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Can the Healthy Primary School of the Future offer perspective in the on-going obesity epidemic in young children? – a quasi-experimental study

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Abstract

Objectives: Schools play an important role in promoting healthy behaviours in children and can offer perspective in the on-going obesity epidemic. The 'Healthy Primary School of the Future' (HPSF) aims to improve children's health and well-being by enhancing school health promotion. The current study aims to assess the effect of HPSF on children's BMI z-score after one and two years' follow-up and to investigate whether HPSF has different effects within specific subgroups of children.

Design: A longitudinal quasi-experimental design.

Setting: Four intervention and four control schools participated; located in a low socio-economic status region in the Netherlands.

Participants: 1676 children (aged 4-12 years).

Interventions: HPSF uses a contextual systems approach and includes health-promoting changes in the school. Central to HPSF are the provision of a daily healthy lunch and structured physical activity sessions each day. Two intervention schools implemented both changes (full HPSF), two intervention schools implemented only the physical activity change (partial HPSF).

Main outcome measures: BMI z-score, determined by measurements of children's height and weight at baseline, after one and two years' follow-up.

Results: The intervention effect was significant after one-year follow-up in the partial HPSF (standardized effect size ES=-0.05), not significant in the full HPSF (ES=-0.04). After two years' follow-up, BMI z-score had significantly decreased in children of both the full HPSF (ES=-0.08) and the partial HPSF (ES=-0.07) compared with children of the control schools, whose mean BMI z-score increased from baseline to two years. None of the potential effect-modifiers (gender, baseline study year, socio-economic status, and baseline weight status) were significant.

Conclusions: HPSF was effective after one and two years' follow-up in lowering children's BMI z-scores. No specific subgroups of children could be identified who benefitted more from the intervention.

Trial registration: The study was registered in the ClinicalTrials.gov database on 14 June 2016 (NCT02800616).

Strengths and limitations of this study

- Due to the longitudinal quasi-experimental study 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.
- Since the lack of randomization could have resulted in confounding bias, we controlled for baseline BMI z-score, gender, study year at T0, SES score, and ethnicity in all analyses.
- The high number of children enrolled in the measurements, the low drop-out rate, and the objectively measured BMI were strengths of this study.
- Due to some missing data, multiple imputations were used and a sensitivity analysis was conducted, where only complete cases were included.
- Participants did not significantly differ from non-responders in the participating schools and other children in the region with regard to health and lifestyle.

Introduction

Overweight and obesity can lead to health problems, such as type 2 diabetes, cardiovascular diseases, and psychological problems (e.g., low self-esteem) [1, 2]. Globally, the prevalence of overweight and obesity among children and adolescents (aged 5-19) has risen dramatically from 4% in 1975 to more than 18% in 2016 [3, 4]. The prevalence is highest among children with a low socio-economic background [5]. In the Netherlands, the prevalence of childhood overweight and obesity has also increased in the last decennia: 13–15% of children (aged 2–21 years) are overweight, and 1.8–2.2% are classified as obese, which is a 2- to 3-fold increase compared with 1980 [6]. The ongoing epidemic increase is particularly caused by unhealthy behaviours, such as unhealthy dietary intake and low levels of physical activity (PA) [7]. Such unhealthy behaviours at a young age often track into adulthood [8] and are related to health and psychosocial problems, reduced quality of life, higher health care costs, and lower educational achievement and labor participation [9-11]. A vicious circle is emerging, transferring problems, such as obesity, from one generation to the next [12]. Promoting healthy behaviours at an early age may help to improve children's health as well as their educational achievements; both may lead to improved health in later life [13].

Schools can play an important role in promoting healthy behaviours in children and thereby help to offer perspective in the on-going obesity epidemic in young children, since a significant proportion of a child's day is spent there, and schools reach all children [14-16]. Many different school-based interventions (e.g. related to education, environment, policy, monitoring) have been implemented to integrate health into the school system and reduce childhood overweight and obesity. The meta-analysis of both Cook-Cottone et al. and Oosterhoff et al. found that the significant effect of school-based interventions on children's Body Mass Index (BMI) z-score had an overall weighted effect size of approximately -0.05 [17, 18]. Several studies indicated that effects are often hampered by underestimation of the challenges associated with implementing meaningful changes to the school system [19-21]. These challenges occur because an intervention always interacts with the specific school context [20, 21]. Therefore, solutions for the challenges associated with changing school systems vary between schools as they all have their own dynamics [20-22]. Consequently, an intervention can be seen as an attempt to positively disrupt the prior functioning of a school system [23, 24]. Some other reviews stated that specific subgroups of children benefit more from a school-based intervention. The review of Stewart-Brown et al. [25] found that several studies indicated gender-specific results, with some school-based interventions being more effective in girls and others in boys. Age-specific effects were often found, with some interventions being more effective in older children and others in younger children [25]. Cook-Cotton et al. found that children's socio-economic background can be an influential factor and that children already having overweight can respond more slowly or to a lesser extent to school-based interventions than other children [17].

A Dutch initiative that embraces a contextual systems approach is the 'Healthy Primary School of the Future' (HPSF) [26, 27]. HPSF aims to improve the health and well-being of all children in the school which should contribute to a healthier future generation and thereby offer perspective in the on-going obesity epidemic [28]. HPSF includes top-down and bottom-up processes to create health-promoting changes in the school. Two changes were initiated to create some form of positive disruption in the school: 1) providing a free healthy lunch each day and 2) daily structured physical activity (PA) sessions after lunch. While in other national school systems this may represent usual practice, these changes are hypothesized as disruptive to the Dutch school system because the provision of school lunches and structured PA sessions are not usual practice in Dutch schools. The two changes aimed to create momentum to implement additional health-promoting changes in the school, such as a healthy school policy or creating a PA-friendly schoolyard. All changes together should favourably affect the health behaviours of all school children, which should lead to improved health and a more normal weight status [26, 27].

The aim of the current study was to assess the effect of HPSF on children's BMI z-score after one and two years' follow-up and to investigate whether HPSF has different effects within specific subgroups of children. The current study is part of an overall study to investigate the effects of HPSF. The overall study has a broad scope and includes a multi-disciplinary research group, which focuses on many different outcomes, such as children's health behaviours, educational achievements, and well-being. This study explicitly concentrates on the primary outcome, BMI z-score, as described in the study design of Willeboordse et al. [26].

Methods

Study design

The current study had a longitudinal quasi-experimental design with four intervention schools and four control schools, which maintained the school curriculum that is currently common practice in the Netherlands. Ethical approval (14-N-142) was given by the Zuyderland Medical Ethics Committee located in Heerlen (Parkstad, the Netherlands). Parents had to sign an informed consent form to participate in all measurements for themselves and their child(ren). Measurements were conducted in September-November of 2015 (T0), 2016 (T1) and 2017 (T2). A detailed description of the study and the power calculation is reported in Willeboordse et al. [26].

The Healthy Primary School of the Future

Three collaborating organisations, i.e., the regional educational board 'Movare', the regional public health services and Maastricht University, developed the idea for HPSF [26]. The two changes, i.e. providing daily a free healthy lunch and structured PA sessions after lunch, were both led by external pedagogical employees provided by childcare organizations. Two of the four intervention schools decided to implement both the daily lunch and the structured PA sessions and are referred to as the 'full HPSF'. The other two intervention schools decided to only implement the structured PA sessions, and are referred to as the 'partial HPSF'.

The time for having lunch (in the full HPSF) was increased to 20–30 min. The total lunch break time in these schools was prolonged by about 60 min. For this reason, the school day was extended: children of the full HPSF attend school to approximately 15:30/15:45 instead of 15:00. A dietician of the caterer developed a lunch menu cycle that changed every 10 weeks, in which at least 80% of the products met the advice of the Dutch Health Council [29]. A mid-morning snack, consisting of fruits and/or nuts, was also provided. The lunch, a bread-based cold meal, was typically Dutch. During lunch break time, 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. Employees of sports and leisure organizations supported the external pedagogical employees during implementation when needed, and after a year they provided a training course (8 sessions of 2h) to supply them with additional tools for how to motivate children for active participation during the PA sessions.

All schools could implement additional health-promoting changes, that fit their school context [27, 30]. 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. Implementation started in all four intervention schools in November 2015.

Patient and public involvement

Public involvement was a key feature of HPSF. This intervention intended to establish a co-creation movement in schools aimed at the systematic incorporation of health and well-being. The two top-down changes and the additional health-promoting changes were developed and contextualized by bottom-up involvement. Teachers and parents were involved in the adoption decision and the process of adapting the two changes into the school context. Moreover, all four schools used a children voice group, with representatives from each class in school, to get insight into the opinion of children regarding HPSF. In this way, the experiences of children were being heard and the changes could be further contextualized to fit better to the children's needs and wishes. HPSF was led by an executive board with representatives of the three collaborating organisations: Movare, the regional public health services and Maastricht University. They discussed the study design, the relevant outcome measures, and the interpretation of the results. The representative of Movare advised explicitly on school and participant recruitment and the communication to schools. No patients were involved in this study.

Study population

All intervention and control schools are situated in the Parkstad region in the southern part of the Netherlands. This region has a low average socio-economic status (SES), and unhealthy lifestyle behaviours and overweight are highly prevalent compared with the rest of the Netherlands [31]. More information on the recruitment of the schools has been described elsewhere [26]. All children (N=2326 at T0) and their parents in the eight schools were invited to participate in the study. This included children from study year one to eight (age 4 to 12 years), which is comparable to two years of Kindergarten and six primary school grades. Recruitment was done via information brochures for parents. In addition, the research team visited the classrooms to inform children about the study and encourage them to ask

202 their parents for participation [26]. Due to the dynamic population in the schools (new children enter and other children finish school each year), we focused in this study only on the children who were enrolled in the schools at baseline till the end of this 2-year study. The population of children included in this study 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 of these study years who joined the study at T1 or T2 were included, even though no baseline data was available. Even though these children joined the study later, they were at baseline already participating in their school and thus also exposed to HPSF during the full 2 years of this study. Children who switched to other schools between 2015 and 2017 were excluded.

Measurements

In each school, the data were gathered annually during one week of measurements. Inter-rater variability was minimised by training researchers according to a strict protocol [26]. Children's age, study year, and gender were collected via the database of the educational board Movare. A digital questionnaire for parents was used to obtain information about the children's socioeconomic background and ethnicity. SES was calculated as the mean of standardized scores on maternal education level, paternal educational level, and household income (adjusted for household size) [32]. The mean scores were categorized into low, middle and high SES scores based on tertiles. Children's ethnicity was determined by the country of birth of both parents and divided into 1) Western background (including the Netherlands) and 2) non-Western background [33]. If one of the parents was born in a non-Western country, the child's ethnicity was assigned to non-Western. The distinction between Western and non-Western was created because of differences in socio-economic and cultural position between the two backgrounds [33].

BMI z-score

Height and weight were measured in children from study year two to eight. The measurements were integrated in the school hours allocated to physical education. Weight was measured to the nearest 0.1 kg (Weighing Scale 803, Seca, Hamburg, Germany) and height was measured to the nearest 0.1 cm (Stadiometer 213, Seca, Birmingham, United Kingdom). Children were measured with light sports clothing and no shoes. All anthropometric measurements were performed twice, and a third measurement was conducted if the difference between the first two measurements exceeded a pre-set limit (weight ≥ 0.2 kg, height ≥ 0.5 cm). BMI was assessed by height and weight; age- and gender-specific BMI cut-off points were used to define overweight and obesity [34]. BMI z-scores were calculated by using Dutch reference values [6].

Statistical analyses

Data were analyzed using IBM SPSS Statistics for Windows (version 23.0. Armonk, NY: IBM Corp). Pearson's chi-square tests and ANOVA tests were conducted to analyze the comparability of the observed participant characteristics among the full HPSF, the partial HPSF, and control schools at baseline. Linear mixed model analyses were used to assess the longitudinal intervention effects on the children's BMI z-score. Since measurements were repeated within participants, we used a two-level model with repeated measurements as the first level and participants as the second level. The fixed part of the model consisted of group (full HPSF, partial HPSF, and Control), time (T0, T1, T2) and the interaction terms of group with time. We were not able to include class as a level in the model, because often several divisions of one class existed, e.g. 4a or 4b, and children often did not have fixed class divisions for all years. All analyses were adjusted for gender, study year at baseline, SES, and ethnicity. Missing covariates and BMI z-scores were imputed using multiple imputation method with fully conditional specification (FCS) and 10 iterations, generating 50 complete datasets. Gender, study year at baseline, school type, ethnicity, SES score, and BMI z-score were used to impute the missing data. We performed two sensitivity analyses. First, we replicated the analyses by only selecting the children who had no missing BMI z-score at all three time points (complete-case analysis). Second, we replicated the analyses while excluding children with an extremely low BMI z-score at baseline (BMI z-score ≤ -2), to study the effects only in children for which a decrease in BMI z-score is favorable.

To study whether the intervention effects were similar for all subgroups of children, the following potential effect modifiers were considered: gender (boys/girls), study year at baseline (lower (1-4)/higher (5-8) grades), SES (low/middle/high) and baseline weight status (non-overweight/overweight). To assess this potential effect modification, the interaction term group*time*effect modifier, with all corresponding two-way interactions, was added to the above mentioned model. If this interaction term was significant (here we used a significance level of 0.10 to deal with the fact that the power of a test for interaction is relatively low and we did not want to miss any effect-modification), the intervention effects were reported for all categories of the effect-modifier separately. For all other analyses, a two-sided p-value ≤0.05 was considered statistically significant. Standardized effect sizes (ES) at each time-point were included, which were defined as estimated mean difference at that time point (T1 or T2) divided by the square root of the residual variance at baseline (pooled over all three groups).

Results

Of all children (n=2326) invited to participate in the (overall) study, 60.3% joined the study at baseline (n=1403) (Figure 1). Because of the study's dynamic population, a total of 1974 children and their parents participated in the study within the two-year follow-up period (data collected at one time-point at least). Due to the selection used for the current study, i.e., only including the children who were in study year one to seven at baseline, we included 1676 children in the analysis. Of these children, 47.4% were boys, their mean age was 7.5 years old, and 94.1% had a Western ethnicity (Table 1). In total, 19.9% of these children suffered from overweight or obesity, which is higher compared with the national average of 13% [35]. BMI z-scores at baseline differed significantly between the three school groups (p=0.034): the average BMI z-score of children in the control schools (z-score=0.232) was higher compared with children in the full HPSF (z-score=0.051) and the partial HPSF (z-score=0.092). Significantly more children suffered from overweight or obesity in these control schools (24.1%) than the full HPSF (16.5%) and the partial HPSF (17.9%) (p=0.006).

Figure 1. *Flowchart*

Table 1. *Characteristics of study sample at baseline (T0)*

Observed data at T1 showed a decrease in BMI z-score compared with baseline in all three groups, with the full HPSF (Δz-score: -0.074) and the partial HPSF (Δz-score: -0.098) having the largest decrease, and control schools a smaller decrease (Δz-score: -0.018). At T2, a decrease in BMI z-score compared with baseline was observed in the full HPSF (Δz-score: -0.039) and the partial HPSF (Δz-score: -0.012), and an increase in the control schools (Δz-score: +0.058) (Figure 2). The extent of observed increase or decrease at T1 and T2 compared with baseline of individual children in the three different groups is visualized in Figure S1 (Supplementary file 1). This figure shows that compared to the control schools, in the full and partial HPSF a higher percentage of children had decreased BMI z-scores. This was particularly visible after one-year follow-up. The figure also indicates that, on an individual level, mostly minimal to moderate changes (-0.6 ≤ Δz-score ≤ +0.6) were realized. The variation in changes increased over time, i.e. the percentage of large and extreme decreases and increases was larger after two years' follow-up compared with one-year follow-up.

Figure 2. *Observed change in children's BMI z-score at one year and two years' follow-up*

Mixed model analyses were conducted to study the differences in effect among the three groups. The intervention effect was, compared with control schools, significant after one-year follow-up in the partial HPSF (ES=-0.05), not significant in the full HPSF (ES=-0.04) (Table 2). After two years' follow-up a significant intervention effect on children's BMI z-score was found in both versions of HPSF. Children's BMI z-score had decreased significantly more in the full HPSF (ES=-0.08) and the partial HPSF (ES=-0.07), compared with children of the control schools, whose estimated mean BMI z-score increased from baseline to two years as reported above. No significant difference in effect was found between the full and partial HPSF at T1 and T2. Both complete case analyses (N=759) and the sensitivity analyses in which children with an extremely low BMI z-score at baseline were excluded ($N_{excluded}$=14), resulted in comparable effect sizes. None of the interaction terms of the potential effect modifiers, i.e., gender, study year, SES and weight status, was significant (Table S1 in Supplementary file 1).

Table 2. *One- and two-year estimated intervention effects on children's BMI z-score*

Discussion

This study assessed the effects of HPSF on children's BMI z-score after one and two years' follow-up compared with children of control schools. The findings showed a favorable decreasing effect at T2 on children's BMI z-scores in both the full HPSF (standardized effect size (ES) =-0.08) and the partial HPSF (ES=-0.07) compared with control schools, where the BMI z-score actually increased at T2 compared with baseline. According to Lipsey's guidelines [36], these findings can be indicated as a small effect (effect size between 0 and 0.32). These small intervention effects are promising for three reasons: 1) they are already visible after two years of implementation, 2) they indicate a change in the increasing BMI trend observed in the control schools, and 3) they are slightly higher than the effect sizes found in several meta-analyses regarding school-based interventions [17, 18, 37]. The decrease in BMI z-score found in this study in the full and partial HPSF can therefore be considered as a favorable and promising intervention effect. No significant differences were found between the full and partial HPSF. The main distinction between them was the provision of a healthy lunch. However, the process evaluation of Bartelink et al. has shown that providing this lunch led to the implementation of additional health-promoting changes (e.g. health promoting policy, educational lunch) [30]. Additional health-promoting changes were not implemented in the partial HPSF [30]. However, since no significant differences were found between the full and partial HPSF, this might indicate that the differences between the two versions of HPSF did not have an additional favorable effect on the children's BMI z-score. Further research is needed to investigate whether an added value of the lunch and its additional health-promoting changes is visible in children's health behaviours.

Even though the effects of HPSF on children's BMI z-score seem promising, it is important to realize that two years' follow-up is too short to conclude that HPSF has led to sustainable changes. The favorable effects on children's BMI z-scores seem to indicate that the children improved their health behaviours, but this should be investigated in more depth. A longer follow-up period is also needed to study whether the results found are not only due to the children's enthusiasm for and cooperation with the new changes in school, which might result in intervention effects that diminish after longer follow-up periods. This can be the reason for the smaller observed change scores after two years' follow-up compared to after one year, shown in Figure 2. On the other hand, the favorable results that are still found after two years' follow-up might indicate that new habits and routines have developed in children's health behaviours. The latter is not easy to change and requires a shift in the social norms of all people in the school regarding 'normal' health behaviours. Therefore, further research into HPSF should investigate its long-term effects on children's BMI z-score. Other outcomes should also be investigated to study the effects of HPSF, including children's educational achievements and well-being and the cost-effectiveness of the intervention. This broader scope of the effects of HPSF is included in the overall study design and will be investigated by our multi-disciplinary research group [26]. The specific focus in the current study enabled us to investigate the effects of HPSF on children's BMI z-score in much more detail.

The second research question investigated whether HPSF has different effects within specific subgroups of children. Effect-modification analyses showed no significant interactions at T1 and T2. However, the big difference in group sizes in the subgroups of, for example, children's weight status, influenced the p-value. Therefore, effect sizes give a better indication. They all showed similar patterns to the overall analyses. These results seem to indicate that no specific subgroups of children were found to benefit more from HPSF, which is promising as often school-based interventions only seem effective for specific subgroups [17, 25]. These results are especially promising when related to health inequalities, because even when interventions are successful in improving children's health, they may still increase health inequalities. This can happen when an intervention is of greater benefit to advantaged groups, e.g., high SES, than to disadvantaged groups, e.g., low SES [38]. Given the results of the effect modification analyses, HPSF can be seen as an example of an intervention that does not seem to increase health inequalities among children. Further research with longer follow-up periods should investigate whether HPSF contributes to reducing the health inequalities.

Limitations and strengths

The longitudinal quasi-experimental design can be seen as a limitation of this study, since we were unable to (cluster-) randomize schools. However, due to this design, we were able to test the effectiveness in terms of differences in children's BMI z-scores 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. Moreover, participants did not significantly differ from non-responders in the participating schools and other children in the region with regard to health and lifestyle [39].The lack of randomization could, however, have resulted in confounding bias. Therefore, we controlled for baseline BMI z-score, gender, study year at T0, SES score, and ethnicity in all analyses. The significant differences in children's BMI z-scores at baseline between the three groups could indicate that children in the control schools are less open to change: their habits in unhealthy behaviours are stronger as they have already led to overweight or obesity. On the other hand, this difference, which we controlled for, may have resulted in an underestimation of the effect: more room for improvement existed for the children in the control schools compared with the full and partial HPSF.

Next, HPSF seemed to affect all children in the intervention schools. However, a decrease in BMI z-score might not be favorable for all of them, for example when they already have an extremely low BMI z-score. Therefore, to ensure that the findings reflected the children for whom a decrease in BMI z-score is favorable, we conducted extra sensitivity analyses in which we excluded the children with extremely low BMI z-scores at baseline. These analyses showed comparable results. The high number of children enrolled in the measurements, the low drop-out rate, and the objectively measured BMI were other strengths of this study. There were missing data because some participants did not participate from the start, other participants finished school before the last measurement period in 2017, the parental questionnaire was not completed, respondents skipped questions, or data could not be obtained due to the absence of the child. To deal with the missing data, multiple imputations were used, and a sensitivity analysis, in which only complete cases were included, was conducted. Complete case analysis showed similar results to the original analysis, which increased the reliability of the findings in this study.

Conclusions

Taking all the results and limitations into account, it can be concluded that HPSF was effective in lowering children's BMI z-scores after one and two years' follow-up and no specific subgroups of children were found to benefit more from the intervention. Even though longer follow-up periods are needed to draw hard conclusions, both versions of the initiative seem promising in offering perspective in the on-going obesity epidemic in young children.

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Competing interests

The authors declare that they have no competing interests.

Ethics approval and consent to participate

Ethical approval was given by the Medical Ethics Committee Zuyderland located in Heerlen (MEC 14-N-142). All participants were required to complete an informed consent form, signed by (both) parents.

Data sharing

The data that support the findings of this study were collected as part of the ‘Healthy Primary School of the Future’ quasi-experimental study. Data collection will take place until 2019 to study the effects after 4 years of exposure. Data on the 4-year effects and potential other comparative studies in the Netherlands will become available following article publication.

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Authors' contributions

NB, PvA, SK, HS, MW, OvS, and MJ were part of designing the intervention. NB, MO, MW collected the data for the manuscript. NB and BW analysed the data. NB drafted and revised the manuscript. PvA, SK, HS, MO, MW, OvS, BW, and MJ critically reviewed the manuscript during the writing process. All authors have read and approved the final manuscript.

Supplementary Information

Supplementary file 1 (doc): A graphical presentation of individual changes in BMI z-scores at one year (T1) and two years’ (T2) follow-up compared with baseline. A table with potential effect-modifiers of the intervention effects on children’s BMI z-score.

Supplementary file 2 (pdf): The original protocol for the study. The protocol is also published by Willeboordse et al. [26].

License statement

References

1. Ogden CL, Carroll MD, Flegal KM. Epidemiologic trends in overweight and obesity. Endocrinology and metabolism clinics. 2003;32(4):741-60.

2. Strauss RS. Childhood obesity and self-esteem. Pediatrics. 2000;105(1):e15-e.

3. WHO. Report of the commission on ending childhood obesity: World Health Organization; 2016.

4. WHO. Obesity and overweight 2018 [Available from: http://www.who.int/en/news-room/fact-sheets/detail/obesity-and-overweight.

5. Arcaya MC, Arcaya AL, Subramanian S. Inequalities in health: definitions, concepts, and theories. Global health action. 2015;8(1):27106.

6. Schönbeck Y, Talma H, van Dommelen P, Bakker B, Buitendijk SE, HiraSing RA, et al. Increase in prevalence of overweight in Dutch children and adolescents: a comparison of nationwide growth studies in 1980, 1997 and 2009. PloS one. 2011;6(11):e27608.

7. Marmot M, Allen J, Bell R, Bloomer E, Goldblatt P. WHO European review of social determinants of health and the health divide. The Lancet. 2012;380(9846):1011-29.

8. Craigie AM, Lake AA, Kelly SA, Adamson AJ, Mathers JC. Tracking of obesity-related behaviours from childhood to adulthood: a systematic review. Maturitas. 2011;70(3):266-84.

9. Han E, Norton EC, Powell LM. Direct and indirect effects of body weight on adult wages. Economics & Human Biology. 2011;9(4):381-92.

10. Stein D, Weinberger-Litman SL, Latzer Y. Psychosocial perspectives and the issue of prevention in childhood obesity. Frontiers in public health. 2014;2.

469 11.Kelsey MM, Zaepfel A, Bjornstad P, Nadeau KJ. Age-related consequences of childhood obesity. Gerontology. 2014;60(3):222-8.

471 12.Lynch JW, Kaplan GA, Salonen JT. Why do poor people behave poorly? Variation in adult health behaviours and psychosocial characteristics by stages of the socioeconomic lifecourse. Social science & medicine. 1997;44(6):809-19.

474 13.Suhrcke M, de Paz Nieves C. The impact of health and health behaviours on educational outcomes in high-income countries: a review of the evidence: World Health Organization, Regional Office for Europe Copenhagen, Denmark; 2011.

477 14.Dooris M, Poland B, Kolbe L, De Leeuw E, McCall DS, Wharf-Higgins J. Healthy settings. Global perspectives on health promotion effectiveness: Springer; 2007. p. 327-52.

479 15.Langford R, Campbell R, Magnus D, Bonell CP, Murphy SM, Waters E, et al. The WHO Health Promoting School framework for improving the health and well-being of students and staff. Cochrane Database Syst Rev. 2011;1.

482 16.Verrotti A, Penta L, Zenzeri L, Agostinelli S, De Feo P. Childhood obesity: prevention and strategies of intervention. A systematic review of school-based interventions in primary schools. Journal of endocrinological investigation. 2014;37(12):1155-64.

485 17.Cook-Cottone C, Casey CM, Feeley TH, Baran J. A meta-analytic review of obesity prevention in the schools: 1997–2008. Psychology in the Schools. 2009;46(8):695-719.

487 18.Oosterhoff M, Joore M, Ferreira I. The effects of school-based lifestyle interventions on body mass index and blood pressure: a multivariate multilevel meta-analysis of randomized controlled trials. Obesity Reviews. 2016;17(11):1131-53.

490 19.Deschesnes M, Martin C, Hill AJ. Comprehensive approaches to school health promotion: how to achieve broader implementation? Health Promot Int. 2003;18(4):387-96.

492 20.Darlington EJ, Violon N, Jourdan D. Implementation of health promotion programmes in schools: an approach to understand the influence of contextual factors on the process? BMC Public Health. 2018;18(1):163.

495 21.Keshavarz N, Nutbeam D, Rowling L, Khavarpour F. Schools as social complex adaptive systems: a new way to understand the challenges of introducing the health promoting schools concept. Soc Sci Med. 2010;70(10):1467-74.

22.Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. BMJ. 2015;350:h1258.

23.Hawe P, Shiell A, Riley T. Theorising interventions as events in systems. Am J Commun Psychol. 2009;43(3-4):267-76.

24.Mason M. What is complexity theory and what are its implications for educational change? Educ Philos Theory. 2008;40(1):35-49.

25.Stewart-Brown S. What is the Evidence on School Health Promotion in Improving Health Orpreventing Disease And, Specifically, what is the Effectiveness of the Health Promoting Schools Approach?: World Health Organization; 2006.

26.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.

27.Bartelink NH, van Assema P, Jansen MW, Savelberg HH, Willeboordse M, Kremers SP. The Healthy Primary School of the Future: A Contextual Action-Oriented Research Approach. International Journal of Environmental Research and Public Health. 2018;15(10):2243.

28.Young I, St Leger L, Buijs G. School health promotion: evidence for effective action. Background paper SHE factsheet. 2013;2.

29.Gezondheidsraad. Dutch Dietary Guidelines 2015. The Hague, The Netherlands: Health Council of the Netherlands; 2015.

30.Bartelink NH, van Assema P, Jansen MW, Savelberg HH, Moore GF, Hawkins J, et al. Process evaluation of the Healthy Primary School of the Future: The key learning points. Submitted.

31.Vermeer AJM BN, Hesdahl MH, Janssen-Goffin MJH, Linssen ECAJ, Rutten N, Hajema KJ. Lokale rapporten Volksgezondheid Toekomst Verkenning: Een nieuwe kijk op gezondheid in Heerlen, Kerkrade, Landgraaf en Brunssum; [Local reports on Public Health Development: A new perspective on health in Heerlen, Kerkrade, Landgraaf and Brunssum]. Geleen: GGD Zuid Limburg; 2014.

32.Shavers VL. Measurement of socioeconomic status in health disparities research. Journal of the national medical association. 2007;99(9):1013.

33.Keij I. Hoe doet het CBS dat nou? Standaarddefinitie allochtonen [How does CBS work? Standard definition immigrants]. Index: Feiten en Cijfers over onze Samenleving. 2000;10:24-5.

34.Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for child overweight and obesity worldwide: international survey. Bmj. 2000;320(7244):1240.

35.Volksgezondheidenzorg.info. Overgewicht kinderen [Overweight children] 2017 [Available from: https://www.volksgezondheidenzorg.info/onderwerp/overgewicht/cijfers-context/huidige-situatie#node-overgewicht-kinderen.

36.Lipsey MW. Design sensitivity: Statistical power for experimental research: Sage; 1990.

37.Lister-Sharp D, Chapman S, Stewart-Brown S, Sowden A. Health promoting schools and health promotion in schools: two systematic reviews. 1999.

38.Lorenc T, Petticrew M, Welch V, Tugwell P. What types of interventions generate inequalities? Evidence from systematic reviews. J Epidemiol Community Health. 2013;67(2):190-3.

39.Boudewijns E, Pepels JJS, Van Kann D, Konings K, van Schayck CP, Willeboordse M. Healthy, happy, and rich? A cross-sectional assessment of nonresponse and external validity in a school-based quasi-experimental study. Submitted.

Figure 1. Flowchart

* Reasons for drop-out T1: switched to other included school (n=2), other reasons, e.g., moved away or actively stopped participation (n=62).
** Reasons for drop-out T2: finished school (n=228), switched to other included school (n=17), other reasons e.g. moved away or actively stopped participation (n=45).
***Selection for effect study: 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.

Table 1. Characteristics of study sample at baseline (T0)

		Total		Full HPSF		Partial HPSF		Control		Chi-square / F-value	p-value
		N [a]	% / Mean (±SD)	N	% / Mean (±SD)	N	% / Mean (±SD)	N	% / Mean (±SD)		
Gender (% boys)		1676	47.4%	537	47.7%	478	47.3%	661	47.2%	.029 [c]	.986
Age (years)		1676	7.5 (±2.16)	537	7.6 (±2.16)	478	7.4 (±2.22)	661	7.6 (±2.13)	1.610	.200
Study year [b]		1676	4.0 (±2.00)	537	4.0 (±2.00)	478	3.8 (±2.01)	661	4.1 (±1.99)	2.526	.080
Ethnicity (% Western)		1016	94.1%	341	93.0%	326	96.0%	349	93.4%	3.239 [c]	.198
SES (%)	*Lowest tertile*	1117	32.6%	361	28.8%	365	32.3%	391	36.3%	5.636 [c]	.228
	Middle tertile		34.0%		35.7%		35.6%		30.9%		
	Highest tertile		33.4%		35.5%		32.1%		32.7%		
BMI z-score		1109	.135 (±1.02)	321	.051 (±1.01)	352	.092 (±.95)	436	.232 (±1.07)	3.399	**.034**
Overweight/ obese (%)		1109	19.9%	321	16.5%	352	17.9%	436	24.1%	14.156[b]	**.006**

[a] Observed N, missing data was due to later participation in the study, incomplete parent questionnaire, or because no height/weight was measured in study year 1.
[b] Study year 1-8 in Dutch system is comparable to two years of kindergarten followed by grade 1-6.
[c] Chi-square test.
Bold p-value = significant (<.05) difference
Abbreviations: SD = standard deviation; C.I. = confidence interval; ES = Effect size.

Figure 2. Observed change in children's BMI z-score at one year and two years' follow-up compared with baseline

Table 2. One- and two-year estimated intervention effects on children's BMI z-score [a]

		Full HPSF vs. control			Partial HPSF vs. control			Full HPSF vs. Partial HPSF		
		B (95% C.I.)	p	ES	B (95% C.I.)	p	ES	B (95% C.I.)	p	ES
BMI z-score	**T1**	-0.038 (-0.09 - 0.01)	.15	-.04	-0.051 (-0.10 - -0.01)	**.03**	-.05	0.013 (-0.04 - 0.06)	.62	.01
	T2	-0.083 (-0.15 - -0.02)	**.01**	-.08	-0.066 (-0.13 - 0.00)	**.05**	-.07	-0.017 (-0.09 - 0.05)	.63	-.02

[a] Adjusted for baseline, gender, study year at T0, SES, and ethnicity.
Bold p-value = significant (<.05) difference
Abbreviations: C.I. = confidence interval; ES = Effect size.

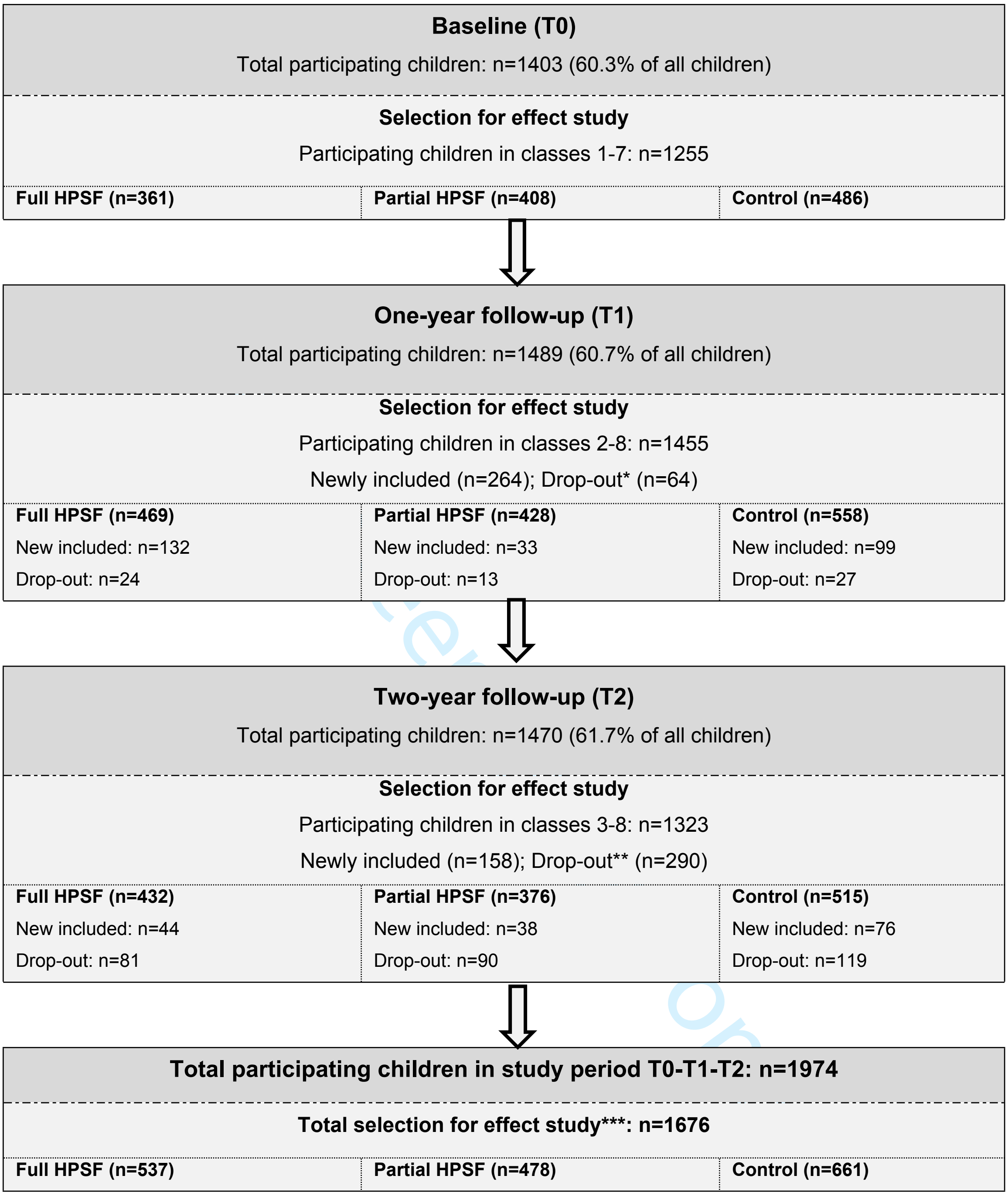

Figure 1. Flowchart

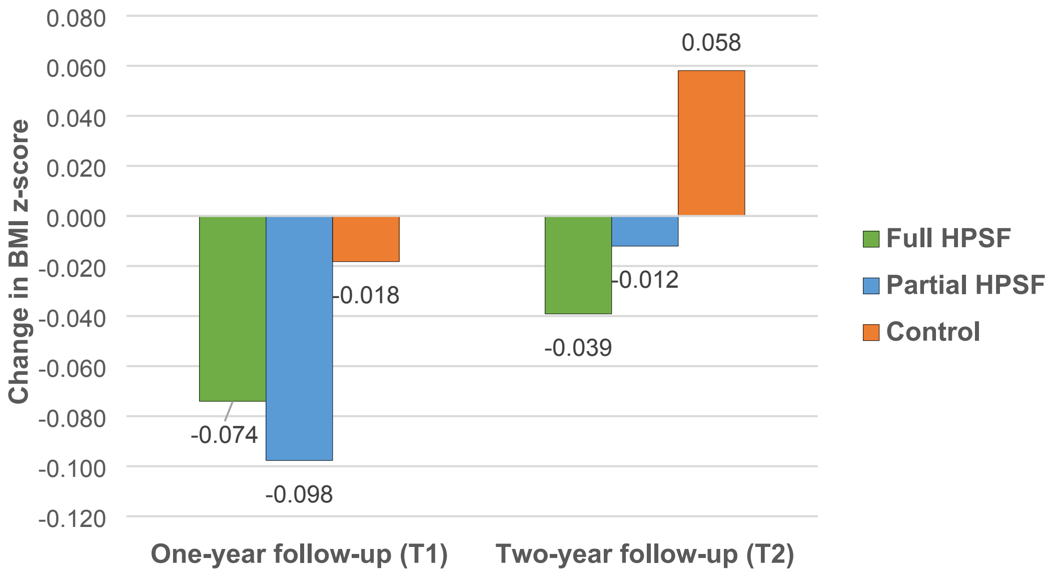

Figure 2. Observed change in children's BMI z-score at one year and two years' follow-up compared with baseline

Supplementary file 1

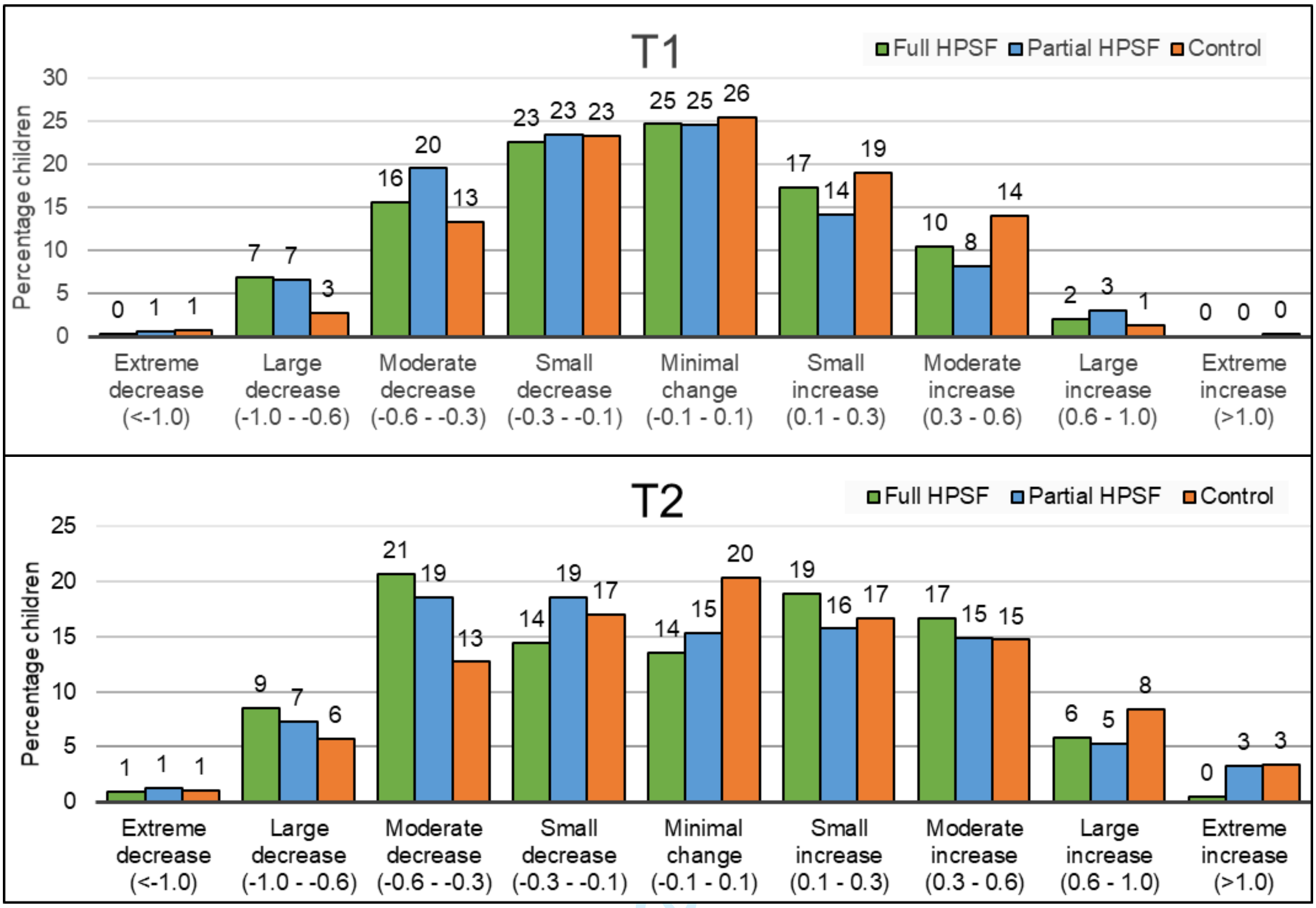

Figure S1. Graphical presentation of individual changes in BMI z-scores at one year (T1) and two years' (T2) follow-up compared with baseline

Table S1. Potential effect-modifiers of the intervention effects on children's BMI z-score [a]

		Full HPSF vs. control			Partial HPSF vs. control			Full HPSF vs. Partial HPSF		
	N [b]	B (95% C.I.)	p	ES	B (95% C.I.)	p	ES	B (95% C.I.)	p	ES
AFTER ONE-YEAR FOLLOW-UP (T1)										
Gender										
Interaction-term			.73			.70			.47	
- *Boys*	*794*	*-0.046 (-0.11 - 0.02)*	*.18*	*-.05*	*-0.041 (-0.11 - 0.03)*	*.22*	*-.04*	*-0.005 (-0.08 - 0.07)*	*.89*	*-.01*
- *Girls*	*882*	*-0.030 (-0.10 - 0.04)*	*.38*	*-.03*	*-0.060 (-0.12 - 0.00)*	*.07*	*-.06*	*0.029 (-0.04 - 0.10)*	*.39*	*.03*
Study year										
Interaction-term			.60			.63			.98	
- *1-4*	*970*	*-0.027 (-0.09 - 0.04)*	*.43*	*-.03*	*-0.039 (-0.10 - 0.02)*	*.23*	*-.04*	*0.011 (-0.05 - 0.08)*	*.73*	*.01*
- *5-8*	*706*	*-0.052 (-0.12 - 0.02)*	*.15*	*-.05*	*-0.062 (-0.13 - 0.01)*	*.07*	*-.06*	*0.010 (-0.07 - 0.09)*	*.79*	*.01*
SES										
Interaction-term [c]			≥.35			≥.71			≥.42	
- *Low*	*364*	*-0.058 (-0.15 - 0.03)*	*.19*	*-.06*	*-0.056 (-0.14 - 0.03)*	*.19*	*-.06*	*-0.002 (-0.10 - 0.10)*	*.96*	*.00*
- *Middle*	*380*	*-0.005 (-0.09 - 0.08)*	*.91*	*.00*	*-0.050 (-0.13 - 0.03)*	*.24*	*-.05*	*0.046 (-0.04 - 0.13)*	*.29*	*.05*
- *High*	*373*	*-0.036 (-0.12 - 0.05)*	*.39*	*-.04*	*-0.034 (-0.12 - 0.05)*	*.42*	*-.03*	*-0.003 (-0.09 - 0.08)*	*.95*	*.00*
Weight status at baseline										
Interaction-term			.90			.32			.30	
- *Non-overweight*	*888*	*-0.039 (-0.10 - 0.02)*	*.17*	*-.05*	*-0.039 (-0.09 - 0.01)*	*.12*	*-.05*	*0.000 (-0.06 - 0.06)*	*.99*	*.00*
- *Overweight*	*221*	*-0.032 (-0.14 - 0.08)*	*.58*	*-.04*	*-0.100 (-0.21 - 0.01)*	*.07*	*-.14*	*0.069 (-0.05 - 0.18)*	*.24*	*.09*
AFTER TWO-YEAR FOLLOW-UP (T2)										
Gender										
Interaction-term			.57			.94			.54	
- *Boys*	*794*	*-0.101 (-0.19 - -0.01)*	***.03***	*-.10*	*-0.063 (-0.15 - 0.03)*	*.18*	*-.06*	*-0.038 (-0.13 - 0.06)*	*.43*	*-.04*
- *Girls*	*882*	*-0.066 (-0.15 - 0.02)*	*.13*	*-.07*	*-0.068 (-0.16 - 0.02)*	*.13*	*-.07*	*0.002 (-0.09 - 0.10)*	*.97*	*.00*
Study year										
Interaction-term			.18			.75			.33	
- *1-4*	*970*	*-0.046 (-0.13 - 0.04)*	*.29*	*-.05*	*-0.052 (-0.13 - 0.03)*	*.21*	*-.05*	*0.006 (-0.08 - 0.09)*	*.89*	*.01*
- *5-8*	*706*	*-0.130 (-0.23 - -0.03)*	***<.01***	*-.13*	*-0.072 (-0.17 - 0.03)*	*.16*	*-.07*	*-0.058 (-0.16 - 0.05)*	*.27*	*-.06*
SES										
Interaction-term [c]			≥.52			≥.85			≥.64	
- *Low*	*364*	*-0.103 (-0.22 - 0.02)*	*.10*	*-.10*	*-0.067 (-0.18 - 0.05)*	*.24*	*-.07*	*-0.036 (-0.16 - 0.09)*	*.58*	*-.04*
- *Middle*	*380*	*-0.049 (-0.16 - 0.06)*	*.39*	*-.05*	*-0.056 (-0.18 - 0.06)*	*.35*	*-.06*	*0.007 (-0.11 - 0.13)*	*.91*	*.01*
- *High*	*373*	*-0.063 (-0.18 - 0.05)*	*.28*	*-.06*	*-0.051 (-0.16 - 0.06)*	*.38*	*-.05*	*-0.012 (-0.12 - 0.10)*	*.84*	*-.01*
Weight status at baseline										
Interaction-term			.82			.92			.90	
- *Non-overweight*	*888*	*-0.088 (-0.16 - -0.02)*	***.02***	*-.12*	*-0.069 (-0.14 - 0.00)*	*.06*	*-.09*	*-0.019 (-0.09 - 0.06)*	*.61*	*-.03*
- *Overweight*	*221*	*-0.069 (-0.22 - -0.08)*	*.36*	*-.09*	*-0.061 (-0.20 - 0.08)*	*.40*	*-.08*	*-0.008 (-0.17 - 0.15)*	*.92*	*-.01*

[a] Adjusted for baseline, gender, study year at T0, SES, and ethnicity.
[b] Observed N per subgroup. Missing data were due: to later participation in the study, incomplete parent questionnaire, no measurement of height/weight, or drop-out during the study.
[c] Pair-wise comparisons:
T1, Full HPSF vs. Control: low vs. middle (p=.35), low vs. high (p=.71), middle vs. high (p=.58).
T1, Partial HPSF vs. Control: low vs. middle (p=.93), low vs. high (p=.71), middle vs. high (p=.79).
T1, Full HPSF vs. Partial HPSF: low vs. middle (p=.48), low vs. high (p=1.00), middle vs. high (p=.42).
T2, Full HPSF vs. Control: low vs. middle (p=.52), low vs. high (p=.64), middle vs. high (p=.87).
T2. Partial HPSF vs. Control: low vs. middle (p=.90), low vs. high (p=.85), middle vs. high (p=.95).
T2, Full HPSF vs. Partial HPSF: low vs. middle (p=.64), low vs. high (p=.78), middle vs. high (p=.81).
Bold p-value = significant difference (interaction term: p ≤.10; subgroups: p ≤.05)
Abbreviations: C.I. = Confidence Interval; ES = Effect Size; p = p-value; SES = Socio-Economic Status.

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Trial record **1 of 1** for: Saved Studies

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The Healthy Elementary School of the Future (THESF)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators.

Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT02800616

Recruitment Status : Enrolling by invitation

First Posted : June 15, 2016

Last Update Posted : June 15, 2016

Sponsor:

Maastricht University

Information provided by (Responsible Party):

Maastricht University

Study Details | **Tabular View** | **No Results Posted** | Disclaimer | How to Read a Study Record

Study Description

Go to

Brief Summary:

Unhealthy lifestyles in early childhood are a major global health challenge. These lifestyles often persist from generation to generation and contribute to a vicious cycle of health-related and social problems. We present a study protocol that examines the effectiveness of two novel, integrated healthy school interventions. One is a full intervention called 'The Healthy Primary School of the Future', the other is a partial intervention called 'The Physical Activity School'. These intervention approaches will be compared with the regular school approach that is currently common practice in the Netherlands. The main outcome measure will be changes in children's body mass index (BMI). In addition, lifestyle behaviours, academic achievement, child well-being, socio-economic differences, and societal costs will be examined.

Condition or disease	Intervention/treatment	Phase

Overweight Physical Activity Malnutrition Child Development Lifestyle-related Condition Socioeconomic Difficulty	Other: The Healthy Primary School of the Future Behavioral: The Physical Activity School	Not Applicable

Detailed Description:

In close collaboration with various stakeholders, a quasi-experimental study was developed, for which children of four intervention schools (n = 1200) in the southern part of the Netherlands are compared with children of four control schools (n = 1200) in the same region. The interventions started in November 2015. In two of the four intervention schools, a whole-school approach named 'The Healthy Primary School of the Future', is implemented with the aim of improving physical activity and dietary behaviour. For this intervention, pupils are offered an extended curriculum, including a healthy lunch, more physical exercises, and social and educational activities, next to the regular school curriculum. In the two other intervention schools, a physical-activity school approach called 'The Physical Activity School', is implemented, which is essentially similar to the other intervention, except that no lunch is provided.

We hypothesize that these healthy school interventions will result in normalized BMI distributions that are more in line with national and international standards (smaller standard deviations) among primary school children, with a more pronounced effect in the full intervention schools (due to the expected synergy between exercise and diet) than in the partial intervention schools. Also, our multi-disciplinary research group will study a wide range of outcome measures, including lifestyle behaviours, academic achievement, child well-being, socio-economic differences, and societal costs. Moreover, an evaluation will be performed of the legal consequences of a healthy school approach in the Netherlands, as well as the conflicting interests of the stakeholders. Data collection is conducted within the school system. The interventions proceed during a period of four years. The baseline measurements started in September 2015 and yearly follow-up measurements are taking place until 2019.

Our primary research question is: What is the effect of the full intervention ('The Healthy Primary School of the Future') on the BMI of primary school children compared to no intervention (control schools)? Our secondary research question is: What is the effect of the full intervention on the BMI of primary school children compared to the partial intervention ('The Physical Activity School')? Our tertiary research questions are: (1) What is the effect of the full intervention in comparison with the partial intervention and the regular school approach (control schools) on: (a) children's levels of physical activity and sedentary behaviour, nutritional knowledge, healthy food preferences and behaviour, cognitive and non-cognitive performance, HR-QoL, socio-emotional development, and sick leave? (b) parenting and teacher practices regarding physical activity and nutrition? (c) parental HR-QoL, well-being, labour participation and sick leave? (d) benefits across different socio-economic backgrounds? (e) long and short term cost-effectiveness? (f) satisfaction among the involved stakeholders (children, parents, teachers, and child care partners)? (2) Which determinants influence the quality of the implementation of the intervention? (3) What is the scope of children's human rights to health, what is the legal role of primary schools in realizing these rights (e.g., obligations and responsibilities of state and non-state actors, conflicts of interests and legal solutions to these conflicts), and is the intervention feasible within Dutch educational law?

A whole-school approach is a new concept in the Netherlands. Due to its innovative, multifaceted nature and sound scientific foundation, these integrated programmes have the potential to form a template for primary schools worldwide. The effects of this approach may extend further than the outcomes associated with well-being and academic achievement, potentially impacting legal and cultural aspects in our society.

Study Design

Go to

Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	1800 participants
Allocation:	Non-Randomized
Intervention Model:	Factorial Assignment
Masking:	None (Open Label)
Primary Purpose:	Prevention
Official Title:	The Healthy Elementary School of the Future
Study Start Date:	September 2015
Estimated Primary Completion Date:	November 2020
Estimated Study Completion Date:	November 2020

Arms and Interventions

Go to

Arm	Intervention/treatment
Experimental: Full intervention group The full intervention ('The Healthy Primary School of the Future') is implemented in two schools involving extended school hours in which healthy nutrition, physical exercise, environmental, social, and educational activities are incorporated, during a period of four years.	Other: The Healthy Primary School of the Future In two out of four intervention schools, a whole-school approach named 'The Healthy Primary School of the Future', is implemented with the aim of improving physical activity and dietary behaviour. For this intervention, pupils are offered an extended curriculum, including a healthy lunch, more physical exercises, and social and educational activities, next to the regular school curriculum.
Experimental: Partial intervention group	Behavioral: The Physical Activity School

The partial intervention ('The Physical Activity School') is implemented in two other schools: involving extended school hours in which healthy nutrition, physical exercise, environmental, social, and educational activities are incorporated, during a period of four years. Hence, this intervention only differs from the full intervention on the absence of nutritional intervention. Instead, children bring their own food from home, as they normally do.	In the two other intervention schools, a physical-activity school approach called 'The Physical Activity School', is implemented, which is essentially similar to the other intervention, except that no lunch is provided.
No Intervention: Control group Four primary schools will function as control schools. The control schools have a representative Dutch school environment in terms of lifestyle education, school hours and amount of Physical Education (PE) lessons.	

Outcome Measures

Go to

Primary Outcome Measures :

1. Child absolute change in BMI Z-score, based on weight and height. [Time Frame: Four years]

   Weight is measured using a weighing scale, to the nearest 0.1 kg; height is measured using a measuring rod, to the nearest 0.1 cm.

Secondary Outcome Measures :

1. Child hip and waist circumferences [Time Frame: Four years]

   Using a measuring tape, to the nearest 0.1 cm, following the World Health Organization's assessment protocol

2. Child handgrip strength [Time Frame: Four years]

   Measured using a calibrated Jamar hydraulic hand dynamometer to the nearest 0.5 kg

3. Child disease status since birth, hospital admissions (number and duration), healthcare visits (number), and medication use in the previous twelve months [Time Frame: Four years]

   Self-report measure (online parental questionnaire)

4. Child pre-school blood pressure (data obtained between the ages of 4 to 6), birth weight, and information on disease history. [Time Frame: Obtained once]

   Data previously obtained by the regional Public Health Services.

5. Parental BMI is assessed by self-reported height and weight of both parents/caregivers [Time Frame: Four years]

   Self-report measure (online parental questionnaire).

6. Parental practices regarding nutrition using the shortened version (nine items) of the Comprehensive Snack Parenting Questionnaire (CSPQ) [Time Frame: Four years]

   Self-report measure (online parental questionnaire).

7. Parental practices regarding physical activity are assessed with a questionnaire developed in the same style as he Comprehensive Snack Parenting Questionnaire (CSPQ) [Time Frame: Four Years]

   Self-report measure (online parental questionnaire).

8. Labour participation of parents is assessed by current employment status (self-report measure). [Time Frame: Four years]

   Current employment status is combined with parental education level and household income to determine SES.

9. Parents' ethnicity and level of (material) deprivation [Time Frame: Four years]

   Self-report measure (online parental questionnaire).

10. Parental sick leave and absence from work or education because of illness of their child. [Time Frame: Four years]

    Self-report measure (online parental questionnaire). Labour participation is combined with parental sick leave rates to determine productivity losses from work.

11. Child health-related quality of life [Time Frame: Four years]

    Examined with the validated EuroQol 5-Dimensions Youth version questionnaire (EQ-5D-Y) and the proxy version for parents. Child-specific HR-QoL is measured by the validated Paediatric Quality of Life Inventory (PedsQL) and parents complete the proxy version of this questionnaire.

12. Child psychological attributes (emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems and prosocial behaviour) [Time Frame: Four years]

Assessed using the Strength and Difficulties Questionnaire.

13. Child social, emotional, and academic self-efficacy. [Time Frame: Four years]

    Tested using the Self-Efficacy Questionnaire for Children (SEQ-C).

14. Child self-confidence, social skills, self-efficacy, school well-being, future expectations, and social support [Time Frame: Four years]

    Assessed with OnderwijsMonitor Limburg programme

15. Child physical activity and sedentary behavior assessed using the Actigraph accelerometer [Time Frame: Four years]

    In the week in which the child is wearing the accelerometer, parents fill in a short activity diary on their child's physical activity and swimming behaviour and exceptional circumstances (e.g., illness of the child)

16. Sports club membership, active forms of transport to school, and leisure time physical activities (e.g., children's activities in weekends: watching TV, music or theatre, playing outdoors, practicing sports etc.) assessed in both children and parents. [Time Frame: Four years]

    Self-report measure

17. Child food intake [Time Frame: Four years]

    Assessed using a food frequency questionnaire and a dietary recall tool to be completed by both children and parents.

18. Child food preferences and familiarity with healthy food products. [Time Frame: Four years]

    Self-report measure: The questions mainly consist of pictures of food items, for which children can indicate whether they have ever eaten these items and whether they like them or not.

19. Parental practices regarding nutricion and physical activity [Time Frame: Four years]

    Self-report measure

20. Parental wellbeing [Time Frame: Four years]

    measured by the Satisfaction With Life Survey (SWLS)

21. Parental health-related quality of life [Time Frame: Four years]

    Measured with the EuroQol - 5-Dimensions Questionnaire (EQ-5D)

22. Socioeconomic status [Time Frame: Four years]

    Self-report measure

23. School/ teacher practices regarding nutrition and physical activity [Time Frame: Four years]

    E.g. modelling eating healthy food products and encouraging children's physical activity. Measured using adapted version of the Parental Practices Instrument

24. Teacher's self-reported height, weight and transport forms to work [Time Frame: Four years]

    Written questionnaire

25. Child academic achievements [Time Frame: Four years]

    Monitored using the Dutch national test called Centrale Eindtoets Basisonderwijs (CITO), and various other tests used by the schools. The CITO test measures language, maths and world orientation. In addition to the CITO test, many schools use a wide range of tests throughout the children's school careers. This also includes tests on maths (taken twice a year) and various aspects of language such as decoding skills, spelling, vocabulary, and reading comprehension.

26. School advice and the actual level of secondary school opted for (Dutch secondary education is hierarchically ordered). [Time Frame: Four years]

    School registration system

27. School absenteeism and repeating classes [Time Frame: Four years]

    School registration system

28. Process evaluation using a school satisfaction questionnaire [Time Frame: Four years]

    Self-report measure: general parental satisfaction with their children's school (including safety, communication, quality of education, challenges to children, and professionalism of teachers). Implementation of the intervention is evaluated by qualitative outcome measures such as interviews with parents and children, and classroom observations.

29. Juridical evaluation through literature study and interviews [Time Frame: Four years]

    Legal aspects will be addressed by a thorough scientific literature study and examination of policy and legislation instruments and case-law on the scope of children's right to health. Interviews with the parties involved in the healthy school setting will determine the juridical-related interests and possibilities.

Eligibility Criteria

Go to

Information from the National Library of Medicine

NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	4 Years to 12 Years (Child)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

- All children and their caregivers enrolled at one of the participating schools

Exclusion Criteria:

- None. Participants who switch schools during the four-year study period will not be followed-up.

Contacts and Locations

Go to

Information from the National Library of Medicine

NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02800616***

Sponsors and Collaborators

Maastricht University

Investigators

Principal Investigator: Onno van Schayck, Prof. Dr. Professor at Maastricht University

More Information

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Additional Information:

Official website about this project for various stakeholders (in Dutch)

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Can the Healthy Primary School of the Future offer perspective in the on-going obesity epidemic in young children? – a Dutch quasi-experimental study

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Can the Healthy Primary School of the Future offer perspective in the on-going obesity epidemic in young children? – a Dutch quasi-experimental study

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Abstract

Objectives: Schools play an important role in promoting healthy behaviours in children and can offer perspective in the on-going obesity epidemic. The 'Healthy Primary School of the Future' (HPSF) aims to improve children's health and well-being by enhancing school health promotion. The current study aims to assess the effect of HPSF on children's BMI z-score after one and two years' follow-up and to investigate whether HPSF has different effects within specific subgroups of children.

Design: A longitudinal quasi-experimental design.

Setting: Four intervention and four control schools participated; located in a low socio-economic status region in the Netherlands.

Participants: 1676 children (aged 4-12 years).

Interventions: HPSF uses a contextual systems approach and includes health-promoting changes in the school. Central to HPSF are the provision of a daily healthy lunch and structured physical activity sessions each day. Two intervention schools implemented both changes (full HPSF), two intervention schools implemented only the physical activity change (partial HPSF).

Main outcome measures: BMI z-score, determined by measurements of children's height and weight at baseline, after one and two years' follow-up.

Results: The intervention effect was significant after one-year follow-up in the partial HPSF (standardized effect size ES=-0.05), not significant in the full HPSF (ES=-0.04). After two years' follow-up, BMI z-score had significantly decreased in children of both the full HPSF (ES=-0.08) and the partial HPSF (ES=-0.07) compared with children of the control schools, whose mean BMI z-score increased from baseline to two years. None of the potential effect-modifiers (gender, baseline study year, socio-economic status, and baseline weight status) were significant.

Conclusions: HPSF was effective after one and two years' follow-up in lowering children's BMI z-scores. No specific subgroups of children could be identified who benefitted more from the intervention.

Trial registration: The study was registered in the ClinicalTrials.gov database on 14 June 2016 (NCT02800616).

Strengths and limitations of this study

- Due to the longitudinal quasi-experimental study 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.
- Since the lack of randomization could have resulted in confounding bias, we controlled for baseline BMI z-score, gender, study year at T0, SES score, and ethnicity in all analyses.
- The high number of children enrolled in the measurements, the low drop-out rate, and the objectively measured BMI were strengths of this study.
- Due to some missing data, multiple imputations were used and a sensitivity analysis was conducted, where only complete cases were included.
- Participants did not significantly differ from non-responders in the participating schools and other children in the region with regard to health and lifestyle.

Introduction

Overweight and obesity can lead to health problems, such as type 2 diabetes, cardiovascular diseases, and psychological problems (e.g., low self-esteem) [1, 2]. Globally, the prevalence of overweight and obesity among children and adolescents (aged 5-19) has risen dramatically from 4% in 1975 to more than 18% in 2016 [3, 4]. The prevalence is highest among children with a low socio-economic background [5]. In the Netherlands, the prevalence of childhood overweight and obesity has also increased in the last decennia: 13–15% of children (aged 2–21 years) are overweight, and 1.8–2.2% are classified as obese, which is a 2- to 3-fold increase compared with 1980 [6]. The ongoing epidemic increase is particularly caused by unhealthy behaviours, such as unhealthy dietary intake and low levels of physical activity (PA) [7]. The health behaviours of children in the Netherlands are suboptimal. For example, 42% of children (aged 4–9 years) consume at least 150 g of fruit per day, which drops to 20% for 9–12 year olds [8]. Regarding PA, only half (48%) of Dutch children (aged 4–12) meet the guidelines for PA of 60 min of moderate-to-vigorous physical activity (MVPA) per day [9]. Unhealthy behaviours at a young age often track into adulthood [10] and are related to health and psychosocial problems, reduced quality of life, higher health care costs, lower educational achievement and labor participation [11-13]. A vicious circle is emerging, transferring problems, such as obesity, from one generation to the next [14]. Promoting healthy behaviours at an early age may help to improve children's health on the short and long run [10]. Moreover, promoting health behaviours could also lead to better educational and academic achievements, which have been found to be related to improved health in later life as well [15].

Schools can play an important role in promoting healthy behaviours in children since a significant proportion of a child's day is spent there and they reach all children [16-18]. As such, school-based interventions may be an important instrument to offer perspective in the on-going obesity epidemic in young children. Many different school-based interventions (e.g. related to education, environment, policy, monitoring) have been implemented to integrate health into the school system and reduce childhood overweight and obesity. The meta-analysis of both Cook-Cottone et al. and Oosterhoff et al. found that the significant effect of school-based interventions on children's Body Mass Index (BMI) z-score had an overall weighted effect size of approximately -0.05 [19, 20]. Several studies indicated that effects are often hampered by underestimation of the challenges associated with implementing meaningful changes to the school system [21-23]. These challenges occur because an intervention always interacts with the specific school context [22, 23]. Therefore, solutions for the challenges associated with changing school systems vary between schools as they all have their own dynamics [22-24]. Consequently, an intervention can be seen as an attempt to positively disrupt the prior functioning of a school system [25, 26]. Some other reviews stated that specific subgroups of children benefit more from a school-based intervention. The review of Stewart-Brown et al. [27] found that several studies indicated gender-specific results, with some school-based interventions being more effective in girls and others in boys. Age-specific effects were often found, with some interventions being more effective in older children and others in younger children [27]. Cook-Cotton et al. found that children's socio-economic background can be an influential factor and that children already having overweight can respond more slowly or to a lesser extent to school-based interventions than children with a healthy weight [19].

A Dutch initiative that embraces a contextual systems approach is the 'Healthy Primary School of the Future' (HPSF) [28, 29]. HPSF aims to improve the health and well-being of all children in the school which should contribute to a healthier future generation and thereby offer perspective in the on-going obesity epidemic [30]. HPSF includes top-down and bottom-up processes to create health-promoting changes in the school. Two changes were initiated to create some form of positive disruption in the school: 1) providing a free healthy lunch each day and 2) daily structured physical activity (PA) sessions after lunch. While in other national school systems this may represent usual practice, these changes are hypothesized as disruptive to the Dutch school system because the provision of school lunches and structured PA sessions are not usual practice in Dutch schools. The two changes aimed to create momentum to implement additional health-promoting changes in the school, such as a healthy school policy or creating a PA-friendly schoolyard. All changes together should favourably affect the health behaviours of all school children, which should lead to improved health and a more normal weight status [28, 29].

The aim of the current study was to assess the effect of HPSF on children's BMI z-score after one and two years' follow-up and to investigate whether HPSF has different effects within specific subgroups of children. The current study is part of an overall study to investigate HPSF. The overall study has a broad scope and includes a multi-disciplinary research group, which focuses on many different outcomes, such as children’s health behaviours, educational achievements, and well-being. The studies that have been published previously, focused on the implementation process of HPSF [31] and the effects of HPSF on children’s dietary and PA behaviours [32]. The current study explicitly concentrates on children’s BMI z-score to focus in much detail on the primary outcome as described in the study design of Willeboordse et al. [28].

Methods

Study design

The current study had a longitudinal quasi-experimental design with four intervention schools and four control schools, which maintained the school curriculum that is currently common practice in the Netherlands. Ethical approval (14-N-142) was given by the Zuyderland Medical Ethics Committee located in Heerlen (Parkstad, the Netherlands). Parents had to sign an informed consent form to participate in all measurements for themselves and their child(ren). Measurements were conducted in September-November of 2015 (T0), 2016 (T1) and 2017 (T2). A detailed description of the study and the power calculation is reported in Willeboordse et al. [28].

The Healthy Primary School of the Future

Three collaborating organisations, i.e., the regional educational board ‘Movare’, the regional public health services and Maastricht University, developed the idea for HPSF [28]. In March 2013, 12 out of 53 schools governed by the Movare educational board were informed about the initiative. Four schools gave their initial consent and spent a whole school year (2014/2015) creating bottom-up support for HPSF. Two of the four intervention schools decided to implement both the daily lunch and the structured PA sessions and are referred to as the ‘full HPSF’. The other two intervention schools decided to only implement the structured PA sessions, and are referred to as the ‘partial HPSF’. All schools could implement additional health-promoting changes, that fit their school context [29, 31]. 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.

Implementation started in all four intervention schools in November 2015. The time for having lunch (in the full HPSF) was increased to 20–30 min. The total lunch break time in these schools was prolonged by about 60 min. For this reason, the school day was extended: children of the full HPSF attend school to approximately 15:30/15:45 instead of 15:00. A dietician of the caterer developed a lunch menu cycle that changed every 10 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. During lunch break time, 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.

The two changes, i.e. providing daily a free healthy lunch and structured PA sessions after lunch, were both led by external pedagogical employees provided by childcare organizations to not increase the workload of teachers even further. This integration of the childcare organization during school hours is not to provide a temporary solution, but to change the school's organization in a sustainable way. The aim for the future is to bring school and childcare more together and thereby create an integrated day for children, whereby children are supervised by the same people prior, during and after school hours. Employees of sports and leisure organizations supported the external pedagogical employees during implementation when needed, and after a year they provided a training course (8 sessions of 2h) to supply them with additional tools for how to motivate children for active participation during the PA sessions. A health promoter from the regional Public Health Services was assigned to each school to provide support when needed. In this study, researchers from Maastricht University monitored and fed back results to the schools to support the processes of change. Funding for implementation of HPSF is provided by the provincial authorities until the end of 2019. However, the four schools have committed to continued implementation after 2019 and make the changes sustainable in their school.

Patient and public involvement

Public involvement was a key feature of HPSF. This intervention intended to establish a co-creation movement in schools aimed at the systematic incorporation of health and well-being. The two top-down changes and the additional health-promoting changes were developed and contextualized by bottom-up involvement. Teachers and parents were involved from the start in the adoption decision and the process of adapting the several changes into the school context. Moreover, all four schools used a children voice group, with representatives from each class in school, to get insight into the opinion of children regarding HPSF. In this way, the experiences of children were being heard and the changes could be further contextualized to fit better to the children's needs and wishes. Each of the four intervention schools selected a teacher as school coordinator, who managed HPSF in their school. Overarching, HPSF was led by an executive board with representatives of the three collaborating organisations: Movare, the regional public health services and Maastricht University. They discussed the study design, the relevant outcome measures, and the interpretation of the results. The representative of Movare advised explicitly on school and participant recruitment and the communication to schools. A project team was created with representatives of all partners involved: the four schools, Movare, regional Public Health Services, Maastricht University, the Limburg provincial authorities, childcare organizations, the caterer, and sports and leisure organizations. No patients were involved in this study.

Study population

All intervention and control schools are situated in the Parkstad region in the southern part of the Netherlands. This region has a low average socio-economic status (SES), and unhealthy lifestyle behaviours and overweight are highly prevalent compared with the rest of the Netherlands [34]. More information on the recruitment of the schools has been described elsewhere [28]. All children (N=2326 at T0) and their parents in the eight schools were invited to participate in the study. This included children from study year one to eight (age 4 to 12 years), which is comparable to two years of Kindergarten and six primary school grades. Recruitment was done via information brochures for parents. In addition, the research team visited the classrooms to inform children about the study and encourage them to ask their parents for participation [28]. Due to the dynamic population in the schools (new children enter and other children finish school each year), we focused in this study only on the children who were enrolled in the schools at baseline till the end of this 2-year study. The population of children included in this study 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 of these study years who joined the study at T1 or T2 were included, even though no baseline data was available. Even though these children joined the study later, they were at baseline already participating in their school and thus also exposed to HPSF during the full 2 years of this study. Children who switched to other schools between 2015 and 2017 were excluded.

Measurements

In each school, the data were gathered annually during one week of measurements. Inter-rater variability was minimised by training researchers according to a strict protocol [28]. Children's age, study year, and gender were collected via the database of the educational board Movare. A digital questionnaire for parents was used to obtain information about the children's socioeconomic background and ethnicity. SES was calculated as the mean of standardized scores on maternal education level, paternal educational level, and household income (adjusted for household size) [35]. The mean scores were categorized into low, middle and high SES scores based on tertiles. Children's ethnicity was determined by the country of birth of both parents and divided into 1) Western background (including the Netherlands) and 2) non-Western background [36]. If one of the parents was born in a non-Western country, the child's ethnicity was assigned to non-Western. The distinction between Western and non-Western was created because of differences in socio-economic and cultural position between the two backgrounds [36].

BMI z-score

Anthropometric measurements, i.e., height, weight, hip and waist circumference, were conducted in children from study year two to eight. The measurements were integrated in the school hours allocated to physical education. Weight was measured to the nearest 0.1 kg (Weighing Scale 803, Seca, Hamburg, Germany) and height was measured to the nearest 0.1 cm (Stadiometer 213, Seca, Birmingham, United Kingdom). Hip and waist circumference were measured with a measuring tape to the nearest 0.1 cm (model 201, Seca, Hamburg, Germany). Children were measured with light sports clothing and no shoes. All anthropometric measurements were performed twice, and a third measurement was conducted if the difference between the first two measurements exceeded a pre-set limit (weight ≥ 0.2 kg, height ≥ 0.5 cm, hip and waist circumference ≥ 1.0 cm). Unfortunately, hip and waist circumference were excluded from further analyses due to measurement errors. BMI was

262 assessed by height and weight; age- and gender-specific BMI cut-off points were used to define overweight and obesity [37]. BMI z-scores were calculated by using Dutch reference values [6].

265 **Statistical analyses**

266 Data were analyzed using IBM SPSS Statistics for Windows (version 23.0. Armonk, NY: IBM Corp). Pearson's chi-square tests and ANOVA tests were conducted to analyze the comparability of the observed participant characteristics among the full HPSF, the partial HPSF, and control schools at baseline. Linear mixed model analyses were used to assess the longitudinal intervention effects on the children's BMI z-score. Since measurements were repeated within participants, we used a two-level model with repeated measurements as the first level and participants as the second level, where an unstructured covariance structure was considered for the repeated measures. The fixed part of the model consisted of group (full HPSF, partial HPSF, and Control), time (T0, T1, T2) and the interaction terms of group with time. We were not able to include class as a level in the model, because often several divisions of one class existed, e.g. 4a or 4b, and children often did not have fixed class divisions for all years. All analyses were adjusted for gender, study year at baseline, SES, and ethnicity. Missing covariates and BMI z-scores were imputed using multiple imputation method with fully conditional specification (FCS) and 10 iterations, generating 50 complete datasets. Gender, study year at baseline, school type, ethnicity, SES score, and BMI z-score were used to impute the missing data. We performed two sensitivity analyses. First, we replicated the analyses by only selecting the children who had no missing BMI z-score at all three time points (complete-case analysis). Second, we replicated the analyses while excluding children with an extremely low BMI z-score at baseline (BMI z-score ≤ -2), to study the effects only in children for which a decrease in BMI z-score is favourable.

285 To study whether the intervention effects were similar for all subgroups of children, the following potential effect modifiers were considered: gender (boys/girls), study year at baseline (lower (1-4)/higher (5-8) grades), SES (low/middle/high) and baseline weight status (non-overweight/overweight). To assess this potential effect modification, the interaction term group*time*effect modifier, with all corresponding two-way interactions, was added to the above mentioned model. If this interaction term was significant (here we used a significance level of 0.10 to deal with the fact that the power of a test for interaction is relatively low and we did not want to miss any effect-modification), the intervention effects were reported for all

categories of the effect-modifier separately. For all other analyses, a two-sided p-value ≤0.05 was considered statistically significant. Standardized effect sizes (ES) at each time-point were included, which were defined as estimated mean difference at that time point (T1 or T2) divided by the square root of the residual variance at baseline (pooled over all three groups).

Results

Of all children (n=2326) invited to participate in the (overall) study, 60.3% joined the study at baseline (n=1403) (Figure 1). Because of the study's dynamic population, a total of 1974 children and their parents participated in the study within the two-year follow-up period (data collected at one time-point at least). Due to the selection used for the current study, i.e., only including the children who were in study year one to seven at baseline, we included 1676 children in the analysis. Of these children, 47.4% were boys, their mean age was 7.5 years old, and 94.1% had a Western ethnicity (Table 1). In total, 19.9% of these children suffered from overweight or obesity, which is higher compared with the national average of 13% [38]. BMI z-scores at baseline differed significantly between the three school groups (p=0.034): the average BMI z-score of children in the control schools (z-score=0.232) was higher compared with children in the full HPSF (z-score=0.051) and the partial HPSF (z-score=0.092). Significantly more children suffered from overweight or obesity in these control schools (24.1%) than the full HPSF (16.5%) and the partial HPSF (17.9%) (p=0.006).

Figure 1. *Flowchart*

Table 1. *Characteristics of study sample at baseline (T0)*

Observed data at T1 showed a decrease in BMI z-score compared with baseline in all three groups, with the full HPSF (Δz-score: -0.074) and the partial HPSF (Δz-score: -0.098) having the largest decrease, and control schools a smaller decrease (Δz-score: -0.018). At T2, a decrease in BMI z-score compared with baseline was observed in the full HPSF (Δz-score: -0.039) and the partial HPSF (Δz-score: -0.012), and an increase in the control schools (Δz-score: +0.058) (Figure 2). The extent of observed increase or decrease at T1 and T2 compared with baseline of individual children in the three different groups is visualized in Figure S1 (Supplementary file 1). This figure shows that compared to the control schools, in the full and partial HPSF a higher percentage of children had decreased BMI z-scores. This was particularly visible after one-year follow-up. The figure also indicates that, on an individual level, mostly minimal to moderate changes (-0.6 ≤ Δz-score ≤ +0.6) were realized. The variation in changes increased over time, i.e. the percentage of large and extreme decreases and increases was larger after two years' follow-up compared with one-year follow-up.

Figure 2. *Observed change in children's BMI z-score at one year and two years' follow-up*

Mixed model analyses were conducted to study the differences in effect among the three groups. The intervention effect was, compared with control schools, significant after one-year follow-up in the partial HPSF (ES=-0.05), not significant in the full HPSF (ES=-0.04) (Table 2). After two years' follow-up a significant intervention effect on children's BMI z-score was found in both versions of HPSF. Children's BMI z-score had decreased significantly more in the full HPSF (ES=-0.08) and the partial HPSF (ES=-0.07), compared with children of the control schools, whose estimated mean BMI z-score increased from baseline to two years as reported above. No significant difference in effect was found between the full and partial HPSF at T1 and T2. Both complete case analyses (N=759) and the sensitivity analyses in which children with an extremely low BMI z-score at baseline were excluded ($N_{excluded}$=14), resulted in comparable effect sizes. None of the interaction terms of the potential effect modifiers, i.e., gender, study year, SES and weight status, was significant (Table S1 in Supplementary file 1).

Table 2. *One- and two-year estimated intervention effects on children's BMI z-score*

Discussion

This study assessed the effects of HPSF on children's BMI z-score after one and two years' follow-up compared with children of control schools. The findings showed a favourable decreasing effect at T2 on children's BMI z-scores in both the full HPSF (standardized effect size (ES) =-0.08) and the partial HPSF (ES=-0.07) compared with control schools, where the BMI z-score actually increased at T2 compared with baseline. According to Lipsey's guidelines [39], these findings can be indicated as a small effect (effect size between 0 and 0.32). These small intervention effects are promising for three reasons: 1) they are already visible after two years of implementation, 2) they indicate a change in the increasing

BMI trend observed in the control schools, and 3) they are slightly higher than the effect sizes found in several meta-analyses regarding school-based interventions [19, 20, 40]. The decrease in BMI z-score found in this study in the full and partial HPSF can therefore be considered as a favourable and promising intervention effect. No significant differences were found between the full and partial HPSF. The main distinction between them was the provision of a healthy lunch. However, the process evaluation of Bartelink et al. has shown that providing this lunch led to the implementation of additional health-promoting changes (e.g. health promoting policy, educational lunch) [31]. Additional health-promoting changes were not implemented in the partial HPSF [31]. However, since no significant differences were found between the full and partial HPSF, this might indicate that the differences between the two versions of HPSF did not have an additional favourable effect on the children's BMI z-score.

The favourable effects on children's BMI z-scores seem to indicate that the children improved their health behaviours. Indeed, significant favourable intervention effects were found after one- and two-years' follow-up for the full HPSF on children's dietary behaviours for, among others, school water consumption and lunch intake of vegetables and dairy products [32]. Children's sedentary time and light PA significantly improved after two years' follow-up. Almost no significant favourable results on children's health behaviours were found in the partial HPSF. Since it is the co-existence and interaction of several nutrition and PA behaviours that results in a positive (or negative) energy balance and weight gain (or loss) [41, 42], the results suggest that many small improvements on several different health behaviours have occurred in the children of the partial HPSF, leading to the favourable effects on their BMI z-score.

Even though the effects of HPSF on children's BMI z-score seem promising, it is important to realize that two years' follow-up is too short to conclude that HPSF has led to sustainable changes. A longer follow-up period is needed to study whether the results found are not only due to the children's enthusiasm for and cooperation with the new changes in school, which might result in intervention effects that diminish after longer follow-up periods. This can be the reason for the smaller observed change scores after two years' follow-up compared to after one year, shown in Figure 2. On the other hand, the favourable results that are still found after two years' follow-up might indicate that new habits and routines have developed in children's health behaviours. The latter is not easy to change and requires a shift in the social norms of all people in the school regarding 'normal' health behaviours. Therefore, further research into HPSF should investigate its long-term effects on children's BMI z-score. Other outcomes should also be investigated to study the effects of HPSF, including children's educational achievements and well-being and the cost-effectiveness of the intervention. This broader scope of the effects of HPSF is included in the overall study design and will be investigated by our multi-disciplinary research group [28]. The specific focus in the current study enabled us to investigate the effects of HPSF on children's BMI z-score in much more detail.

The second research question investigated whether HPSF has different effects within specific subgroups of children. Effect-modification analyses showed no significant interactions at T1 and T2. However, effect sizes give a better indication since the big difference in group sizes in the subgroups of, for example, children's weight status, influenced the p-value. All effect sizes showed similar patterns to the overall analyses. These results seem to indicate that no specific subgroups of children were found to benefit more from HPSF, which is promising as often school-based interventions only seem effective for specific subgroups [19, 27]. These results are especially promising when related to health inequalities, because even when interventions are successful in improving children's health, they may still increase health inequalities. This can happen when an intervention is of greater benefit to advantaged groups, e.g., high SES, than to disadvantaged groups, e.g., low SES [43]. Given the results of the effect modification analyses, HPSF can be seen as an example of an intervention that does not seem to increase health inequalities among children. Further research with longer follow-up periods should investigate whether HPSF contributes to reducing the health inequalities.

Limitations and strengths

The longitudinal quasi-experimental design can be seen as a limitation of this study, since we were unable to (cluster-) randomize schools. However, due to this design, we were able to test the effectiveness in terms of differences in children's BMI z-scores 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. Moreover, participants did not significantly differ from non-responders in the participating schools and other children in the region with regard to health and lifestyle [44].The lack of randomization could, however, have resulted in confounding bias. Therefore, we controlled for baseline BMI z-score, gender, study year at T0, SES score, and ethnicity in all analyses. The significant differences in children's BMI z-scores at baseline between the three groups could indicate that children in the control schools are less open to change: their habits in unhealthy behaviours are stronger as they have already led to overweight or obesity. On the other hand, this difference, which we controlled for, may have resulted in an underestimation of the effect: more room for improvement existed for the children in the control schools compared with the full and partial HPSF.

Next, HPSF seemed to affect all children in the intervention schools. However, a decrease in BMI z-score might not be favourable for all of them, for example when they already have an extremely low BMI z-score. Therefore, to ensure that the findings reflected the children for whom a decrease in BMI z-score is favourable, we conducted extra sensitivity analyses in which we excluded the children with extremely low BMI z-scores at baseline. These analyses showed comparable results. The high number of children enrolled in the measurements, the low drop-out rate, and the objectively measured BMI were other strengths of this study. There were missing data because some participants did not participate from the start, other participants finished school before the last measurement period in 2017, the parental questionnaire was not completed, respondents skipped questions, or data could not be obtained due to the absence of the child. To deal with the missing data, multiple imputations were used, and a sensitivity analysis, in which only complete cases were included, was conducted. Complete case analysis showed similar results to the original analysis, which increased the reliability of the findings in this study.

Conclusions

Taking all the results and limitations into account, it can be concluded that HPSF was effective in lowering children's BMI z-scores after one and two years' follow-up and no specific subgroups of children were found to benefit more from the intervention. Even though longer follow-up periods are needed to draw hard conclusions, both versions of the initiative seem promising in offering perspective in the on-going obesity epidemic in young children.

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Competing interests

The authors declare that they have no competing interests.

Ethics approval and consent to participate

Ethical approval was given by the Medical Ethics Committee Zuyderland located in Heerlen (MEC 14-N-142). All participants were required to complete an informed consent form, signed by (both) parents.

Data sharing

The data that support the findings of this study were collected as part of the 'Healthy Primary School of the Future' quasi-experimental study. Data collection will take place until 2019 to study the effects after 4 years of exposure. Data on the 4-year effects and potential other comparative studies in the Netherlands will become available following article publication.

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Authors' contributions

NB, PvA, SK, HS, MW, OvS, and MJ were part of designing the intervention. NB, MO, MW collected the data for the manuscript. NB and BW analysed the data. NB drafted and revised the manuscript. PvA, SK, HS, MO, MW, OvS, BW, and MJ critically reviewed the manuscript during the writing process. All authors have read and approved the final manuscript.

Supplementary Information

Supplementary file 1 (PDF): A graphical presentation of individual changes in BMI z-scores at one year (T1) and two years' (T2) follow-up compared with baseline. A table with potential effect-modifiers of the intervention effects on children's BMI z-score.

License statement

References

1. Ogden CL, Carroll MD, Flegal KM. Epidemiologic trends in overweight and obesity. Endocrinol Metab Clin North Am. 2003;32(4):741-60.
2. Strauss RS. Childhood obesity and self-esteem. J Pediatr. 2000;105(1):e15-e.
3. WHO. Report of the commission on ending childhood obesity: World Health Organization; 2016.
4. WHO. Obesity and overweight 2018 [Available from: http://www.who.int/en/news-room/fact-sheets/detail/obesity-and-overweight.
5. Arcaya MC, Arcaya AL, Subramanian S. Inequalities in health: definitions, concepts, and theories. Glob Health Action. 2015;8(1):27106.
6. Schönbeck Y, Talma H, van Dommelen P, Bakker B, Buitendijk SE, HiraSing RA, et al. Increase in prevalence of overweight in Dutch children and adolescents: a comparison of nationwide growth studies in 1980, 1997 and 2009. PLoS One. 2011;6(11):e27608.
7. Marmot M, Allen J, Bell R, Bloomer E, Goldblatt P. WHO European review of social determinants of health and the health divide. Lancet. 2012;380(9846):1011-29.

8. CBS, RIVM, The Netherlands Nutrition Centre. Kinderen eten te weinig fruit, groente en vis [Children eat to less fruit, vegetables and fish] 2017 [Available from: https://www.cbs.nl/nl-nl/nieuws/2017/46/kinderen-eten-te-weinig-fruit-groente-en-vis.

9. Volksgezondheidenzorg.info. Beweeggedrag kinderen [Physical activity behaviour of children] 2018 [Available from: https://www.volksgezondheidenzorg.info/onderwerp/sport-en-bewegen/cijfers-context/huidige-situatie#node-beweeggedrag-kinderen.

10.Craigie AM, Lake AA, Kelly SA, Adamson AJ, Mathers JC. Tracking of obesity-related behaviours from childhood to adulthood: a systematic review. Maturitas. 2011;70(3):266-84.

11.Han E, Norton EC, Powell LM. Direct and indirect effects of body weight on adult wages. Econ Hum Biol. 2011;9(4):381-92.

12.Stein D, Weinberger-Litman SL, Latzer Y. Psychosocial perspectives and the issue of prevention in childhood obesity. Front Public Health. 2014;2.

13.Kelsey MM, Zaepfel A, Bjornstad P, Nadeau KJ. Age-related consequences of childhood obesity. J Gerontol. 2014;60(3):222-8.

14.Lynch JW, Kaplan GA, Salonen JT. Why do poor people behave poorly? Variation in adult health behaviours and psychosocial characteristics by stages of the socioeconomic lifecourse. Soc Sci Med. 1997;44(6):809-19.

15.Suhrcke M, de Paz Nieves C. The impact of health and health behaviours on educational outcomes in high-income countries: a review of the evidence. Copenhagen, Denmark: World Health Organization, Regional Office for Europe 2011.

16.Dooris M, Poland B, Kolbe L, De Leeuw E, McCall DS, Wharf-Higgins J. Healthy settings. Global perspectives on health promotion effectiveness. Berlin, Germany: Springer; 2007. p. 327-52.

17.Langford R, Campbell R, Magnus D, Bonell CP, Murphy SM, Waters E, et al. The WHO Health Promoting School framework for improving the health and well-being of students and staff. Cochrane Database Syst Rev. 2011;1.

18.Verrotti A, Penta L, Zenzeri L, Agostinelli S, De Feo P. Childhood obesity: prevention and strategies of intervention. A systematic review of school-based interventions in primary schools. J Endocrinol Invest. 2014;37(12):1155-64.

19.Cook-Cottone C, Casey CM, Feeley TH, Baran J. A meta-analytic review of obesity prevention in the schools: 1997–2008. Psychol Sch. 2009;46(8):695-719.

530 20.Oosterhoff M, Joore M, Ferreira I. The effects of school-based lifestyle interventions on body mass index and blood pressure: a multivariate multilevel meta-analysis of randomized controlled trials. Obes Rev. 2016;17(11):1131-53.

533 21.Deschesnes M, Martin C, Hill AJ. Comprehensive approaches to school health promotion: how to achieve broader implementation? Health Promot Int. 2003;18(4):387-96.

535 22.Darlington EJ, Violon N, Jourdan D. Implementation of health promotion programmes in schools: an approach to understand the influence of contextual factors on the process? BMC Public Health. 2018;18(1):163.

538 23.Keshavarz N, Nutbeam D, Rowling L, Khavarpour F. Schools as social complex adaptive systems: a new way to understand the challenges of introducing the health promoting schools concept. Soc Sci Med. 2010;70(10):1467-74.

541 24.Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. BMJ. 2015;350:h1258.

543 25.Hawe P, Shiell A, Riley T. Theorising interventions as events in systems. Am J Commun Psychol. 2009;43(3-4):267-76.

545 26.Mason M. What is complexity theory and what are its implications for educational change? Educ Philos Theory. 2008;40(1):35-49.

547 27.Stewart-Brown S. What is the Evidence on School Health Promotion in Improving Health Or preventing Disease And, Specifically, what is the Effectiveness of the Health Promoting Schools Approach? Copenhagen, Denmark: World Health Organization, Regional Office for Europe; 2006.

550 28.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.

553 29.Bartelink N, van Assema P, Jansen M, Savelberg H, Willeboordse M, Kremers S. The Healthy Primary School of the Future: A Contextual Action-Oriented Research Approach. Int J Environ Res Public Health. 2018;15(10):2243.

556 30.Young I, St Leger L, Buijs G. School health promotion: evidence for effective action. Background paper SHE factsheet. 2013;2.

31.Bartelink N, van Assema P, Jansen M, Savelberg H, Moore G, Hawkings J, et al. Process evaluation of the Healthy primary School of the Future: The key learning points. BMC Public Health. 2019;19(1):698.

32.Bartelink NH, van Assema P, Kremers SP, Savelberg HH, Oosterhoff M, Willeboordse M, et al. One- and Two-Year Effects of the Healthy Primary School of the Future on Children's Dietary and Physical Activity Behaviours: A Quasi-Experimental Study. Nutrients. 2019;11(3):689.

33.Gezondheidsraad. Dutch Dietary Guidelines 2015. The Hague, The Netherlands: Health Council of the Netherlands; 2015.

34.Vermeer AJM, Boot NMWM, Hesdahl MH, Janssen-Goffin MJH, Linssen ECAJ, Rutten N, et al. Lokale rapporten Volksgezondheid Toekomst Verkenning: Een nieuwe kijk op gezondheid in Heerlen, Kerkrade, Landgraaf en Brunssum; [Local reports on Public Health Development: A new perspective on health in Heerlen, Kerkrade, Landgraaf and Brunssum]. Geleen: GGD Zuid Limburg; 2014.

35.Shavers VL. Measurement of socioeconomic status in health disparities research. J Natl Med Assoc. 2007;99(9):1013.

36.Keij I. Hoe doet het CBS dat nou? Standaarddefinitie allochtonen [How does Statistics Netherlands do this? Standard definition of emigrants]. 2000.

37.Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for child overweight and obesity worldwide: international survey. BMJ. 2000;320(7244):1240.

38.Volksgezondheidenzorg.info. Overgewicht kinderen [Overweight children] 2017 [Available from: https://www.volksgezondheidenzorg.info/onderwerp/overgewicht/cijfers-context/huidige-situatie#node-overgewicht-kinderen.

39.Lipsey MW. Design sensitivity: Statistical power for experimental research. Pugey, France: Sage; 1990.

40.Lister-Sharp D, Chapman S, Stewart-Brown S, Sowden A. Health promoting schools and health promotion in schools: two systematic reviews. In Database of Abstracts of Reviews of Effects (DARE): Quality-assessed Reviews [Internet]. London, UK: Centre for Reviews and Dissemination; 1999.

41.Hill JO, Wyatt HR, Melanson EL. Genetic and environmental contributions to obesity. Med Clin North Am. 2000;84(2):333-46.

42.Kremers SP, De Bruijn G-J, Visscher TL, Van Mechelen W, De Vries NK, Brug J. Environmental influences on energy balance-related behaviors: a dual-process view. Int J Behav Nutr Phys Act. 2006;3(1):9.

43.Lorenc T, Petticrew M, Welch V, Tugwell P. What types of interventions generate inequalities? Evidence from systematic reviews. J Epidemiol Community Health. 2013;67(2):190-3.

44.Boudewijns E, Pepels J, van Kann D, Konings K, van Schayck C, Willeboordse M. Non-response and external validity in a school-based quasi-experimental study 'The Healthy Primary School of the Future': A cross-sectional assessment. Prev Med Rep. 2019:100874.

Figure 1. Flowchart

* Reasons for drop-out T1: switched to other included school (n=2), other reasons, e.g., moved away or actively stopped participation (n=62).
** Reasons for drop-out T2: finished school (n=228), switched to other included school (n=17), other reasons e.g. moved away or actively stopped participation (n=45).
***Selection for effect study: 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.

Table 1. Characteristics of study sample at baseline (T0)

		Total		Full HPSF		Partial HPSF		Control			
		N [a]	% / Mean (±SD)	N	% / Mean (±SD)	N	% / Mean (±SD)	N	% / Mean (±SD)	Chi-square / F-value	p-value
Gender (% boys)		1676	47.4%	537	47.7%	478	47.3%	661	47.2%	.029 [c]	.986
Age (years)		1676	7.5 (±2.16)	537	7.6 (±2.16)	478	7.4 (±2.22)	661	7.6 (±2.13)	1.610	.200
Study year [b]		1676	4.0 (±2.00)	537	4.0 (±2.00)	478	3.8 (±2.01)	661	4.1 (±1.99)	2.526	.080
Ethnicity (% Western)		1016	94.1%	341	93.0%	326	96.0%	349	93.4%	3.239 [c]	.198
SES (%)	*Lowest tertile*	1117	32.6%	361	28.8%	365	32.3%	391	36.3%	5.636 [c]	.228
	Middle tertile		34.0%		35.7%		35.6%		30.9%		
	Highest tertile		33.4%		35.5%		32.1%		32.7%		
BMI z-score		1109	.135 (±1.02)	321	.051 (±1.01)	352	.092 (±.95)	436	.232 (±1.07)	3.399	**.034**
Overweight/ obese (%)		1109	19.9%	321	16.5%	352	17.9%	436	24.1%	14.156[c]	**.006**

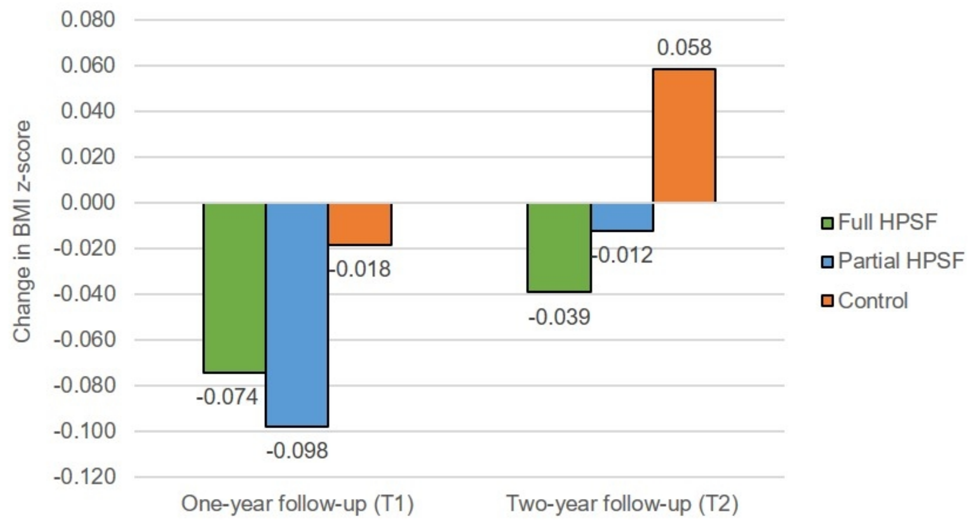
[a] Observed N, missing data was due to later participation in the study, incomplete parent questionnaire, or because no height/weight was measured in study year 1.
[b] Study year 1-8 in Dutch system is comparable to two years of kindergarten followed by grade 1-6.
[c] Chi-square test.
Bold p-value = significant (<.05) difference
Abbreviations: SD = standard deviation; C.I. = confidence interval; ES = Effect size.

Figure 2. Observed change in children's BMI z-score at one year and two years' follow-up compared with baseline

Table 2. One- and two-year estimated intervention effects on children's BMI z-score [a]

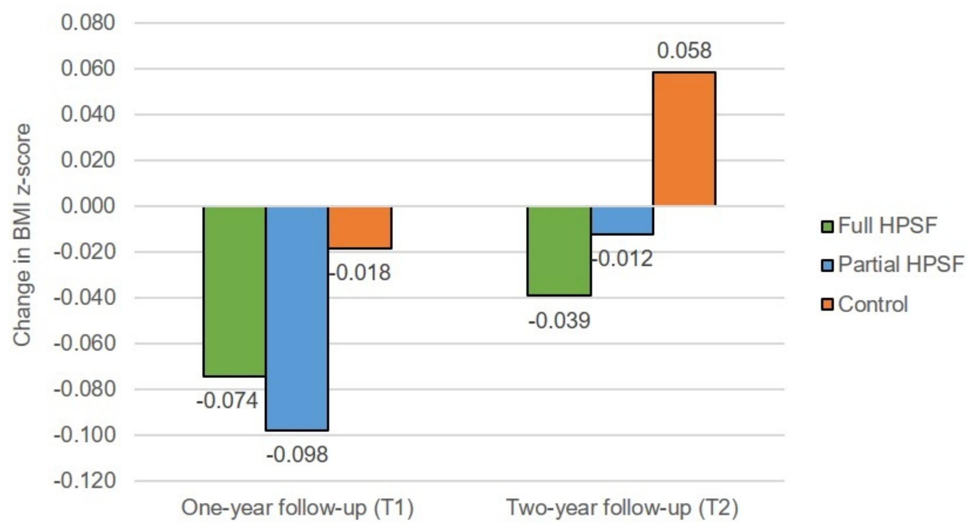
		Full HPSF vs. control			Partial HPSF vs. control			Full HPSF vs. Partial HPSF		
		B (95% C.I.)	p	ES	B (95% C.I.)	p	ES	B (95% C.I.)	p	ES
BMI z-score	**T1**	-0.038 (-0.09 - 0.01)	.15	-.04	-0.051 (-0.10 - -0.01)	**.03**	-.05	0.013 (-0.04 - 0.06)	.62	.01
	T2	-0.083 (-0.15 - -0.02)	**.01**	-.08	-0.066 (-0.13 - 0.00)	**.05**	-.07	-0.017 (-0.09 - 0.05)	.63	-.02

[a] Adjusted for baseline, gender, study year at T0, SES, and ethnicity.
Bold p-value = significant (<.05) difference
Abbreviations: C.I. = confidence interval; ES = Effect size.



* Reasons for drop-out T1: switched to other included school (n=2), other reasons, e.g., moved away or actively stopped participation (n=62).
** Reasons for drop-out T2: finished school (n=228), switched to other included school (n=17), other reasons e.g. moved away or actively stopped participation (n=45).
***Selection for effect study: 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.

144x77mm (150 x 150 DPI)



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Supplementary file 1

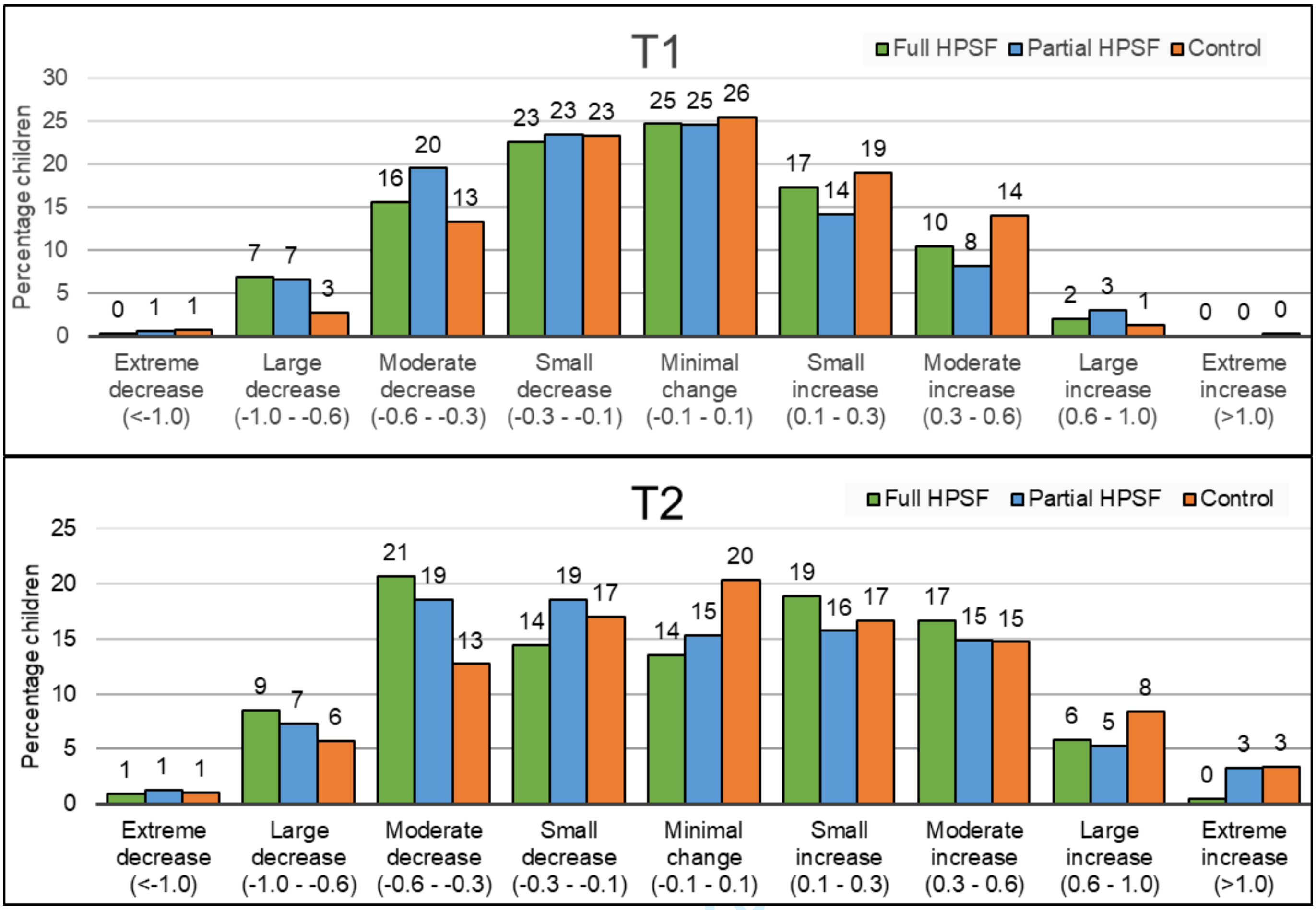

Figure S1. Graphical presentation of individual changes in BMI z-scores at one year (T1) and two years' (T2) follow-up compared with baseline

Table S1. Potential effect-modifiers of the intervention effects on children's BMI z-score [a]

	N [b]	Full HPSF vs. control B (95% C.I.)	p	ES	Partial HPSF vs. control B (95% C.I.)	p	ES	Full HPSF vs. Partial HPSF B (95% C.I.)	p	ES
AFTER ONE-YEAR FOLLOW-UP (T1)										
Gender										
Interaction-term			.73			.70			.47	
Boys	794	-0.046 (-0.11 - 0.02)	.18	-.05	-0.041 (-0.11 - 0.03)	.22	-.04	-0.005 (-0.08 - 0.07)	.89	-.01
Girls	882	-0.030 (-0.10 - 0.04)	.38	-.03	-0.060 (-0.12 - 0.00)	.07	-.06	0.029 (-0.04 - 0.10)	.39	.03
Study year										
Interaction-term			.60			.63			.98	
1-4	970	-0.027 (-0.09 - 0.04)	.43	-.03	-0.039 (-0.10 - 0.02)	.23	-.04	0.011 (-0.05 - 0.08)	.73	.01
5-8	706	-0.052 (-0.12 - 0.02)	.15	-.05	-0.062 (-0.13 - 0.01)	.07	-.06	0.010 (-0.07 - 0.09)	.79	.01
SES										
Interaction-term [c]			≥.35			≥.71			≥.42	
Low	364	-0.058 (-0.15 - 0.03)	.19	-.06	-0.056 (-0.14 - 0.03)	.19	-.06	-0.002 (-0.10 - 0.10)	.96	.00
Middle	380	-0.005 (-0.09 - 0.08)	.91	.00	-0.050 (-0.13 - 0.03)	.24	-.05	0.046 (-0.04 - 0.13)	.29	.05
High	373	-0.036 (-0.12 - 0.05)	.39	-.04	-0.034 (-0.12 - 0.05)	.42	-.03	-0.003 (-0.09 - 0.08)	.95	.00
Weight status at baseline										
Interaction-term			.90			.32			.30	
Non-overweight	888	-0.039 (-0.10 - 0.02)	.17	-.05	-0.039 (-0.09 - 0.01)	.12	-.05	0.000 (-0.06 - 0.06)	.99	.00
Overweight	221	-0.032 (-0.14 - 0.08)	.58	-.04	-0.100 (-0.21 - 0.01)	.07	-.14	0.069 (-0.05 - 0.18)	.24	.09
AFTER TWO-YEAR FOLLOW-UP (T2)										
Gender										
Interaction-term			.57			.94			.54	
Boys	794	-0.101 (-0.19 - -0.01)	**.03**	-.10	-0.063 (-0.15 - 0.03)	.18	-.06	-0.038 (-0.13 - 0.06)	.43	-.04
Girls	882	-0.066 (-0.15 - 0.02)	.13	-.07	-0.068 (-0.16 - 0.02)	.13	-.07	0.002 (-0.09 - 0.10)	.97	.00
Study year										
Interaction-term			.18			.75			.33	
1-4	970	-0.046 (-0.13 - 0.04)	.29	-.05	-0.052 (-0.13 - 0.03)	.21	-.05	0.006 (-0.08 - 0.09)	.89	.01
5-8	706	-0.130 (-0.23 - -0.03)	**<.01**	-.13	-0.072 (-0.17 - 0.03)	.16	-.07	-0.058 (-0.16 - 0.05)	.27	-.06
SES										
Interaction-term [c]			≥.52			≥.85			≥.64	
Low	364	-0.103 (-0.22 - 0.02)	.10	-.10	-0.067 (-0.18 - 0.05)	.24	-.07	-0.036 (-0.16 - 0.09)	.58	-.04
Middle	380	-0.049 (-0.16 - 0.06)	.39	-.05	-0.056 (-0.18 - 0.06)	.35	-.06	0.007 (-0.11 - 0.13)	.91	.01
High	373	-0.063 (-0.18 - 0.05)	.28	-.06	-0.051 (-0.16 - 0.06)	.38	-.05	-0.012 (-0.12 - 0.10)	.84	-.01
Weight status at baseline										
Interaction-term			.82			.92			.90	
Non-overweight	888	-0.088 (-0.16 - -0.02)	**.02**	-.12	-0.069 (-0.14 - 0.00)	.06	-.09	-0.019 (-0.09 - 0.06)	.61	-.03
Overweight	221	-0.069 (-0.22 - -0.08)	.36	-.09	-0.061 (-0.20 - 0.08)	.40	-.08	-0.008 (-0.17 - 0.15)	.92	-.01

[a] Adjusted for baseline, gender, study year at T0, SES, and ethnicity.
[b] Observed N per subgroup. Missing data were due: to later participation in the study, incomplete parent questionnaire, no measurement of height/weight, or drop-out during the study.
[c] Pair-wise comparisons:
T1, Full HPSF vs. Control: low vs. middle (p=.35), low vs. high (p=.71), middle vs. high (p=.58).
T1, Partial HPSF vs. Control: low vs. middle (p=.93), low vs. high (p=.71), middle vs. high (p=.79).
T1, Full HPSF vs. Partial HPSF: low vs. middle (p=.48), low vs. high (p=1.00), middle vs. high (p=.42).
T2, Full HPSF vs. Control: low vs. middle (p=.52), low vs. high (p=.64), middle vs. high (p=.87).
T2. Partial HPSF vs. Control: low vs. middle (p=.90), low vs. high (p=.85), middle vs. high (p=.95).
T2, Full HPSF vs. Partial HPSF: low vs. middle (p=.64), low vs. high (p=.78), middle vs. high (p=.81).
Bold p-value = significant difference (interaction term: p ≤.10; subgroups: p ≤.05)
Abbreviations: C.I. = Confidence Interval; ES = Effect Size; p = p-value; SES = Socio-Economic Status.