Author's response to reviews

Title: The Program SI! intervention for enhancing a healthy lifestyle in preschoolers: First results from a cluster randomized trial

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Author's response to reviews: see over
Dear Editor,

Please find attached the amended version of our paper entitled ‘The Program SI! intervention for enhancing a healthy lifestyle in preschoolers: First results from a cluster randomized trial’ addressing all Reviewers’ suggestions.

We very much appreciated the comments as they raised very important points, which allowed for major improvements in our manuscript. You will find below a point-by-point answer to the comments made by the reviewers (in italics), and indications to the changes made to improve the manuscript.

Following Editorial remarks, we have also ensured that the paper conforms to the journal style, and we have therefore split Results and Discussion into two separate sections. This has added clarity to the message, as well as revising the English grammar throughout the paper one more time.


**Reviewer's report 1**

**Major Compulsory Revisions:**

*Particularly in the methods section, the text is written in a mix of past and present, which may confuse the reader.*

Language has been revised throughout the text, and specially in the indicated section.

*Page 4-5: It is unclear whether the “series of inclusion/exclusion criteria” mentioned on page 4 are those mentioned on page 5 (e.g. whether having school canteen services were an inclusion criterion, and receiving student scholarships as exclusion criterion), or whether additional - undescribed – criteria were used. The paragraph has been rewritten for clarity. All the inclusion/exclusion criteria are mentioned in this part of the manuscript.*

*Page 7: The paper would improve if the description of the used questionnaire is more thorough. How where the scores obtained? A more detailed description of the questionnaires has been included.*

*Page 10, paragraph 2, line 6-7: Do the confidence intervals and the p-value refer to the same difference in scores? If so, please put them in the same line to clarify. Corrected according to suggestion.*

*Page 12: Please provide a reference on the study from Colombia Reference provided.*

**Minor Essential Revisions**

*Page 4: I think it is more correct to write “chance of a type-I error of 0.05” rather than “type-I error of 0.05”*  
Re-written accordingly.

*Page 7: Something may be missing after “12” in the first parenthesis Changed to ‘(3 notes per component for a total of 12 notes)’*
This paper reports on the effectiveness of a year-long intervention in 12 preschools in Spain. Effects of the intervention on 3-5 year-old children’s outcomes such as attitudes and health behaviors are compared to changes observed in children of 12 control schools. The design is a sound cluster-randomized trial and the statistical analysis using a mixed linear model and testing interactions seems reasonable. The intervention approach is innovative as it targets—in addition to traditional lifestyle factors such as diet and physical activity—the children’s emotional control (as part of an integrative approach). The paper however does not give detailed explanation of what really was done in the intervention schools to promote emotional control of children, nor can this information be found in the cited study design paper. Also, details on which items are contained in the outcome scores are lacking, both in the manuscript and in the referenced BMC Public Health Paper.

Very detailed information on the intervention strategies and materials for emotional control and other components has been provided on page 7. Additional information on the questionnaires scoring has been introduced on pages 9 and 10.

The involvement of parents in the SI! intervention relies on health education strategies, e.g. the provision of a website and homework tasks over the weekend. Previous research however has repeatedly suggested that health education and knowledge communication might not be sufficient to achieve behavior change—which might be mirrored in lacking effects on the parent and teacher level in this study. Another explanation for lacking effects on the parent and teacher level could be that the intervention did not reach into these target groups. However, the authors do not provide any information on the issue of to what extent the target groups were reached. Modern articles on intervention effectiveness should at least incorporate some measures of intervention process, e.g. by describing reach, adoption, fidelity, maintenance of the intervention. The authors do not take this opportunity, probably because they do not have data on the intervention process. This however is a major shortcoming of the manuscript.

Before release, the Program SI! for preschoolers underwent pilot testing on volunteer schools of Madrid and Barcelona, and strategies and materials were improved after qualitative evaluation through focal groups of teachers, and parents. Results on the satisfaction questionnaires were 8.4/10 for school principal and 7.3/10 for teachers.

After one year, a very small effect has been observed in parents and teachers but we foresee a greater impact at the end of the evaluation, with is the primary endpoint of this trial—a 3-year change in KAH for children, parents, and teachers. We present here these data as interim results and as a proof-of-concept that our intervention is successful.

Intervention on teachers and parents goes beyond the simple transfer of information. We suggest simple activities focused on facilitating time and space for parents to interact with their children. Both parents and teachers have access to the password-restricted Program SI! website, which contains a large number of extra resources available for parents who are interested in learning more and all the materials for teachers. Likewise, teachers have access to a blog and a forum where they can share their experiences, as well as on training sessions. A more detailed description of the teachers and parents intervention has been included on pages 7 and 8.

Major Compulsory Revisions

1. The authors’ comparison with previous literature is limited to a study in Colombia (which is their own) and one in native Americans. The authors should cite other relevant studies e.g. in UK and Europe (countries which might be more comparable to Spain) and compare with intervention studies in preschool age, which used behavioral outcomes such as diet or physical activity as outcome measures.
This section has been re-structured and re-written accordingly. Other relevant studies have been added for comparison but we have purposely restricted our discussion to those that focus mostly on intermediate indicators such as KAH. There have identified >28 references on interventions in preschoolers that we aim to introduce in future papers, after we calculate the impact of our intervention in clinical outcomes (i.e. obesity).

2. The clinical relevance of the changes in the "knowledge-attitudes-habits" scores remains unclear. What does a change of 3.45 on a scale from 0-30 mean in terms of health benefits? The authors have to discuss the potential health benefits of the improvements on their scores.

A sentence addressing this point has been added into the discussion: There is a 5.1% differential increase in the overall score for the intervened children. This differential improvement is likely to continue increasing until the end of preschool, providing children with the appropriate tools to maintain healthy lifestyle habits. Also, the use of intermediate indicators (scores) as opposed to hard outcomes (obesity) is thoroughly argued on the discussion section.

3. This underlines a general problem of this study: Interpretation of effect sizes in the unit of scores, which are not commonly used and under-explained in the paper seems hardly possible for readers. The referenced BMC Public Health Paper does not describe the specific items used for the author’s outcome scores and their measurement, either. The authors should provide more information for clarification. They should also explain which characteristics of the school environment were measured. It is not enough to mention that the teachers filled out a questionnaire (page 7).

As it is stated in Material and Methods, we used scores that were developed in our first Study in Colombia. Full information can be found in the given references. Anyhow, a brief explanation on the questionnaires is now included. Also, detailed information on the school environment questionnaire has been added (page 10).

4. More information is needed on the specific intervention strategies to promote emotional wellbeing, as they seem to be the innovative part of the SI! Intervention compared to previous dietary and physical activity interventions in preschool age.

Information on the intervention strategies and materials for emotional control has been provided on page 7.

5. There are several limitations that the authors should mention:

6. A limitation of the current study – in comparison with previous studies – is the lack of any “hard outcomes” such as anthropometric. In most previous intervention studies, short-term behavioral changes as reported in this study have been shown to be not sustainable, so the overall intervention benefit is unclear unless anthropometry outcomes are included. The authors have to discuss this issue.

Anthropometric measurements are included in the protocol, and are currently ongoing. In this paper we present the results of the 1st year of a 3-years intervention and we purposely did not include ‘hard outcomes’ as we would like this report to be a proof-of-concept of the success of the Program SI! intervention.

7. The authors use the „social cognitive model” and trans-theoretical model as theoretical framework for their intervention approach and their outcome measurements in young children. However, several authors have noted that differences between dietary behaviours and the addictive behaviours upon which the transtheoretical model was originally based may cause problems for the model (Povey et al, Health Educ. Res. (1999) 14 (5): 641-651.). Also, a transfer of the stages of change model to children of young ages seems questionable (Corden and Somerton, British Journal of Social Work (2004)34,1025–1044). The authors should – if possible - reference papers investigating the validity and the
transferability of both the social cognitive model and the stages of change model to children of ages 3-6 years.

We used the concept of the Trans-Theoretical Model of Change as the basis of behavior change, but we did not use the 5 stages of change to categorize the participants. For this study, we have aggregated the 5 levels in a KAH-score, we aggregated "pre – contemplative" and "contemplative" stages as the acquisition of knowledge (K), the "preparation" phase as an intention to change and therefore attitude (A), and the last stages "action" and "maintenance" as the acquisition of the habit (H). Our questionnaires have been developed specifically to calculate a score that allow us to assess the changes on each area (KAH) and component (D, PA, HB, E). In the questionnaires in any case are the stages of the Trans - Theoretical Model of Change, so we do not have the risk of misclassification when applying the method in this population of children and adults since they do not have to classify themselves into different stages of change (Povey et al 99).

The sentence „This structure corresponds to children’s cognitive development from understanding concepts (K), through intending to set this knowledge into practice (A), to eventually acquiring the desired behavioral pattern (H).” should be formulated much more cautious (or a reference should be given).

The sentence has been reformulated as to be more cautious following Reviewer’s concern.

The potential invalidity of theory in young preschool children should be mentioned in limitation section.

A full paragraph has been included in the limitations section addressing this issue. References have also been provided.

8. The manuscript lacks details on the intervention’s processes: If no effects in teachers nor parents were seen, is this due to a low reach into the teacher population? How about the fidelity with which the intervention was delivered? Was it maintained throughout the school year? The authors should present at least some intervention process data, otherwise the results and the relevance of the effects are not well interpretable.

Information on the intervention strategies for teachers has been included on pages 7 and 8. School’s adherence to the intervention is enhanced by the continuous support in each school from external (Program SI! coordinator) and in-house (school coordinator) supervisors that monitor all intervention processes and compliance with the minimum requirements. Program SI! coordinator meets teachers at least once per quarter, thus we can assure the fidelity is maintained throughout the school year. As mentioned before, teachers have access to a blog and a forum where they discuss any aspect of the intervention and where the Program SI! coordinators are actively involved, collecting metrics and reports on the different processes.

9. The involvement of parents in the SI! intervention relies on health education strategies, e.g the provision of a website and homework tasks over the weekend. Previous research has shown that health education and knowledge communication might not be enough to achieve behavior change – which might be mirrored in lacking effects on parent and teacher level in this study. Please discuss this and mention under limitations.

Although it is true that a very small effect has been observed in parents and teachers, it has to be remembered that the primary endpoint of this trial is a 3-year change. We present here these data as additional information, until the final endpoint is reached. As mentioned before, the intervention on parents goes beyond the simple transfer of information. We suggest simple activities focused on facilitating time and space for parents to interact with their children.
Minor Essential Revisions

1. **Page 4:** Please mention the primary outcome on which you powered the study. Also explain, to what extent your study was powered for the subgroup analyses presented in figure 2.

   The primary endpoint for power calculation was the overall-KAH score for children. Sample size and power were calculated assuming 50 children of age 3, 50 children of age 4, and 50 children of age 5, per cluster (that is 6 classes of 25 children per school). Therefore age-stratified analyses were planned at the design stage.

2. **Page 5:** the exclusion criteria mentioned are too vague: what was a high percentage of immigrant background?

   This information is provided in the referenced study protocol, but the paragraph has been re-written for clarification.

3. **Page 7:** Please include the intervention website’s url-address to check for the interested reader.

   Information on the website is now provided.

4. **Page 12:** The authors’ comparison of their own behavioral outcomes with studies using objective anthropometric outcomes is inadequate. The authors do not know whether their intervention is more successful than "Previous school-based intervention studies that focused on clinical outcomes" as they have not measured clinical outcomes. Please rephrase.

   The paragraph has been rephrased to indicate more precisely the meaning of the phrase.

Discretionary Revisions

1. **Page 13:** "would be necessary" - Please add dot at the end of the sentence

   Done