 7, lines 23 and 24:

“The inconsistencies in the selection will be resolved with a third researcher”.

13. Comments: Regarding data extraction and data items, it would be useful to clarify here that two reviewers will independently extract data (as per in the highlights), and also say how the extracted data will be combined. In terms of data items, it would be useful to also extract/state that you are going to extract the control condition (what it involves), setting (e.g. school, community, family) and effectiveness data. Will there be any piloting of the data extraction process? If not, why not?

Authors: Thank you for the reviewer’s comment. As suggested, we have included in data items information regarding control groups. Regarding piloting of the data, we have included the following sentence in Selection of studies and data extraction section:

Page 7. Lines 20 to 22:

“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”

14. Comments: I have already mentioned the need to do a meta-analysis of comparative data (intervention versus control from pre- to post-intervention). Regarding the subgroup analyses, could lifestyle physical activity interventions be added (p.9, line 20) (see above)? Also, for “time”, do you mean “duration” (p.10, line 1)? A bit more clarity and detail on the role of narrative synthesis in the review would also help. For instance, will narrative synthesis be conducted for any studies not eligible for inclusion in the meta-analysis, but eligible for inclusion in the review (p.8, lines 23-25)?

Authors: Thank you for the reviewer’s comment. We have included lifestyle physical activity in subgroup analysis as reviewer suggested above. Also, we have change “duration” by “time”. Finally, we have clarified the role of narrative synthesis as follows. Page 8, lines 27 to 30 and page 9, lines 1 and 2:

“[...]. A narrative synthesis of the data extracted in Table of characteristics of the studies included will be conducted, then a meta-analysis will be performed based on studies that show BMI pre-post intervention. Separating studies that included physical activity interventions from those in which physical activity and nutritional health are combined. Studies providing insufficient data to carry out the analyses will be included in the systematic review but omitted from meta-analysis.”

Discussion

15. Comments:

It is useful that you have highlighted the policy and intervention implications (p.11, lines 9-11). I wonder if it might be possible, from your review findings (when conducted), to tease apart a little bit some of the things that policymakers and intervention developers might be able to use? For example, which types of intervention are more effective in children of which age and gender? I realise that a realist synthesis is well beyond the scope of the current review, however looking at the data extraction and synthesis, it looks like you should be able to say something along these lines - in which case, it might be useful to mention that here too.

Authors: We really appreciate the reviewer’s thoughtful comment. As suggested, we have included information in discussion section regarding this issue as follows:

Page 11, lines 4 to 7:

“This could allow knowing which type of interventions bring the best benefits to reduce the values of BMI, considering the setting (schools, health care centres or others), type of population (according to their nutritional status), intensity, duration and number of sessions.”

Figure 1

16. Comments:

Please could you clarify what the last excluded records box (X3 records excluded, with reasons) is for? Is this studies excluded at the point of narrative synthesis? Or is it for records that are excluded from the quantitative synthesis? If the latter, it would be clearer I think to rephrase this as “records included in the narrative synthesis but not the meta-analysis” or similar, or leave out altogether, since these are still included in the review. Also, I think it would be useful to keep terms consistent with the main text, so use “narrative synthesis” and “meta-analysis” instead of qualitative and quantitative synthesis, for clarity.

Authors: Thank you for the reviewer’s comment. As suggested, we have modified Figure 1.

17. Comments: Lastly, I have noticed a few (minor) grammatical errors/typos, and addressing these would also improve the clarity of the manuscript. A further proofread may be beneficial. If you are struggling to spot these, I am happy to make comments on the manuscript to highlight these if needed.

Authors: Thank you for the reviewer’s comment. The manuscript has been reviewed by a proof-reading service.

VERSION 2 – REVIEW

| | |
|------------------------|--|
| REVIEWER | Natalie Pearson Loughborough University, UK |
| REVIEW RETURNED | 23-Jul-2019 |

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| GENERAL COMMENTS | <p>This manuscript presents a protocol of a systematic review and meta analysis of studies examining the effect of physical activity interventions in Latin american children and adolescents. While the concept of this review is promising, the manuscript requires some attention to detail in particular the English language and grammar...</p> <p>specific comments</p> <p>Abstract:</p> <ol style="list-style-type: none">1. English language to be checked2. first sentence is too long and messy. consider splitting into two.3. line 7 - the word 'any' is misplaced, should this be none of them?4. line 9 - replace 'on the' with examining5. include the word 'statement' after PRISMA6. pre-intervention is misplaced on line 197. include details of the statistical package you will use for the meta-analysis <p>8. remove the word 'the' before BMI (page 4)</p> <p>Introduction</p> <ol style="list-style-type: none">1. English language and grammar to be checked throughout2. first sentence is too long3. paragraph 2 is repeating some of the information in paragraph 1, consider merging these two paragraphs to one short paragraph.4. lines 22-26 need to be clearer and to the point. There are more than several interventions targeting obesity. consider shortening this, making it specific to Latin-America and merging with the next paragraph.5. remove 'the' from before BMI throughout |
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| | <p>6. describe the reviews that have already been conducted and what have they found, is there really a need for another review. what additional information will a meta-analysis provide and are these results important? if so, to who and why?</p> <p>7. none of them, instead of 'any'</p> <p>8. check your spelling throughout (e.g. synthesise, line 3, page 6)</p> <p>9. line 5-6 on page 6 are out of place?</p> <p>Methods</p> <p>1. searches (line 23) not search</p> <p>2. why December 2018 when it is already July 2019?</p> <p>3. why have you decided to search grey literature? can you guarantee that this is systematic and that you wont miss anything? Typically systematic reviews are of published literature</p> <p>4. no need to list the key terms as they are presented in the table</p> <p>5. the inclusion criteria are poorly described: why only one type of activity? do you mean have BMI as an outcome of the intervention that was assessed pre-and post? include the last search date.</p> <p>6. studies excluded if they provide self-report data on what?</p> <p>7. no need to have 3 of your exclusion because it is part of your inclusion</p> <p>8. line 19-21 (page 8) is a long sentence that can be cut after systematic review.</p> <p>9. excluding duplicates is the first thing you would do after merging all of the searches into one database?</p> <p>10. will you also extract length of intervention, location of intervention (setting), outcome measures - what type of information would you need for your meta-analysis?</p> <p>11. why wouldn't a meta-analysis be possible? do you mean appropriate (i.e. the data doesn't lend itself well to a meta-analysis)</p> <p>12. line 13-18 on page 10 is unclear. what if the intervention included nutrition? unclear what the difference is in the interventions described in point 1 and 2</p> <p>13. what about setting of intervention for subgroup analysis?</p> <p>Discussion</p> <p>1. line 29 (page 11), but in the introduction you reference several other systematic reviews that have been conducted in latin america?</p> <p>2. check language and grammar throughout</p> |
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| REVIEWER | Emma Hock University of Sheffield, UK |
| REVIEW RETURNED | 29-Jul-2019 |

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| GENERAL COMMENTS | <p>Peer review of bmjopen-2019-030332.R1: 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</p> <p>Recommendation Minor revision Comments for authors</p> <p>It is clear that the authors have worked hard on this manuscript and as a result it reads much better and is more coherent. I am satisfied that most of my comments have been addressed, including the main point of making an intervention versus control pre-post comparison. Some of my comments, however, seem to have been misunderstood, so I will endeavour to make these</p> |
|-------------------------|--|

clearer. I have also noticed a few other aspects that warrant attention. They are as follows:

Abstract

It is useful that the part about there being no evidence has been reworded - this is now a lot clearer and more precise. For clarity, please reword "any" to "none" (as in "none have meta-analyzed the results...").

The objective still needs re-wording for clarity, to bring it in line with the PRISMA-P criteria (p.3, lines 8-10). At the moment it seems to relate to what the paper is going to describe, whereas PRISMA-P states that it needs to be the objective of the review - so please amend this to the objective of the review, or review question.

Introduction

The description of BMI has been reworded and added to, with some evidence, however the problematic nature of BMI as a measure in children and young people has not been discussed or considered. Given that this is fairly well known, and given the need for an appropriately critical angle on the subject matter, these debates need to be acknowledged when discussing the use of BMI as a measure.

The latter part of the Introduction relates to prior research, which is appropriate. The mention of previous systematic reviews is interesting, and it is immediately clear how the current study proposes to build on these, methodologically. However, it would be remiss not to briefly summarise the findings of these previous systematic reviews. Please add in a couple of lines relating to the findings of this prior evidence. Also, please delete the sentence "Therefore, the purpose of the protocol is to provide the methodology for a meta-analysis..." (p.6, lines 2-4) as it does not add anything and is difficult to understand.

Objective

The objective still relates more to the paper rather than the proposed systematic review, whereas PRISMA-P states the objective presented here in the protocol needs to be the objective of the systematic review. Please present the objective of the systematic review here.

Methods and analysis

Much of the Methods section is now much clearer. There are, however, some minor amendments to be made to further improve clarity. First, the ordering of the sections could be clearer and more intuitive. Please revise to the following order: inclusion criteria; search strategy; selection of studies; data extraction. This way, each section builds on and is informed by the previous one. It seems remiss to be presenting search terms before the inclusion criteria have been presented.

In terms of searching, it is useful that a sentence on searching reference lists has been added. Reading over the whole section, I think this part would fit better at the end of the Search Strategy section. Also, please can you clarify whether citation searching will be undertaken, and how (e.g. using Google Scholar)? It would also be useful to clarify why MeSH headings and truncations will not be used. While a little clearer, the search strategy is still not completely clear, nor in a standard format. I strongly urge you to

look at the paper by Aromataris and Riitano (2014) of the Joanna Briggs Institute or other similar literature, and present a search strategy in the standard format, for clarity and ease of replication.

The revised sentence "Inconsistencies in data collection will be resolved with a third researcher" (p.7, lines 23-24) is clearer. Please further clarify the process, including the role of the third researcher.

The addition of a study selection section is useful and aids clarity. Again, I think a few small changes could further clarify. First, the sentence, "Also, this first review will be done to identify and exclude duplicate documents" (p.8, lines 21-22) suggests that de-duplication will not be undertaken until screening, whereas ideally the database should be de-duplicated prior to first screening. Inevitably, some duplicates will sneak through, however the bulk of the process should be done prior to screening, and this should be reflected in the flow diagram. Please amend accordingly. Second, the sentences from "Each author will extract..." to the end of the paragraph (p.8, lines 23-27) should be moved to the Data Extraction section. Further, the newly added sentence, "Each author will extract the data of the same five studies..." (p.8, lines 23-25) does not pertain to piloting. It might aid clarity to revise this sentencing to something general like "The extraction tool will be piloted by all reviewers on the first five studies, to ensure consistency in data extraction."

It is useful that physical activity types have now been listed in the data extraction section (p.9, lines 4-5), however is this list comprehensive? Could it also include lifestyle physical activity?

The additional information on synthesis is useful. Please check the grammar of the sentence, "Separating studies that included physical activity interventions..." (p.10, lines 2-4) as something seems to be missing here.

The additional fields added to Table 2 again aid clarity and comprehensiveness. Please consider presenting this in landscape orientation for additional clarity. What I presume to be the final column (there may be more that are now off the page) is partly obstructed by the page margins and is largely unreadable.

Figure 1

I am not sure what happened in the process of uploading this figure, however it is now largely unreadable on the PDF available from the reviewer centre. Please can this be amended to clarify? Also, it is still unclear what X3 relates to, as there is no prior mention before $(N3 - X3) = N4$.

Lastly, I have noticed a few (minor) grammatical errors/typos, mainly in the new text. Again, I am happy to make comments on the manuscript to highlight these if needed.

References

Aromataris, E. & Riitano, D. (2014). Constructing a search strategy and searching for evidence. A guide to the literature search for a systematic review. *American Journal of Nursing*, 114(5), 49-56. doi: 10.1097/01.NAJ.0000446779.99522.f6.

VERSION 2 – AUTHOR RESPONSE

Reviewer 3:

Comments: While the concept of this review is promising, the manuscript requires some attention to detail in particular the English language and grammar...

Authors: Thank you for the reviewer's comment. A Native English-speaking colleague has reviewed the manuscript. We also sent the manuscript to a professional copyediting service.

Abstract:

Comments1: English language to be checked.

Authors: Thank you for the reviewer's comment. A Native English-speaking colleague has reviewed the manuscript. We also sent the manuscript to a professional copyediting service.

Comments 2: first sentence is too long and messy. consider splitting into two.

Authors: Thank you for the reviewer's comment. Done.

Page 2, lines 2 to 9.

In Latin America, the number of children and adolescents who are overweight or obese has significantly increased in recent decades, and this situation has become a major public-health concern. To address this problem, several intervention programmes, based on factors such as physical activity and nutrition, have been implemented, and body mass index (BMI) has been widely used as a means of measuring the impact of such interventions. Although some Latin-America-based systematic reviews have been performed, there have been no previous meta-analyses of findings regarding the effect of physical-activity interventions on BMI.

Comments 3: line 7 - the word 'any' is misplaced, should this be none of them?

Authors: Thank you. Done.

Comments 4: line 9 - replace 'on the' with examining.

Authors: Thank you. Done.

Comments 5: include the word 'statement' after PRISMA.

Authors: Thank you. Done.

Comments 6: pre-intervention is misplaced on line 19.

Authors: Thank you. We have removed pre-intervention on line 19.

Comments 7: include details of the statistical package you will use for the meta-analysis.

Authors: Thank you. Done.

Page 2, line 22.

... For the meta-analysis the statistical program STATA V.14 will be used.

Comments 8: remove the word 'the' before BMI (page 4).

Authors: Thank you. Done.

Introduction

Comments 1: English language and grammar to be checked throughout.

Authors: Thank you for the reviewer's comment. A Native English-speaking colleague has reviewed the manuscript. We also sent the manuscript to a professional copyediting service.

Comments 2: first sentence is too long.

Authors: Thank you for the reviewer's comment. The sentence has been modified as follows:

Page 5, lines 2 to 4.

Latin America is a region where children and adolescents overweight and obesity have significantly increased in the last decades and this situation has become a major public health concern.

Comments 3: paragraph 2 is repeating some of the information in paragraph 1, consider merging these two paragraphs to one short paragraph.

Authors: Thank you for the reviewer's comment. The two paragraphs were merged as follows:

Page 5, lines 2 to 12.

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

Comments 4: lines 22-26 need to be clearer and to the point. There are more than several interventions targeting obesity. consider shortening this, making it specific to Latin-America and merging with the next paragraph.

Authors: Thank you for the reviewer's comment. As suggested, we have modified lines 22-26 and merged with the following paragraph as follows:

Page 5, lines 19 to 30 and page 6, lines 1 and 2.

Physical activity plays an important role in reducing BMI, along with lowering risk factors for cardiovascular disease and improving cardiorespiratory fitness; this, in turn, leads to a reduction in risk factors for overall health. As a result of these benefits, researchers have implemented physical-activity-focussed interventions, nutritional-focussed interventions, or a combination of both, and have used BMI to measure their effect. Underlining this approach, previous systematic reviews performed in Latin America have shown that, while few studies have implemented physical-activity interventions to treat overweight and obesity, the implementation of physical-education policies and programmes is necessary to promote children's and adolescents' health, because these interventions can effectively create positive changes among this population. However, there have been no previous Latin-America-based meta-analyses of the effects physical-activity interventions have on BMI. Considering this, the present study aims to attract more attention to the necessity of such interventions, and to generate evidence that can encourage changes in public policy that can contribute to addressing this public-health crisis.

Comments 5:

Authors: Thank you. Done.

Comments 6: describe the reviews that have already been conducted and what have they found, is there really a need for another review. what additional information will a meta-analysis provide and are these results important? if so, to who and why?.

Authors: Thank you for the reviewer's comment. As suggested we have included information about the previous reviews as follows:

Page 5, lines 24 to 30 and page 6, lines 1 and 2.

Underlining this approach, previous systematic reviews performed in Latin America have shown that, while few studies have implemented physical-activity interventions to treat overweight and obesity, the implementation of physical-education policies and programmes is necessary to promote children's and adolescents' health, because these interventions can effectively create positive changes among this population. However, there have been no previous Latin-America-based meta-analyses of the effects physical-activity interventions have on BMI. Considering

this, the present study aims to attract more attention to the necessity of such interventions, and to generate evidence that can encourage changes in public policy that can contribute to addressing this public-health crisis.

Comments 7: none of them, instead of 'any'.

Authors: Thank you for the reviewer's comment. Done.

Comments 8: check your spelling throughout (e.g. synthesise, line 3, page 6).

Authors: Thank you for the reviewer's comment. This word has been removed and the spelling has been checked.

Comments 9: line 5-6 on page 6 are out of place?.

Authors: Thank you for the reviewer's comment. These lines have been removed.

Methods

Comments 1: searches (line 23) not search.

Authors: Thank you for the reviewer's comment. The change was made.

Comments 2: why December 2018 when it is already July 2019?.

Authors: Thank you for the reviewer's comment. The date has been updated to include more recent literature.

Page 6, lines 24 and 25.

...published before July 2019.

Comments 3: why have you decided to search grey literature? can you guarantee that this is systematic and that you wont miss anything? Typically systematic reviews are of published literature.

Authors: Thank you for the reviewer's comment. We agree with this comment including grey literature could cast doubt on the results of a systematic review, but after careful reflection and, under the

suggestion of another reviewer, we have decided to include the literature following the guidelines of the Cochrane Handbook on including grey literature as a source for systematic reviews.

Comments 4: no need to list the key terms as they are presented in the table.

Authors: Thank you for the reviewer's comment. We have removed the key terms from the text.

Comments 5: the inclusion criteria are poorly described: why only one type of activity? do you mean have BMI as an outcome of the intervention that was assessed pre-and post? include the last search date.

Authors: Thank you for the reviewer's comment. We have modified the inclusion criteria as follows:

Page 6, lines 20 to 22.

...3) reporting any type of physical activity (physical endurance, sports, or alternative exercise [e.g. games, dancing, optimised physical education classes], which may or may not have included nutritional interventions) ...

Also, the measurement of BMI is necessary for pre and post intervention. We have modified the sentence as follows:

Page 6, lines 23 and 24.

... reporting BMI both before and after the intervention ...

Finally, a new inclusion criteria regarding the date was added.

Page 6, lines 24 and 25.

... 7) published before July 2019.

Comments 6: studies excluded if they provide self-report data on what?.

Authors: Thank you for the reviewer's comment. Self-reported data will not be accepted about BMI.

Page 6, line 27.

... 2) providing self-reported data for BMI.

Comments 7: no need to have 3 of your exclusion because it is part of your inclusion.

Authors: Thank you for the reviewer's comment. This criterion has been removed.

Comments 8: line 19-21 (page 8) is a long sentence that can be cut after systematic review.

Authors: Thank you for the reviewer's comment. As suggested, we have done the change.

Page 8, lines 5 to 7.

... two researchers will independently evaluate the titles and abstracts of the retrieved articles in order to identify eligible studies for the systematic review.

Comments 9: excluding duplicates is the first thing you would do after merging all of the searches into one database?.

Authors: Thank you for the reviewer's comment. As suggested, we have clarified this point as follows:

Page 8, lines 5 to 7.

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.

Comments 10: will you also extract length of intervention, location of intervention (setting), outcome measures - what type of information would you need for your meta-analysis?.

Authors: Thank you for the reviewer's comment. As suggested, we have included this information to perform some secondary analysis of our meta-analysis.

Page 9, lines 10 to 13.

... characteristics of the physical activity in question (length of intervention, intervention setting, number of sessions, duration of each session, type of physical measurement applied [i.e. physical-activity scale, accelerometer, or pedometer]).

Comments 11: why wouldn't a meta-analysis be possible? do you mean appropriate (i.e. the data doesn't lend itself well to a meta-analysis).

Authors: Thank you for the reviewer's comment. The word "possible" was changed for "appropriate".

Page 10, line 17.

For studies for which a meta-analysis is appropriate...

Comments 12: line 13-18 on page 10 is unclear. what if the intervention included nutrition? unclear what the difference is in the interventions described in point 1 and 2 .

Authors: Thank you for the reviewer's comment. As suggested, we have clarified this point as follows:

Page 10, lines 26 to 29.

1) mean difference in BMI pre-post physical-activity-based intervention (with or without nutritional intervention) versus a control group, and 2) mean difference in BMI pre-post physical-activity-based intervention (with or without nutritional intervention), without a control group.

Comments 13: what about setting of intervention for subgroup analysis?.

Authors: Thank you for the reviewer's comment. This information has been added.

Page 11, line 9.

... the setting in which the intervention occurs ...

Discussion

Comments 1: line 29 (page 11), but in the introduction you reference several other systematic reviews that have been conducted in latin america?.

Authors: Thank you for the reviewer's comment. We clarified that there is no meta-analysis of these studies in Latin America.

Page 13, lines 4 and 6.

... However, there have been no previous meta-analyses of the effects of these interventions in the context of Latin America ...

Comments 2: check language and grammar throughout.

Authors: Thank you for the reviewer's comment. A Native English-speaking colleague has reviewed the manuscript. We also sent the manuscript to a professional copyediting service.

Reviewer 4:

Abstract

Comments 1: It is useful that the part about there being no evidence has been reworded - this is now a lot clearer and more precise. For clarity, please reword "any" to "none" (as in "none have meta-analyzed the results...").

Authors: Thank you for the reviewer's comment. Done.

Comments 2: The objective still needs re-wording for clarity, to bring it in line with the PRISMA-P criteria (p.3, lines 8-10). At the moment it seems to relate to what the paper is going to describe, whereas PRISMA-P states that it needs to be the objective of the review - so please amend this to the objective of the review, or review question.

Authors: Thank you for the reviewer's comment. As suggested, we have modified the objective following PRISMA-P states.

Page 2, lines 9 to 13.

... the objective of this study protocol is to provide a standardised and transparent methodology for performing systematic reviews and meta-analyses of study findings regarding the effect physical-activity interventions have on BMI of Latin American children and adolescents aged four to 18 years.

Introduction

Comments 3: The description of BMI has been reworded and added to, with some evidence, however the problematic nature of BMI as a measure in children and young people has not been discussed or considered. Given that this is fairly well known, and given the need for an appropriately critical angle on the subject matter, these debates need to be acknowledged when discussing the use of BMI as a measure.

Authors: Thank you for the reviewer's comment. Information about the problematic nature of using BMI as a measure in children has been added.

Page 5, lines 13 to 18.

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

Comments 4: The latter part of the Introduction relates to prior research, which is appropriate. The mention of previous systematic reviews is interesting, and it is immediately clear how the current study proposes to build on these, methodologically. However, it would be remiss not to briefly summarise the findings of these previous systematic reviews. Please add in a couple of lines relating to the findings of this prior evidence. Also, please delete the sentence "Therefore, the purpose of the protocol is to provide the methodology for a meta-analysis..." (p.6, lines 2-4) as it does not add anything and is difficult to understand.

Authors: Thank you for the reviewer's comment. Information about the findings of the systematic reviews was added. Also, the mentioned sentence was removed.

Page 5, lines 24 to 28.

... previous systematic reviews performed in Latin America have shown that, while few studies have implemented physical-activity interventions to treat overweight and obesity, the implementation of physical-education policies and programmes is necessary to promote children's and adolescents' health, because these interventions can effectively create positive changes among this population

Objective

Comments 5: The objective still relates more to the paper rather than the proposed systematic review, whereas PRISMA-P states the objective presented here in the protocol needs to be the objective of the systematic review. Please present the objective of the systematic review here.

Authors: Thank you for the reviewer's comment. As suggested, we have modified the objective following PRISMA-P states.

Page 6, lines 5 to 8.

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

Methods and analysis

Comments 6: Much of the Methods section is now much clearer. There are, however, some minor amendments to be made to further improve clarity. First, the ordering of the sections could be clearer and more intuitive. Please revise to the following order: inclusion criteria; search strategy; selection of studies; data extraction. This way, each section builds on and is informed by the previous one. It seems remiss to be presenting search terms before the inclusion criteria have been presented.

Authors: Thank you for the reviewer's comment. Done.

Comments 7: In terms of searching, it is useful that a sentence on searching reference lists has been added. Reading over the whole section, I think this part would fit better at the end of the Search Strategy section. Also, please can you clarify whether citation searching will be undertaken, and how (e.g. using Google Scholar)? It would also be useful to clarify why MeSH headings and truncations will not be used. While a little clearer, the search strategy is still not completely clear, nor in a standard format. I strongly urge you to look at the paper by Aromataris and Riitano (2014) of the Joanna Briggs Institute or other similar literature, and present a search strategy in the standard format, for clarity and ease of replication.

Authors: Thank you for the reviewer's comment. As suggested, the search strategy has been changed.

Page 8, Table 1.

Comments 8: The revised sentence "Inconsistencies in data collection will be resolved with a third researcher" (p.7, lines 23-24) is clearer. Please further clarify the process, including the role of the third researcher.

Authors: Thank you for the reviewer's comment. The role of the third investigator was clarified.

Page 8, lines 10 to 12.

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.

Comments 9: The addition of a study selection section is useful and aids clarity. Again, I think a few small changes could further clarify. First, the sentence, "Also, this first review will be done to identify and exclude duplicate documents" (p.8, lines 21-22) suggests that de-duplication will not be undertaken until screening, whereas ideally the database should be de-duplicated prior to first screening. Inevitably, some duplicates will sneak through, however the bulk of the process should be done prior to screening, and this should be reflected in the flow diagram. Please amend accordingly. Second, the sentences

from “Each author will extract...” to the end of the paragraph (p.8, lines 23-27) should be moved to the Data Extraction section. Further, the newly added sentence, “Each author will extract the data of the same five studies...” (p.8, lines 23-25) does not pertain to piloting. It might aid clarity to revise this sentencing to something general like “The extraction tool will be piloted by all reviewers on the first five studies, to ensure consistency in data extraction.”

Authors: Thank you for the reviewer’s comment. The sentence was modified and your suggestion has been added.

Page 8, lines 5 to 8.

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.

Page 9, lines 3 to 5.

For the first five studies, the extraction tool will be operated by all researchers; this is performed to ensure that the data extraction is consistent and to create a ‘Table of Characteristics’ (Table 2).

Comments 10: It is useful that physical activity types have now been listed in the data extraction section (p.9, lines 4-5), however is this list comprehensive? Could it also include lifestyle physical activity?.

Authors: Thank you for the reviewer’s comment. We have included lifestyle physical activity in data extraction section.

Page 9, lines 9 and 10.

...lifestyle physical activity...

Comments 11: The additional information on synthesis is useful. Please check the grammar of the sentence, “Separating studies that included physical activity interventions...” (p.10, lines 2-4) as something seems to be missing here.

Authors: Thank you for the reviewer’s comment. The sentence has been modified.

Page 10, lines 10 to 14.

A narrative synthesis of the data extracted in the Table of Characteristics for the included studies will be conducted, and then a meta-analysis will be performed on studies that featured BMI pre-post interventions (separating studies that included physical-activity interventions from those in which physical activity and nutritional health were combined).

Comments 12: The additional fields added to Table 2 again aid clarity and comprehensiveness. Please consider presenting this in landscape orientation for additional clarity. What I presume to be the final column (there may be more that are now off the page) is partly obstructed by the page margins and is largely unreadable.

Authors: Thank you for the reviewer’s comment. Done.

Comments 13: Figure 1

I am not sure what happened in the process of uploading this figure, however it is now largely unreadable on the PDF available from the reviewer centre. Please can this be amended to clarify? Also, it is still unclear what X3 relates to, as there is no prior mention before (N3 - X3) = N4.

Authors: Thank you for the reviewer’s comment. The figure 1 was clarified.

Comments 14: Lastly, I have noticed a few (minor) grammatical errors/typos, mainly in the new text. Again, I am happy to make comments on the manuscript to highlight these if needed.

Authors: Thank you for the reviewer’s comment. A Native English-speaking colleague has reviewed the manuscript. We also sent the manuscript to a professional copyediting service.

VERSION 3 – REVIEW

| | |
|------------------------|--|
| REVIEWER | Emma Hock University of Sheffield, United Kingdom |
| REVIEW RETURNED | 13-Sep-2019 |

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| GENERAL COMMENTS | <p>I am satisfied that most of my comments have been addressed. Again, however, some of my comments seem to have been misunderstood, so I will endeavour to make these clearer. I have also noticed a few other aspects that warrant attention. They are as follows:</p> <p>Title I think it would read better if “a protocol for systematic reviews” was amended to “a protocol for a systematic review”.</p> <p>Abstract In line with my previous comments, I still think that the objective stated here should be the objective of the review (e.g. “the review aims to...”), as per the requirements of PRISMA-P.</p> <p>Strengths and limitations bullet points Delete the first one - this is implicit and is a function of the nature of a protocol, rather than a strength. Amend “research” to “review” in the second one.</p> <p>Introduction It is good to see that the problematic nature of BMI as a measure in children and young people has now been discussed or considered (p.6, lines 13-18). Reading this now, it seems logical to add in a sentence at the end reconciling these issues with your preference for BMI as a measure (e.g. despite these issues, you’re choosing to use BMI as an outcome measure because of X, Y and Z).</p> <p>It is also useful that you have added in some further detail on the prior evidence. I think there could be a bit more detail here, as this prior literature is what you are seeking to build on. Certainly, where “positive changes” (p.6, line 28) are mentioned, it would be useful to go into a bit of detail about what positive changes were reported.</p> <p>Objective In line with my previous comments, and as per my comment on the abstract, I still think that the objective stated here should be the objective of the review (e.g. “the review aims to...”), as per the requirements of PRISMA-P.</p> <p>Methods and analysis The sentence, “relevant references included in the selected studies will be screened as supplemental sources” (p.8, lines 12-13) could be reworded for clarity, for example to “Reference lists of included papers will be hand-searched” or similar.</p> |
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| | <p>The search strategy is a bit clearer and more detailed, however I still think it could be expressed more clearly, probably in terms of a list of steps (e.g. in an appendix), as is more traditional, as the current table format is still potentially confusing and quite hard to follow.</p> <p>The revised sentence “For the first five studies, the extraction tool will be operated by all researchers; this is performed to ensure that the data extraction is consistent and to create a ‘Table of Characteristics’ (Table 2)” (p.10, lines 3-5) is a bit clearer, however it could still be more clearly expressed. In particular, the part relating to the table of characteristics requires further explanation. Do you mean that this process of piloting will also help to refine this table/the fields in it, as well as being conducted to ensure consistency? Also, the language and phrasing in this sentence requires attention. It would be helpful to state somewhere in this paragraph that two reviewers will independently extract data (if this is the case; it says that in the strengths and limitations bullet points).</p> <p>The revised sentence “A narrative synthesis of the data extracted in the Table of Characteristics for the included studies will be conducted...” (p.11, lines 10-11) required further clarification, as it is usually the findings that are synthesised. If you are referring to a summary of the background and study characteristics, this is expected and doesn’t need to be stated in a protocol.</p> <p>Change “two analysis” (p.11, line 26) to “two analyses”.</p> <p>I think it might be better, certainly in your actual review, if not here, to split your Table 2 into two tables (one for population characteristics and one for intervention characteristics), to make them easier to read once populated.</p> <p>Figure 1 does not appear to be in this version at all - please can this be uploaded.</p> <p>Discussion The penultimate sentence of the Discussion section (beginning “In conclusion..”; p.15, lines 3-5) needs to be reworded in line with my comments on the objective, to something like, “The review we plan to undertake, outlined in this protocol, will provide an up-to-date synthesis of the effects of physical activity interventions on BMI among Latin American children and adolescents.”</p> |
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VERSION 3 – AUTHOR RESPONSE

Reviewer 4:

Title

Comments 1: I think it would read better if “a protocol for systematic reviews” was amended to “a protocol for a systematic review”.

Authors: Thank you. Done.

Abstract

Comments 2: In line with my previous comments, I still think that the objective stated here should be the objective of the review (e.g. “the review aims to...”), as per the requirements of PRISMA-P.

Authors: Thank you for the reviewer’s comment. As suggested, the objective has been restated according to PRISMA-P.

Page 2, lines 9 to 12.

“Thus, the objective of the systematic review and meta-analysis will be to provide an up-to-date synthesis of the effects of physical-activity interventions on BMI of Latin American children and adolescents aged four to 18 years.”

Strengths and limitations bullet points

Comments 3: Delete the first one - this is implicit and is a function of the nature of a protocol, rather than strength.

Amend “research” to “review” in the second one.

Authors: Thank you for the reviewer’s comment. Done.

Introduction

Comments 4: It is good to see that the problematic nature of BMI as a measure in children and young people has now been discussed or considered (p.6, lines 13-18). Reading this now, it seems logical to add in a sentence at the end reconciling these issues with your preference for BMI as a measure (e.g. despite these issues, you’re choosing to use BMI as an outcome measure because of X, Y and Z).

Authors: Thank you for the reviewer’s comment. As suggested, we have included a sentence justifying the use of BMI.

Page 5, lines 18 to 21.

“Despite these problems, BMI will be used because it is one of the most practical methods to evaluate the changes in adiposity in children and adolescents. Furthermore, it is widely used to measure the prevalence of overweight, obesity, and underweight in childhood.”

Comments 5: It is also useful that you have added in some further detail on the prior evidence. I think there could be a bit more detail here, as this prior literature is what you are seeking to build on. Certainly, where “positive changes” (p.6, line 28) are mentioned, it would be useful to go into a bit of detail about what positive changes were reported.

Authors: Thank you for the reviewer’s comment. As suggested, information about the positive changes described in previous evidence was included.

Page 5, line 31, and page 6, lines 1 and 2.

“... such as having a significant positive effect on BMI, as well as some anthropometric variables in children and youth with overweight and obesity, all through the promotion of physical activity and healthy diet.”

Objective

Comments 6: In line with my previous comments, and as per my comment on the abstract, I still think that the objective stated here should be the objective of the review (e.g. “the review aims to...”), as per the requirements of PRISMA-P.

Authors: Thank you for the reviewer’s comment. As suggested, the objective has been restated according to PRISMA-P.

Page 6, lines 9 to 11.

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

Methods

and

analysis

Comments 7: The sentence, “relevant references included in the selected studies will be screened as supplemental sources” (p.8, lines 12-13) could be reworded for clarity, for example to “Reference lists of included papers will be hand-searched” or similar.

Authors: Thank you for the reviewer’s comment. This was restated in the wording proposed by the reviewer.

Page 7, line 15.

“... reference lists of included papers will be hand-searched.”

Comments 8: The search strategy is a bit clearer and more detailed, however I still think it could be expressed more clearly, probably in terms of a list of steps (e.g. in an appendix), as is more traditional, as the current table format is still potentially confusing and quite hard to follow.

Authors: Thank you for the reviewer’s comment. As suggested, we have modified the table in terms of a list of steps.

Comments 9: The revised sentence “For the first five studies, the extraction tool will be operated by all researchers; this is performed to ensure that the data extraction is consistent and to create a ‘Table of Characteristics’ (Table 2)” (p.10, lines 3-5) is a bit clearer, however it could still be more clearly expressed. In particular, the part relating to the table of characteristics requires further explanation. Do you mean that this process of piloting will also help to refine this table/the fields in it, as well as being conducted to ensure consistency? Also, the language and phrasing in this sentence requires attention. It would be helpful to state somewhere in this paragraph that two reviewers will independently extract data (if this is the case; it says that in the strengths and limitations bullet points).

Authors: Thank you for the reviewer’s comment. The sentence was rephrased for clarity and the suggestion about the two reviewers was included.

Page 9, lines 3 to 7.

“Once the included studies will be identified, the information will be summarized in the ‘Table of Characteristics’ (Table 2), being the data independently extracted by two reviewers. For the first five studies, the extraction process will be performed by these two reviewers; this is performed to ensure that the data extraction is consistent.”

Comments 10: The revised sentence “A narrative synthesis of the data extracted in the Table of Characteristics for the included studies will be conducted...” (p.11, lines 10-11) required further clarification, as it is usually the findings that are synthesised. If you are referring to a summary of the background and study characteristics, this is expected and doesn’t need to be stated in a protocol.

Authors: Thank you for the reviewer’s comment. As suggested, the sentence was rephrased for clarity.

Page 10, lines 6 to 12.

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

Comments 11: Change “two analysis” (p.11, line 26) to “two analyses”.

Authors: Thank you for the reviewer’s comment. Done.

Comments 12: I think it might be better, certainly in your actual review, if not here, to split your Table 2 into two tables (one for population characteristics and one for intervention characteristics), to make them easier to read once populated.

Authors: Thank you for the reviewer's comment. In the actual review the table will be split as suggested.

Comments 13: Figure 1 does not appear to be in this version at all - please can this be uploaded.

Authors: Thank you for the reviewer's comment. As suggested, the Figure 1 has been uploaded.

Discussion

Comments 14: The penultimate sentence of the Discussion section (beginning "In conclusion.."; p.15, lines 3-5) needs to be reworded in line with my comments on the objective, to something like, "The review we plan to undertake, outlined in this protocol, will provide an up-to-date synthesis of the effects of physical activity interventions on BMI among Latin American children and adolescents."

Authors: Thank you for the reviewer's comment. The sentence was modified in accordance with the rewriting of the objective.

Page 14, lines 3 to 5.

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

VERSION 4 – REVIEW

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| REVIEWER | Emma Hock University of Sheffield |
| REVIEW RETURNED | 26-Oct-2019 |

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| GENERAL COMMENTS | I am satisfied that my comments have been addressed. There are just a couple of really minor amendments that could further improve the manuscript prior to publication. They are as follows: Methods and analysis In the Study selection subsection, the sentence "Abstracts that do not provide sufficient information regarding the inclusion/exclusion criteria will then be evaluated through a full-text reading." (p.9, lines 8-9) could be amended to "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." for clarity. |
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| | <p>In the Data extraction subsection, the part about the Table of Characteristics needs to come after the part about data extraction (to be consistent with the order of the review process).</p> <p>Thank you for providing Figure 1. I can see that it is much clearer now than in the previous draft. There is just one point of clarification that I can see; “irrelevant records excluded in the basic of title and abstract review” could be amended to “irrelevant records excluded on the basis of title and abstract review” or similar.</p> |
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VERSION 4 – AUTHOR RESPONSE

Reviewer: 4

Methods and analysis

Comments 1: In the Study selection subsection, the sentence “Abstracts that do not provide sufficient information regarding the inclusion/exclusion criteria will then be evaluated through a full-text reading.” (p.9, lines 8-9) could be amended to “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.” for clarity.

Authors: Thank you. Done.

Page 8, lines 8 and 9.

“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.”

Comments 2: In the Data extraction subsection, the part about the Table of Characteristics needs to come after the part about data extraction (to be consistent with the order of the review process).

Authors: Thank you. Done.

Page 9, lines 14 to 17.

“[...] (10) type of nutritional intervention (food education, nutritional counselling, diet intervention); and (11) characteristics of this nutritional intervention (length of intervention). When necessary, the authors of potentially eligible studies will be contacted to obtain any missing data. The information will be summarized in the ‘Table of Characteristics’ (Table 2), being the data independently extracted by two reviewers. For the first five studies, the extraction process will be performed by these two reviewers; this is performed to ensure that the data extraction is consistent.”

Comments 3: Thank you for providing Figure 1. I can see that it is much clearer now than in the previous draft. There is just one point of clarification that I can see; “irrelevant records excluded in the basic of title and abstract review” could be amended to “irrelevant records excluded on the basis of title and abstract review” or similar.

Authors: Thank you. Done.

We would like to thank the reviewer for their involvement and patience in improving this manuscript. We believe that with your comments this protocol and future systematic review have improved substantially