Title: One- and two-year effects of the Healthy Primary School of the Future on children's dietary and physical activity behaviours

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Dear editor,

Thank you for allowing us to submit a revised version of our manuscript. We also want to thank the reviewers for their comments on the manuscript. The comments have been helpful in improving our manuscript. Below we explain how we incorporated the comments in our revision. In the manuscript we have used the track changes option.

Reviewer 2

Dear authors,

Your paper is a very interesting study that illustrates the importance of implementing interventions to promote healthy lifestyles to school children, in a new scope. However, some aspects of methodology and results must be further detailed to improve the data provided. For instance, it is necessary to improve and clarify the readability of the methodology and results section, and the discussion about the clinic relevance of their results.

We thank the reviewer for the positive feedback regarding the importance and the scope of our paper. We will address all the points of the reviewer point-by-point below.

Major Comments:

TITLE AND ABSTRACT:

- clarify in the title if the study is non-randomized. Also, intervention, school-based, and follow-up are important keywords in the title and abstract of this work.

We checked the title, abstract, and the listing of keywords on relevant keywords. We added 'quasi-experimental study' to the title of the manuscript and 'follow-up' to the listing of keywords.

INTRODUCTION

- There is fewer information about other programs focused on improving lifestyles of children in schools. Is the HPS the best initiative? There are other interventions applied at school context that are effective?

We aimed to show that school-based interventions that did not use a health-promoting school approach are often not sustainable in its implementation and its effects because they are often not

integrated in the school system and are characterised by relatively low priority, a lack of coordination, and are often supply-driven. We now stated this more clearly in the introduction section.

Page 2, Line 66-71: *'Schools are increasingly recognized as significant in improving children's health behaviours since a large proportion of a child's day is spent there, and schools reach all children [13, 14]. However, school-based health interventions are often not integrated in the school system and are characterised by relatively low priority, a lack of coordination, and are often supply-driven, resulting in limited effects or effects that diminish on the long term [15, 16].'*

METHODOLOGY

Study Design

- Please, improve the information about the type of study. Also, in general, improve the information of the manuscript. The CONSORT checklist could you help in this process.

We thank the reviewer for this comment. We revised the methodology paragraph and adjusted it to provide more specific information where necessary, in line with the CONSORT checklist. We refer to the other comments, where we indicate the text improvements on study design, the Healthy Primary School of the Future, and the study population.

- Define more specifically the type of intervention: Is a cluster non-randomized study? Is an intervention? is a school-based intervention?

The type of intervention is a whole-school approach, with a focus on reorienting school systems toward sustainable health promotion. The Health Promoting School (HPS) framework focuses not only on classroom-based health education, but also on changes in school policy and the schools' physical and social environment, using bottom-up involvement of pupils, parents, teachers, and staff. The design of the study, used to investigate the effects of HPSF on children's health behaviours, was quasi-experimental. We added the type of design more explicitly in the Methods section and also in the title of the manuscript.

- The control schools started at the same time as intervention schools?

The included control schools use a school approach that is currently common practice in the Netherlands. They did not change anything, but only participated in the measurements. These measurements were conducted at the same time as the intervention schools. We added this information to the manuscript as follows:

Page 3, Line 111-113: *'The current study has a longitudinal quasi-experimental design with four intervention schools (two full and two partial) and four control schools, which use a school approach that is currently common practice in the Netherlands.'*

Page 3, Line 121-122: '*Measurements in all eight included schools were conducted in September-November of 2015 (T0), 2016 (T1) and 2017 (T2);*'

- There is no information about the inclusion and exclusion criteria.

We did not have exclusion criteria. All children and their parents in the eight schools were invited to participate. We now added this information to the study population section:

Page 4, Line 174-175: '*All children (age 4 to 12) and their parents from the eight schools (n=2326 at T0) were invited to participate in the study, no inclusion or exclusion criteria were set.*'

<u>The Healthy Primary School of the Future</u>

- Describe the intervention more specifically. The TIDIER checklist is an interesting tool to explain the interventions in the manuscripts.

The reviewer is right that the information about the components of HPSF was incomplete. We added and improved the information in the methods section, in line with the topics in systematic reporting checklists such as TIDieR:

Page 3, Line 125-166: *'Three collaborating organisations, i.e., the regional educational board 'Movare', the regional Public Health Services and Maastricht University, developed the HPSF initiative. The initiative is based on the principles of the HPS framework and aims to sustainably integrate health and well-being within the whole school system by creating health-promoting changes in different aspects of the school system, i.e., school's physical and social environment, school's health policy, education, and school routines. On top of the HPS framework, the aim was to create some form of positive disruption in the school, by initiating two changes top-down: 1) a free healthy lunch each day (only in full HPSF) and 2) structured PA sessions after lunch. These changes are contextualized bottom-up and should lead to momentum for bottom-up processes to institutionalise health-promoting routines in the school. The time for having lunch (in the full HPSF) was increased to 20-30 minutes. A dietician of the caterer developed a lunch menu cycle that changed every ten weeks, in which at least 80% of the products met the advice of the Dutch Health Council [33]. A mid-morning snack, consisting of fruits and/or nuts, was also provided. The lunch, a bread-based cold meal, was typically Dutch. After lunch, the children participated several times a week in structured PA sessions; one or two times per week they could participate in cultural activities. The PA sessions were carried out in the schoolyard and, when available and needed, in parks, forest, and/or sports hall in the neighbourhood. All schools collaborated with sport clubs or other external partners to offer specific activities as well. Since the two changes were contextualized bottom-up, this resulted in some differences between schools in the form of the changes; the content remained comparable. To not increase the workload of teachers even further, the top-down changes were implemented by external pedagogical employees provided by childcare organizations. Due to this integration of the childcare organization during school hours, the aim is not to provide a temporarily solution, but to change the school's organization in a sustainable way. Employees of sports and leisure organizations supported these pedagogical employees during implementation when needed, and after a year they provided a training course (8 sessions of 2 hours) to teach and improve the methods how to stimulate children to become physically active.'*

… 'Differences existed in the implemented additional health-promoting changes. The full HPSF improved their health policy, provided water bottles to all children, and provided an educational lunch once a week. The partial HPSF did not implement additional health-promoting changes.'

- Why the PA was done after lunch?

The extra PA sessions in the schools did not aim to replace the physical education lessons. The PA sessions aimed to provide a moment during the day where children could be physically active. In Dutch primary schools, children have a break after lunch where they go outside and are free to play, but often they behave mainly sedentary. By structuring this break (both full and partial HPSF) and extending the time for this break (only full HPSF), the aim was to increase children's physical activity.

Study population

- The authors mention a cohort study. It is a cohort? Or it is a follow-up post-intervention study?

The population consists of children from the eight schools, therefore we call it a dynamic cohort, as it changes every year (i.e. new children enter the cohort in the youngest age-group and children in the oldest age-group leave the cohort). From this dynamic cohort we selected a specific cohort of children to include in our study. The cohort of children included were: at baseline (T0) children from study year one to seven, at T1 children from study year two to eight, and at T2 children from study year three to eight. Children in this cohort who joined the study at T1 or T2 were included, even though no baseline data were available. Children who switched to other schools between T0 and T2 were excluded.

Questionnaires

- Why parents have 3 months to fill in the questionnaires?

The parents had access to the digital questionnaire from the moment the measurements started in the school of their child(ren). We had one moment where we closed the digital questionnaire for everybody. The parents of the schools where the measurements were conducted latest had approximately one month to fill out the questionnaire. The parents of the schools where the measurements were conducted first had approximately three months to fill out the questionnaire.

Outcomes

- Please, specify the principal and secondary outcomes.

The overall study to investigate the effects of HPSF includes many different outcomes. The current study is part of this overall study. The primary outcome is BMI z-score. Children's dietary and physical activity behaviours were secondary outcomes. The study design of the overall study is described in Willeboordse et al.

Willeboordse M, Jansen M, van den Heijkant S, Simons A, Winkens B, de Groot R, et al. *The Healthy Primary School of the Future: study protocol of a quasi-experimental study*. BMC Public Health. 2016;16(1):1.

- Which variable is used to calculate the sample size of the study?

The primary outcome of the overall study, BMI z-score, was used to calculate the sample size. This calculation is also described in Willeboordse et al. (2016).

- The lunch of HPS intervention schools is not known by the authors? Why is necessary to assess if it is healthy?

The lunch is a buffet, where many different products are offered; the children can take what they want. Since the children can create their own combinations of lunch, we assessed which food types they consumed during the lunch.

- The children's dietary behaviors questionnaires and the score used by the authors are validated?

The child questionnaires were based on the validated parent questionnaire, but simplified to make it appropriate for children. We did not validate these adapted questionnaires. However, we pretested them for difficulty, length, and content among experts in the field of health promotion, the target group, e.g. individual children and parents, and classes of children in a primary school. We decided to use total scores for healthy and unhealthy dietary behaviours, due to the high number of dietary outcomes, and the fact that small changes in several specific dietary behaviours could be better detected by using total scores. This information has now been included in the revised manuscript,

RESULTS

- The results are not clear. Please, improve the results section, explaining in the text the percentage improved (not only the p-value).

We went through the Results section in order to improve its readability. We only mentioned p-values in the first paragraph of the results section. A percentage improved is not applicable here, in our opinion. In the other paragraphs we mention effect sizes. We did not mention p-values in the text, but only mention the effect sizes, in order to avoid redundancy with the table.

- Moreover, the tables indicate numbers, but which clinical significance represent this? These scholars follow or not the recommendations?

In this study, and according to the current state of art, we aimed to show whether the children improved their health behaviours and to what extent, not whether they meet specific recommendations. We used effect sizes to indicate how large the effects were, in addition to their statistical significance.

- Please, indicate in the footnotes of the tables, the statistical tests used.

We added this information to the footnotes of the tables, as the reviewer suggested. An example of changes in the footnote of table 1:

Page 10, Line 345-351:

** Significantly different at baseline compared with the control schools, analyzed by ANOVA tests (continuous outcomes).*

[a] Improved: Percentage of children who improved, i.e., changed in a favourable direction, compared with their baseline score.

[b] Analyzed by linear mixed model analyses (continuous outcomes), adjusted for baseline, gender, study year at T0, SES, ethnicity, and BMI z-score at T0.

[c] Analyzed by linear mixed model analyses (continuous outcomes), adjusted for baseline, gender, study year at T0, SES, ethnicity, BMI z-score at T0, mean temperature, sun exposure in hours/day and precipitation in hours/day.

- Does the school water represent a problem in primary school scholars?

Yes, this typically is a problem in the Netherlands. Regular primary schools allow children to bring their own drinks, which they can consume during the breaks. Often children bring sugar-sweetened beverages to drink. Moreover, during lessons children are in general not allowed to have a bottle of water next to them on the table. These aspects together, result in a low consumption of water during school hours.

DISCUSSION

- Discussion section should be improved reflecting all the comments to the authors. The most important part, is explained how this project is useful to improve the health of scholars? Which clinical relevance has the results obtained?

We interpret clinical relevance as relevance for public health or practically relevant. Improvements in health behaviours, especially with a moderate or high effect size, can then be seen as practically relevant. In this study we aimed to show this practical relevance by investigating whether the children improved their health behaviours and to what extent. We improved the discussion section by providing more information on the health-promoting aspects of the intervention as follows:

Page 16, Line 426-431: *'HPSF is a health-promoting school initiative that uses a contextual systems approach [17, 27, 28]. The initiative aims to create health-promoting changes in different aspects of the school system, i.e., school's physical and social environment, school's health policy, education, and school routines. On top of the HPS framework, the aim was to create some form of positive disruption in the school, which should lead to momentum for bottom-up processes to institutionalise health-promoting routines in the school.'*

Page 18, Line 529-532: '*By the current study we were able to investigate the effectiveness of the full and partial HPSF compared to control schools regarding children's health behaviours after one and two years' follow-up. Taking all results and limitations into account, we conclude that the full HPSF is effective in promoting children's health behaviours at T1 and T2 compared with control schools.'*

- The major strength of the study is not a strength; the non-randomization is a limitation.

We can see both a strength and a limitation of the study design. We tried to explain this in the manuscript, but agree to the reviewer that we state it in the first sentence too much as only a strength. We changed as follows:

Page 17, Line 501-507: *'The longitudinal quasi-experimental design is both a strength and a limitation of this study. Due to the design, we were able to test the effectiveness in terms of differences in children's health behaviours between the three school groups over time, and were also able to enroll schools on the basis of motivation, which reflects the real-life situation of school health promotion. However, a limitation of the quasi-experimental design is the fact that we were unable to (cluster-)randomize schools. This has probably resulted in significant baseline differences between the three groups.'*

CONCLUSIONS

- The conclusion could be more specific, the intervention is effective at T1 and at T2?

We added this to the conclusion as follows:

Page 18, Line 531-532: '*Taking all results and limitations into account, we conclude that the full HPSF is effective in promoting children's health behaviours at T1 and T2 compared with control schools.'*

- Although the intervention was effective, which clinical relevance had? Which would have to be increased to be considered significant?

In this paper, we interpret clinical relevance as relevance for public health or practically relevant. Improvements in health behaviours, especially with a moderate or high effect size, can then be seen as practically relevant. In this study we aimed to show this practical relevance by investigating whether the children improved their health behaviours and to what extent.

FIGURES AND TABLES

- The authors should use the flow diagram of CONSORT.

We agree to the reviewer that a flow diagram would add to the current paper. This has been reported in another study by the same research group (Bartelink et al. submitted). As such, we refer in the manuscript to this study.

Page 7, Line 317-321: '*Due to the selection used for the current study, i.e., only including the children who were in study years one to seven at baseline and excluding school switchers, we included 1676 children in the analyses. This selection and the study's flow diagram are similar to the study that investigated the one- and two-year effects of HPSF on children's BMI z-score [46].*'