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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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Manuscripts

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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2
3 **38 Abstract**

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5 **39 Objectives:** Schools play an important role in promoting healthy behaviours in children and can offer
6
7 **40** perspective in the on-going obesity epidemic. The 'Healthy Primary School of the Future' (HPSF) aims
8
9 **41** to improve children's health and well-being by enhancing school health promotion. The current study
10
11 **42** aims to assess the effect of HPSF on children's BMI z-score after one and two years' follow-up and to
12
13 **43** investigate whether HPSF has different effects within specific subgroups of children.

14
15 **44 Design:** A longitudinal quasi-experimental design.

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17 **45 Setting:** Four intervention and four control schools participated; located in a low socio-economic status
18
19 **46** region in the Netherlands.

20
21 **47 Participants:** 1676 children (aged 4-12 years).

22
23 **48 Interventions:** HPSF uses a contextual systems approach and includes health-promoting changes in
24
25 **49** the school. Central to HPSF are the provision of a daily healthy lunch and structured physical activity
26
27 **50** sessions each day. Two intervention schools implemented both changes (full HPSF), two intervention
28
29 **51** schools implemented only the physical activity change (partial HPSF).

30
31 **52 Main outcome measures:** BMI z-score, determined by measurements of children's height and weight
32
33 **53** at baseline, after one and two years' follow-up.

34
35 **54 Results:** The intervention effect was significant after one-year follow-up in the partial HPSF
36
37 **55** (standardized effect size $ES=-0.05$), not significant in the full HPSF ($ES=-0.04$). After two years' follow-
38
39 **56** up, BMI z-score had significantly decreased in children of both the full HPSF ($ES=-0.08$) and the partial
40
41 **57** HPSF ($ES=-0.07$) compared with children of the control schools, whose mean BMI z-score increased
42
43 **58** from baseline to two years. None of the potential effect-modifiers (gender, baseline study year, socio-
44
45 **59** economic status, and baseline weight status) were significant.

46
47 **60 Conclusions:** HPSF was effective after one and two years' follow-up in lowering children's BMI z-
48
49 **61** scores. No specific subgroups of children could be identified who benefitted more from the intervention.

50
51 **62 Trial registration:** The study was registered in the ClinicalTrials.gov database on 14 June 2016
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53 **63** (NCT02800616).

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3 **68 Strengths and limitations of this study**
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- 5 69 • Due to the longitudinal quasi-experimental study design, we were able to test the effectiveness
6
7 70 in terms of differences in children's health behaviours between the three school groups over
8
9 71 time, and were also able to enroll schools on the basis of motivation, which reflects the real-life
10
11 72 situation of school health promotion.
12
13 73 • Since the lack of randomization could have resulted in confounding bias, we controlled for
14
15 74 baseline BMI z-score, gender, study year at T0, SES score, and ethnicity in all analyses.
16
17 75 • The high number of children enrolled in the measurements, the low drop-out rate, and the
18
19 76 objectively measured BMI were strengths of this study.
20
21 77 • Due to some missing data, multiple imputations were used and a sensitivity analysis was
22
23 78 conducted, where only complete cases were included.
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25 79 • Participants did not significantly differ from non-responders in the participating schools and other
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27 80 children in the region with regard to health and lifestyle.
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82 Introduction

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

97
98 Schools can play an important role in promoting healthy behaviours in children and thereby help to offer
99 perspective in the on-going obesity epidemic in young children, since a significant proportion of a child's
100 day is spent there, and schools reach all children [14-16]. Many different school-based interventions
101 (e.g. related to education, environment, policy, monitoring) have been implemented to integrate health
102 into the school system and reduce childhood overweight and obesity. The meta-analysis of both
103 Cook-Cottone et al. and Oosterhoff et al. found that the significant effect of school-based interventions
104 on children's Body Mass Index (BMI) z-score had an overall weighted effect size of approximately -0.05
105 [17, 18]. Several studies indicated that effects are often hampered by underestimation of the challenges
106 associated with implementing meaningful changes to the school system [19-21]. These challenges occur
107 because an intervention always interacts with the specific school context [20, 21]. Therefore, solutions
108 for the challenges associated with changing school systems vary between schools as they all have their
109 own dynamics [20-22]. Consequently, an intervention can be seen as an attempt to positively disrupt
110 the prior functioning of a school system [23, 24]. Some other reviews stated that specific subgroups of
111 children benefit more from a school-based intervention. The review of Stewart-Brown et al. [25] found

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3 112 that several studies indicated gender-specific results, with some school-based interventions being more
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5 113 effective in girls and others in boys. Age-specific effects were often found, with some interventions being
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7 114 more effective in older children and others in younger children [25]. Cook-Cotton et al. found that
8
9 115 children's socio-economic background can be an influential factor and that children already having
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11 116 overweight can respond more slowly or to a lesser extent to school-based interventions than other
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13 117 children [17].

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16 119 A Dutch initiative that embraces a contextual systems approach is the 'Healthy Primary School of the
17
18 120 Future' (HPSF) [26, 27]. HPSF aims to improve the health and well-being of all children in the school
19
20 121 which should contribute to a healthier future generation and thereby offer perspective in the on-going
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22 122 obesity epidemic [28]. HPSF includes top-down and bottom-up processes to create health-promoting
23
24 123 changes in the school. Two changes were initiated to create some form of positive disruption in the
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26 124 school: 1) providing a free healthy lunch each day and 2) daily structured physical activity (PA) sessions
27
28 125 after lunch. While in other national school systems this may represent usual practice, these changes
29
30 126 are hypothesized as disruptive to the Dutch school system because the provision of school lunches and
31
32 127 structured PA sessions are not usual practice in Dutch schools. The two changes aimed to create
33
34 128 momentum to implement additional health-promoting changes in the school, such as a healthy school
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36 129 policy or creating a PA-friendly schoolyard. All changes together should favourably affect the health
37
38 130 behaviours of all school children, which should lead to improved health and a more normal weight status
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40 131 [26, 27].

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43 133 The aim of the current study was to assess the effect of HPSF on children's BMI z-score after one and
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45 134 two years' follow-up and to investigate whether HPSF has different effects within specific subgroups of
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47 135 children. The current study is part of an overall study to investigate the effects of HPSF. The overall
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49 136 study has a broad scope and includes a multi-disciplinary research group, which focuses on many
50
51 137 different outcomes, such as children's health behaviours, educational achievements, and well-being.
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53 138 This study explicitly concentrates on the primary outcome, BMI z-score, as described in the study design
54
55 139 of Willeboordse et al. [26].

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58
59 141 **Methods**

142 **Study design**

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

151 **The Healthy Primary School of the Future**

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

159 The time for having lunch (in the full HPSF) was increased to 20–30 min. The total lunch break
160 time in these schools was prolonged by about 60 min. For this reason, the school day was extended:
161 children of the full HPSF attend school to approximately 15:30/15:45 instead of 15:00. A dietician of the
162 caterer developed a lunch menu cycle that changed every 10 weeks, in which at least 80% of the
163 products met the advice of the Dutch Health Council [29]. A mid-morning snack, consisting of fruits
164 and/or nuts, was also provided. The lunch, a bread-based cold meal, was typically Dutch. During lunch
165 break time, the children participated several times a week in structured PA sessions; one or two times
166 per week they could participate in cultural activities. The PA sessions were carried out in the schoolyard
167 and, when available and needed, in parks, forest, and/or sports hall in the neighbourhood. All schools
168 collaborated with sport clubs or other external partners to offer specific activities as well. Since the two
169 changes were contextualized bottom-up, this resulted in some differences between schools in the form
170 of the changes; the content remained comparable. Employees of sports and leisure organizations
171 supported the external pedagogical employees during implementation when needed, and after a year

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3 172 they provided a training course (8 sessions of 2h) to supply them with additional tools for how to motivate
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5 173 children for active participation during the PA sessions.

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7 174 All schools could implement additional health-promoting changes, that fit their school context
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9 175 [27, 30]. The full HPSF improved their health policy, provided water bottles to all children, and provided
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11 176 an educational lunch once a week. The partial HPSF did not implement additional health-promoting
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13 177 changes. Implementation started in all four intervention schools in November 2015.

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16 179 **Patient and public involvement**

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18 180 Public involvement was a key feature of HPSF. This intervention intended to establish a co-creation
19
20 181 movement in schools aimed at the systematic incorporation of health and well-being. The two top-down
21
22 182 changes and the additional health-promoting changes were developed and contextualized by bottom-
23
24 183 up involvement. Teachers and parents were involved in the adoption decision and the process of
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26 184 adapting the two changes into the school context. Moreover, all four schools used a children voice group,
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28 185 with representatives from each class in school, to get insight into the opinion of children regarding HPSF.
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30 186 In this way, the experiences of children were being heard and the changes could be further
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32 187 contextualized to fit better to the children's needs and wishes. HPSF was led by an executive board with
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34 188 representatives of the three collaborating organisations: Movare, the regional public health services and
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36 189 Maastricht University. They discussed the study design, the relevant outcome measures, and the
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38 190 interpretation of the results. The representative of Movare advised explicitly on school and participant
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40 191 recruitment and the communication to schools. No patients were involved in this study.

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43 193 **Study population**

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45 194 All intervention and control schools are situated in the Parkstad region in the southern part of the
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47 195 Netherlands. This region has a low average socio-economic status (SES), and unhealthy lifestyle
48
49 196 behaviours and overweight are highly prevalent compared with the rest of the Netherlands [31]. More
50
51 197 information on the recruitment of the schools has been described elsewhere [26]. All children (N=2326
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53 198 at T0) and their parents in the eight schools were invited to participate in the study. This included children
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55 199 from study year one to eight (age 4 to 12 years), which is comparable to two years of Kindergarten and
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57 200 six primary school grades. Recruitment was done via information brochures for parents. In addition, the
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59 201 research team visited the classrooms to inform children about the study and encourage them to ask
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3 202 their parents for participation [26]. Due to the dynamic population in the schools (new children enter and
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5 203 other children finish school each year), we focused in this study only on the children who were enrolled
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7 204 in the schools at baseline till the end of this 2-year study. The population of children included in this
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9 205 study were: at baseline (T0) children from study year one to seven, at T1 children from study year two
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11 206 to eight, and at T2 children from study year three to eight. Children of these study years who joined the
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13 207 study at T1 or T2 were included, even though no baseline data was available. Even though these
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15 208 children joined the study later, they were at baseline already participating in their school and thus also
16
17 209 exposed to HPSF during the full 2 years of this study. Children who switched to other schools between
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19 210 2015 and 2017 were excluded.

20 211

21 212 **Measurements**

22 213 In each school, the data were gathered annually during one week of measurements. Inter-rater variability
23
24 214 was minimised by training researchers according to a strict protocol [26]. Children's age, study year,
25
26 215 and gender were collected via the database of the educational board Movare. A digital questionnaire for
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28 216 parents was used to obtain information about the children's socioeconomic background and ethnicity.
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30 217 SES was calculated as the mean of standardized scores on maternal education level, paternal
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32 218 educational level, and household income (adjusted for household size) [32]. The mean scores were
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34 219 categorized into low, middle and high SES scores based on tertiles. Children's ethnicity was determined
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36 220 by the country of birth of both parents and divided into 1) Western background (including the
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38 221 Netherlands) and 2) non-Western background [33]. If one of the parents was born in a non-Western
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40 222 country, the child's ethnicity was assigned to non-Western. The distinction between Western and non-
41
42 223 Western was created because of differences in socio-economic and cultural position between the two
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44 224 backgrounds [33].

45 225

46 226 *BMI z-score*

47 227 Height and weight were measured in children from study year two to eight. The measurements were
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49 228 integrated in the school hours allocated to physical education. Weight was measured to the nearest 0.1
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51 229 kg (Weighing Scale 803, Seca, Hamburg, Germany) and height was measured to the nearest 0.1 cm
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53 230 (Stadiometer 213, Seca, Birmingham, United Kingdom). Children were measured with light sports
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55 231 clothing and no shoes. All anthropometric measurements were performed twice, and a third
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3 232 measurement was conducted if the difference between the first two measurements exceeded a pre-set
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5 233 limit (weight ≥ 0.2 kg, height ≥ 0.5 cm). BMI was assessed by height and weight; age- and gender-
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7 234 specific BMI cut-off points were used to define overweight and obesity [34]. BMI z-scores were
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9 235 calculated by using Dutch reference values [6].
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11 236

12 237 **Statistical analyses**

14 238 Data were analyzed using IBM SPSS Statistics for Windows (version 23.0. Armonk, NY: IBM Corp).
16 239 Pearson's chi-square tests and ANOVA tests were conducted to analyze the comparability of the
17 240 observed participant characteristics among the full HPSF, the partial HPSF, and control schools at
18 241 baseline. Linear mixed model analyses were used to assess the longitudinal intervention effects on the
19 242 children's BMI z-score. Since measurements were repeated within participants, we used a two-level
20 243 model with repeated measurements as the first level and participants as the second level. The fixed part
21 244 of the model consisted of group (full HPSF, partial HPSF, and Control), time (T0, T1, T2) and the
22 245 interaction terms of group with time. We were not able to include class as a level in the model, because
23 246 often several divisions of one class existed, e.g. 4a or 4b, and children often did not have fixed class
24 247 divisions for all years. All analyses were adjusted for gender, study year at baseline, SES, and ethnicity.
25 248 Missing covariates and BMI z-scores were imputed using multiple imputation method with fully
26 249 conditional specification (FCS) and 10 iterations, generating 50 complete datasets. Gender, study year
27 250 at baseline, school type, ethnicity, SES score, and BMI z-score were used to impute the missing data.
28 251 We performed two sensitivity analyses. First, we replicated the analyses by only selecting the children
29 252 who had no missing BMI z-score at all three time points (complete-case analysis). Second, we replicated
30 253 the analyses while excluding children with an extremely low BMI z-score at baseline (BMI z-score ≤ -2),
31 254 to study the effects only in children for which a decrease in BMI z-score is favorable.
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49 256 To study whether the intervention effects were similar for all subgroups of children, the following potential
50 257 effect modifiers were considered: gender (boys/girls), study year at baseline (lower (1-4)/higher (5-8)
51 258 grades), SES (low/middle/high) and baseline weight status (non-overweight/overweight). To assess this
52 259 potential effect modification, the interaction term group*time*effect modifier, with all corresponding two-
53 260 way interactions, was added to the above mentioned model. If this interaction term was significant (here
54 261 we used a significance level of 0.10 to deal with the fact that the power of a test for interaction is relatively
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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).

267

268 Results

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

281

282 Figure 1. *Flowchart*

283

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

285

286 Observed data at T1 showed a decrease in BMI z-score compared with baseline in all three groups,
287 with the full HPSF (Δz -score: -0.074) and the partial HPSF (Δz -score: -0.098) having the largest
288 decrease, and control schools a smaller decrease (Δz -score: -0.018). At T2, a decrease in BMI z-score
289 compared with baseline was observed in the full HPSF (Δz -score: -0.039) and the partial HPSF (Δz -
290 score: -0.012), and an increase in the control schools (Δz -score: +0.058) (Figure 2). The extent of
291 observed increase or decrease at T1 and T2 compared with baseline of individual children in the three

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3 292 different groups is visualized in Figure S1 (Supplementary file 1). This figure shows that compared to
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5 293 the control schools, in the full and partial HPSF a higher percentage of children had decreased BMI z-
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7 294 scores. This was particularly visible after one-year follow-up. The figure also indicates that, on an
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9 295 individual level, mostly minimal to moderate changes ($-0.6 \leq \Delta z\text{-score} \leq +0.6$) were realized. The
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11 296 variation in changes increased over time, i.e. the percentage of large and extreme decreases and
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13 297 increases was larger after two years' follow-up compared with one-year follow-up.

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16 299 *Figure 2. Observed change in children's BMI z-score at one year and two years' follow-up*

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20 301 Mixed model analyses were conducted to study the differences in effect among the three groups. The
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22 302 intervention effect was, compared with control schools, significant after one-year follow-up in the partial
23
24 303 HPSF (ES=-0.05), not significant in the full HPSF (ES=-0.04) (Table 2). After two years' follow-up a
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26 304 significant intervention effect on children's BMI z-score was found in both versions of HPSF. Children's
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28 305 BMI z-score had decreased significantly more in the full HPSF (ES=-0.08) and the partial HPSF (ES=-
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30 306 0.07), compared with children of the control schools, whose estimated mean BMI z-score increased
31
32 307 from baseline to two years as reported above. No significant difference in effect was found between the
33
34 308 full and partial HPSF at T1 and T2. Both complete case analyses (N=759) and the sensitivity analyses
35
36 309 in which children with an extremely low BMI z-score at baseline were excluded (N_{excluded}=14), resulted
37
38 310 in comparable effect sizes. None of the interaction terms of the potential effect modifiers, i.e., gender,
39
40 311 study year, SES and weight status, was significant (Table S1 in Supplementary file 1).

41 312

43 313 *Table 2. One- and two-year estimated intervention effects on children's BMI z-score*

45 314

47 315 **Discussion**

49 316 This study assessed the effects of HPSF on children's BMI z-score after one and two years' follow-up
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51 317 compared with children of control schools. The findings showed a favorable decreasing effect at T2 on
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53 318 children's BMI z-scores in both the full HPSF (standardized effect size (ES) =-0.08) and the partial HPSF
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55 319 (ES=-0.07) compared with control schools, where the BMI z-score actually increased at T2 compared
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57 320 with baseline. According to Lipsey's guidelines [36], these findings can be indicated as a small effect
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59 321 (effect size between 0 and 0.32). These small intervention effects are promising for three reasons: 1)

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3 322 they are already visible after two years of implementation, 2) they indicate a change in the increasing
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5 323 BMI trend observed in the control schools, and 3) they are slightly higher than the effect sizes found in
6
7 324 several meta-analyses regarding school-based interventions [17, 18, 37]. The decrease in BMI z-score
8
9 325 found in this study in the full and partial HPSF can therefore be considered as a favorable and promising
10
11 326 intervention effect. No significant differences were found between the full and partial HPSF. The main
12
13 327 distinction between them was the provision of a healthy lunch. However, the process evaluation of
14
15 328 Bartelink et al. has shown that providing this lunch led to the implementation of additional health-
16
17 329 promoting changes (e.g. health promoting policy, educational lunch) [30]. Additional health-promoting
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19 330 changes were not implemented in the partial HPSF [30]. However, since no significant differences were
20
21 331 found between the full and partial HPSF, this might indicate that the differences between the two
22
23 332 versions of HPSF did not have an additional favorable effect on the children's BMI z-score. Further
24
25 333 research is needed to investigate whether an added value of the lunch and its additional health-
26
27 334 promoting changes is visible in children's health behaviours.

28 335
29
30 336 Even though the effects of HPSF on children's BMI z-score seem promising, it is important to realize
31
32 337 that two years' follow-up is too short to conclude that HPSF has led to sustainable changes. The
33
34 338 favorable effects on children's BMI z-scores seem to indicate that the children improved their health
35
36 339 behaviours, but this should be investigated in more depth. A longer follow-up period is also needed to
37
38 340 study whether the results found are not only due to the children's enthusiasm for and cooperation with
39
40 341 the new changes in school, which might result in intervention effects that diminish after longer follow-up
41
42 342 periods. This can be the reason for the smaller observed change scores after two years' follow-up
43
44 343 compared to after one year, shown in Figure 2. On the other hand, the favorable results that are still
45
46 344 found after two years' follow-up might indicate that new habits and routines have developed in children's
47
48 345 health behaviours. The latter is not easy to change and requires a shift in the social norms of all people
49
50 346 in the school regarding 'normal' health behaviours. Therefore, further research into HPSF should
51
52 347 investigate its long-term effects on children's BMI z-score. Other outcomes should also be investigated
53
54 348 to study the effects of HPSF, including children's educational achievements and well-being and the cost-
55
56 349 effectiveness of the intervention. This broader scope of the effects of HPSF is included in the overall
57
58 350 study design and will be investigated by our multi-disciplinary research group [26]. The specific focus in
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60

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2
3 351 the current study enabled us to investigate the effects of HPSF on children's BMI z-score in much more
4
5 352 detail.

6
7 353
8
9 354 The second research question investigated whether HPSF has different effects within specific
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11 355 subgroups of children. Effect-modification analyses showed no significant interactions at T1 and T2.
12
13 356 However, the big difference in group sizes in the subgroups of, for example, children's weight status,
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15 357 influenced the p-value. Therefore, effect sizes give a better indication. They all showed similar patterns
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17 358 to the overall analyses. These results seem to indicate that no specific subgroups of children were found
18
19 359 to benefit more from HPSF, which is promising as often school-based interventions only seem effective
20
21 360 for specific subgroups [17, 25]. These results are especially promising when related to health
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23 361 inequalities, because even when interventions are successful in improving children's health, they may
24
25 362 still increase health inequalities. This can happen when an intervention is of greater benefit to
26
27 363 advantaged groups, e.g., high SES, than to disadvantaged groups, e.g., low SES [38]. Given the results
28
29 364 of the effect modification analyses, HPSF can be seen as an example of an intervention that does not
30
31 365 seem to increase health inequalities among children. Further research with longer follow-up periods
32
33 366 should investigate whether HPSF contributes to reducing the health inequalities.

34 367

35 368 **Limitations and strengths**

37 369 The longitudinal quasi-experimental design can be seen as a limitation of this study, since we were
38
39 370 unable to (cluster-) randomize schools. However, due to this design, we were able to test the
40
41 371 effectiveness in terms of differences in children's BMI z-scores between the three school groups over
42
43 372 time, and were also able to enroll schools on the basis of motivation, which reflects the real-life situation
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45 373 of school health promotion. Moreover, participants did not significantly differ from non-responders in the
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47 374 participating schools and other children in the region with regard to health and lifestyle [39]. The lack of
48
49 375 randomization could, however, have resulted in confounding bias. Therefore, we controlled for baseline
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51 376 BMI z-score, gender, study year at T0, SES score, and ethnicity in all analyses. The significant
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53 377 differences in children's BMI z-scores at baseline between the three groups could indicate that children
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55 378 in the control schools are less open to change: their habits in unhealthy behaviours are stronger as they
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57 379 have already led to overweight or obesity. On the other hand, this difference, which we controlled for,

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3 380 may have resulted in an underestimation of the effect: more room for improvement existed for the
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5 381 children in the control schools compared with the full and partial HPSF.

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7 382 Next, HPSF seemed to affect all children in the intervention schools. However, a decrease in
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9 383 BMI z-score might not be favorable for all of them, for example when they already have an extremely
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11 384 low BMI z-score. Therefore, to ensure that the findings reflected the children for whom a decrease in
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13 385 BMI z-score is favorable, we conducted extra sensitivity analyses in which we excluded the children with
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15 386 extremely low BMI z-scores at baseline. These analyses showed comparable results. The high number
16
17 387 of children enrolled in the measurements, the low drop-out rate, and the objectively measured BMI were
18
19 388 other strengths of this study. There were missing data because some participants did not participate
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21 389 from the start, other participants finished school before the last measurement period in 2017, the
22
23 390 parental questionnaire was not completed, respondents skipped questions, or data could not be
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25 391 obtained due to the absence of the child. To deal with the missing data, multiple imputations were used,
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27 392 and a sensitivity analysis, in which only complete cases were included, was conducted. Complete case
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29 393 analysis showed similar results to the original analysis, which increased the reliability of the findings in
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31 394 this study.

32 395

33 396 **Conclusions**

35 397 Taking all the results and limitations into account, it can be concluded that HPSF was effective in
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37 398 lowering children's BMI z-scores after one and two years' follow-up and no specific subgroups of children
38
39 399 were found to benefit more from the intervention. Even though longer follow-up periods are needed to
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41 400 draw hard conclusions, both versions of the initiative seem promising in offering perspective in the on-
42
43 401 going obesity epidemic in young children.

44 402

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48
49 405 project. We thank the PhD students and research assistants for their help in data collection.

50 406

51 407 **Competing interests**

52 408 The authors declare that they have no competing interests.

53 409

410 **Ethics approval and consent to participate**

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

413

414 **Data sharing**

415 The data that support the findings of this study were collected as part of the 'Healthy Primary School of
416 the Future' quasi-experimental study. Data collection will take place until 2019 to study the effects after
417 4 years of exposure. Data on the 4-year effects and potential other comparative studies in the
418 Netherlands will become available following article publication.

419

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424 interpretation of data, and writing of publications.

425

426 **Authors' contributions**

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

431

432 **Supplementary Information**

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

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

438

439 **License statement**

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541 **Figure 1. Flowchart**

542
543 * Reasons for drop-out T1: switched to other included school (n=2), other reasons, e.g., moved away or actively
544 stopped participation (n=62).

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

547 ***Selection for effect study: at baseline (T0) children from study year one to seven, at T1 children from study year
548 two to eight, and at T2 children from study year three to eight.

549

550 **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

551 ^a Observed N, missing data was due to later participation in the study, incomplete parent questionnaire, or because
552 no height/weight was measured in study year 1.

553 ^b Study year 1-8 in Dutch system is comparable to two years of kindergarten followed by grade 1-6.

554 ^c Chi-square test.

555 Bold p-value = significant (<.05) difference

556 Abbreviations: SD = standard deviation; C.I. = confidence interval; ES = Effect size.

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

566 **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

567 ^a Adjusted for baseline, gender, study year at T0, SES, and ethnicity.

568 Bold p-value = significant (<.05) difference

569 Abbreviations: C.I. = confidence interval; ES = Effect size.

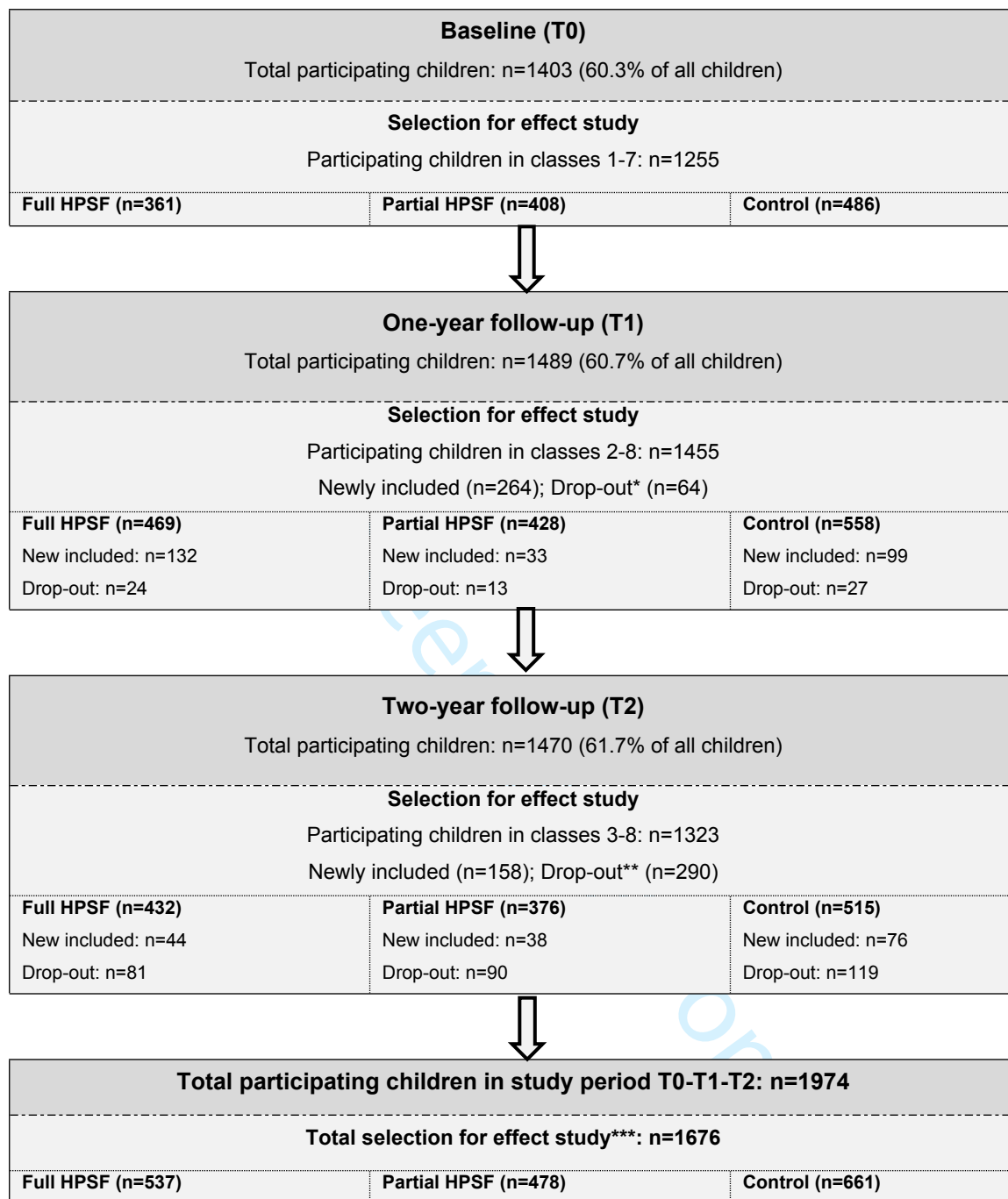


Figure 1. Flowchart

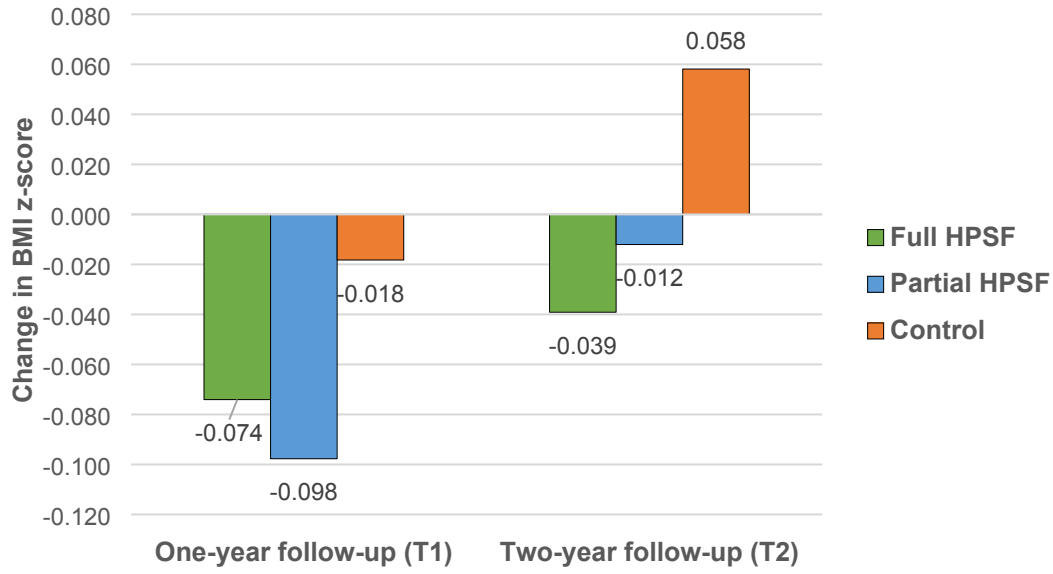


Figure 2. Observed change in children’s BMI z-score at one year and two years’ follow-up compared with baseline

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Supplementary file 1

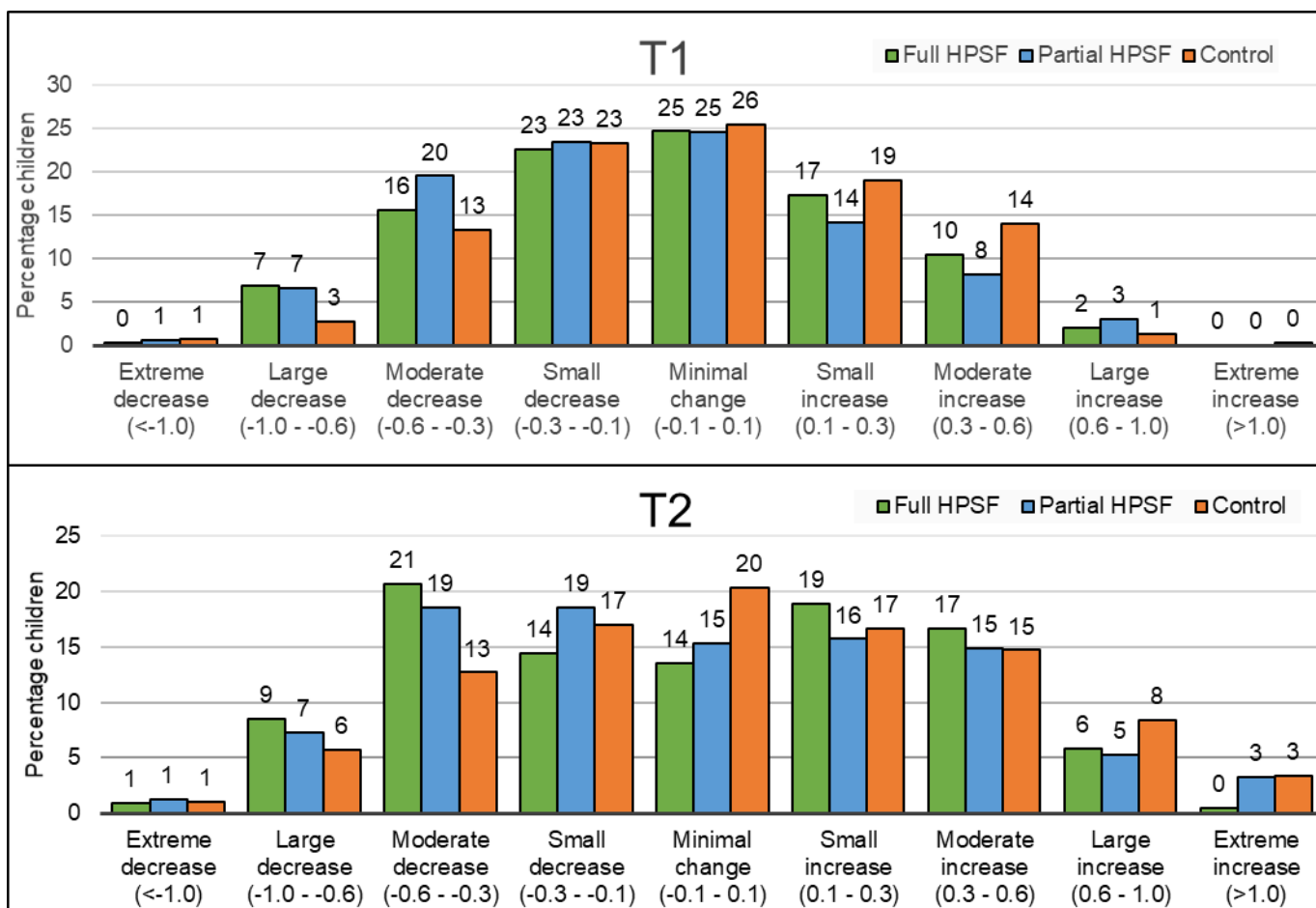


Figure S1. Graphical presentation of individual changes in BMI z-scores at one year (T1) and two years' (T2) follow-up compared with baseline

8
9 **Table S1. Potential effect-modifiers of the intervention effects on children’s BMI z-score ^a**

	N ^b	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
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
165-8	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.



Trial record 1 of 1 for: Saved Studies

Previous Study | [Return to List](#) | Next Study

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](#)

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[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 ⓘ
For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml		

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

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

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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 ⓘ
<p>Experimental: Full intervention group</p> <p>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.</p>	<p>Other: The Healthy Primary School of the Future</p> <p>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.</p>
<p>Experimental: Partial intervention group</p>	<p>Behavioral: The Physical Activity School</p>

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<p>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.</p>	<p>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.</p>
<p>No Intervention: Control group</p> <p>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.</p>	

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)

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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 the 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]

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Assessed using the Strength and Difficulties Questionnaire.

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3 13. Child social, emotional, and academic self-efficacy. [Time Frame: Four years]
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5 Tested using the Self-Efficacy Questionnaire for Children (SEQ-C).
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9 14. Child self-confidence, social skills, self-efficacy, school well-being, future expectations, and
10 social support [Time Frame: Four years]
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12 Assessed with OnderwijsMonitor Limburg programme
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15 15. Child physical activity and sedentary behavior assessed using the Actigraph accelerometer
16 [Time Frame: Four years]
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18 In the week in which the child is wearing the accelerometer, parents fill in a short activity
19 diary on their child's physical activity and swimming behaviour and exceptional
20 circumstances (e.g., illness of the child)
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25 16. Sports club membership, active forms of transport to school, and leisure time physical
26 activities (e.g., children's activities in weekends: watching TV, music or theatre, playing
27 outdoors, practicing sports etc.) assessed in both children and parents. [Time Frame: Four
28 years]
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31 Self-report measure
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35 17. Child food intake [Time Frame: Four years]
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37 Assessed using a food frequency questionnaire and a dietary recall tool to be completed by
38 both children and parents.
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42 18. Child food preferences and familiarity with healthy food products. [Time Frame: Four years]
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44 Self-report measure: The questions mainly consist of pictures of food items, for which
45 children can indicate whether they have ever eaten these items and whether they like them
46 or not.
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50 19. Parental practices regarding nutrition and physical activity [Time Frame: Four years]
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52 Self-report measure
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55 20. Parental wellbeing [Time Frame: Four years]
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57 measured by the Satisfaction With Life Survey (SWLS)
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21. Parental health-related quality of life [Time Frame: Four years]

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

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1 22. Socioeconomic status [Time Frame: Four years]

3 Self-report measure

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

8 E.g. modelling eating healthy food products and encouraging children's physical activity.

9 Measured using adapted version of the Parental Practices Instrument

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

15 Written questionnaire

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

20 Monitored using the Dutch national test called Centrale Eindtoets Basisonderwijs (CITO),
21 and various other tests used by the schools. The CITO test measures language, maths and
22 world orientation. In addition to the CITO test, many schools use a wide range of tests
23 throughout the children's school careers. This also includes tests on maths (taken twice a
24 year) and various aspects of language such as decoding skills, spelling, vocabulary, and
25 reading comprehension.
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32 26. School advice and the actual level of secondary school opted for (Dutch secondary education
33 is hierarchically ordered). [Time Frame: Four years]

34 School registration system

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

40 School registration system

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

45 Self-report measure: general parental satisfaction with their children's school (including
46 safety, communication, quality of education, challenges to children, and professionalism of
47 teachers). Implementation of the intervention is evaluated by qualitative outcome measures
48 such as interviews with parents and children, and classroom observations.
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54 29. Juridical evaluation through literature study and interviews [Time Frame: Four years]

55 Legal aspects will be addressed by a thorough scientific literature study and examination of
56 policy and legislation instruments and case-law on the scope of children's right to health.
57 Interviews with the parties involved in the healthy school setting will determine the juridical-
58 related interests and possibilities.
59
60

Eligibility Criteria

Go to

Information from the National Library of Medicine



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



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

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More Information

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Additional Information:

[Official website about this project for various stakeholders \(in Dutch\)](#) 

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

[Willeboordse M, Jansen MW, van den Heijkant SN, Simons A, Winkens B, de Groot RH, Bartelink N, Kremers SP, van Assema P, Savelberg HH, de Neubourg E, Borghans L, Schils T, Coppens KM, Dietvorst R, Ten Hoopen R, Coomans F, Klosse S, Conjaerts MH, Oosterhoff M, Joore MA, Ferreira I, Muris P, Bosma H, Toppenberg HL, van Schayck CP. The Healthy Primary School of the Future: study protocol of a quasi-experimental study. BMC Public Health. 2016 Jul 26;16:639. doi: 10.1186/s12889-016-3301-9. Erratum in: BMC Public Health. 2017 Apr 11;17 \(1\):314.](#)

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ClinicalTrials.gov Identifier: [NCT02800616](#) [History of Changes](#)
Other Study ID Numbers: UM MOVARE GGD
First Posted: June 15, 2016 [Key Record Dates](#)
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Last Verified: March 2016

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Keywords provided by Maastricht University:

Academic Achievement	Obesity
Accelerometry	Physical Activity
Children	Prevention
Primary school Intervention	School Health
Nutrition	

Additional relevant MeSH terms:

Overweight	Body Weight
Malnutrition	Signs and Symptoms
Mental Disorders	Nutrition Disorders

BMJ Open

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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Keywords:	PUBLIC HEALTH, PREVENTIVE MEDICINE, Community child health < PAEDIATRICS

SCHOLARONE™
Manuscripts

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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1
2
3 **38 Abstract**

4
5 **39 Objectives:** Schools play an important role in promoting healthy behaviours in children and can offer
6
7 40 perspective in the on-going obesity epidemic. The 'Healthy Primary School of the Future' (HPSF) aims
8
9 41 to improve children's health and well-being by enhancing school health promotion. The current study
10
11 42 aims to assess the effect of HPSF on children's BMI z-score after one and two years' follow-up and to
12
13 43 investigate whether HPSF has different effects within specific subgroups of children.

14
15 44 **Design:** A longitudinal quasi-experimental design.

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17 45 **Setting:** Four intervention and four control schools participated; located in a low socio-economic status
18
19 46 region in the Netherlands.

20
21 47 **Participants:** 1676 children (aged 4-12 years).

22
23 48 **Interventions:** HPSF uses a contextual systems approach and includes health-promoting changes in
24
25 49 the school. Central to HPSF are the provision of a daily healthy lunch and structured physical activity
26
27 50 sessions each day. Two intervention schools implemented both changes (full HPSF), two intervention
28
29 51 schools implemented only the physical activity change (partial HPSF).

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31 52 **Main outcome measures:** BMI z-score, determined by measurements of children's height and weight
32
33 53 at baseline, after one and two years' follow-up.

34
35 54 **Results:** The intervention effect was significant after one-year follow-up in the partial HPSF
36
37 55 (standardized effect size $ES=-0.05$), not significant in the full HPSF ($ES=-0.04$). After two years' follow-
38
39 56 up, BMI z-score had significantly decreased in children of both the full HPSF ($ES=-0.08$) and the partial
40
41 57 HPSF ($ES=-0.07$) compared with children of the control schools, whose mean BMI z-score increased
42
43 58 from baseline to two years. None of the potential effect-modifiers (gender, baseline study year, socio-
44
45 59 economic status, and baseline weight status) were significant.

46
47 60 **Conclusions:** HPSF was effective after one and two years' follow-up in lowering children's BMI z-
48
49 61 scores. No specific subgroups of children could be identified who benefitted more from the intervention.

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51 62 **Trial registration:** The study was registered in the ClinicalTrials.gov database on 14 June 2016
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53 63 (NCT02800616).

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3 **68 Strengths and limitations of this study**
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- 5 69 • Due to the longitudinal quasi-experimental study design, we were able to test the effectiveness
6
7 70 in terms of differences in children's health behaviours between the three school groups over
8
9 71 time, and were also able to enroll schools on the basis of motivation, which reflects the real-life
10
11 72 situation of school health promotion.
12
13 73 • Since the lack of randomization could have resulted in confounding bias, we controlled for
14
15 74 baseline BMI z-score, gender, study year at T0, SES score, and ethnicity in all analyses.
16
17 75 • The high number of children enrolled in the measurements, the low drop-out rate, and the
18
19 76 objectively measured BMI were strengths of this study.
20
21 77 • Due to some missing data, multiple imputations were used and a sensitivity analysis was
22
23 78 conducted, where only complete cases were included.
24
25 79 • Participants did not significantly differ from non-responders in the participating schools and other
26
27 80 children in the region with regard to health and lifestyle.
28
29 81

82 Introduction

83 Overweight and obesity can lead to health problems, such as type 2 diabetes, cardiovascular diseases,
84 and psychological problems (e.g., low self-esteem) [1, 2]. Globally, the prevalence of overweight and
85 obesity among children and adolescents (aged 5-19) has risen dramatically from 4% in 1975 to more
86 than 18% in 2016 [3, 4]. The prevalence is highest among children with a low socio-economic
87 background [5]. In the Netherlands, the prevalence of childhood overweight and obesity has also
88 increased in the last decennia: 13–15% of children (aged 2–21 years) are overweight, and 1.8–2.2%
89 are classified as obese, which is a 2- to 3-fold increase compared with 1980 [6]. The ongoing epidemic
90 increase is particularly caused by unhealthy behaviours, such as unhealthy dietary intake and low levels
91 of physical activity (PA) [7]. The health behaviours of children in the Netherlands are suboptimal. For
92 example, 42% of children (aged 4–9 years) consume at least 150 g of fruit per day, which drops to 20%
93 for 9–12 year olds [8]. Regarding PA, only half (48%) of Dutch children (aged 4–12) meet the guidelines
94 for PA of 60 min of moderate-to-vigorous physical activity (MVPA) per day [9]. Unhealthy behaviours at
95 a young age often track into adulthood [10] and are related to health and psychosocial problems,
96 reduced quality of life, higher health care costs, lower educational achievement and labor participation
97 [11-13]. A vicious circle is emerging, transferring problems, such as obesity, from one generation to the
98 next [14]. Promoting healthy behaviours at an early age may help to improve children's health on the
99 short and long run [10]. Moreover, promoting health behaviours could also lead to better educational
100 and academic achievements, which have been found to be related to improved health in later life as well
101 [15].

102
103 Schools can play an important role in promoting healthy behaviours in children since a significant
104 proportion of a child's day is spent there and they reach all children [16-18]. As such, school-based
105 interventions may be an important instrument to offer perspective in the on-going obesity epidemic in
106 young children. Many different school-based interventions (e.g. related to education, environment,
107 policy, monitoring) have been implemented to integrate health into the school system and reduce
108 childhood overweight and obesity. The meta-analysis of both Cook-Cottone et al. and Oosterhoff et al.
109 found that the significant effect of school-based interventions on children's Body Mass Index (BMI) z-
110 score had an overall weighted effect size of approximately -0.05 [19, 20]. Several studies indicated that
111 effects are often hampered by underestimation of the challenges associated with implementing

1
2
3 112 meaningful changes to the school system [21-23]. These challenges occur because an intervention
4
5 113 always interacts with the specific school context [22, 23]. Therefore, solutions for the challenges
6
7 114 associated with changing school systems vary between schools as they all have their own dynamics
8
9 115 [22-24]. Consequently, an intervention can be seen as an attempt to positively disrupt the prior
10
11 116 functioning of a school system [25, 26]. Some other reviews stated that specific subgroups of children
12
13 117 benefit more from a school-based intervention. The review of Stewart-Brown et al. [27] found that several
14
15 118 studies indicated gender-specific results, with some school-based interventions being more effective in
16
17 119 girls and others in boys. Age-specific effects were often found, with some interventions being more
18
19 120 effective in older children and others in younger children [27]. Cook-Cotton et al. found that children's
20
21 121 socio-economic background can be an influential factor and that children already having overweight can
22
23 122 respond more slowly or to a lesser extent to school-based interventions than children with a healthy
24
25 123 weight [19].

26 124
27
28 125 A Dutch initiative that embraces a contextual systems approach is the 'Healthy Primary School of the
29
30 126 Future' (HPSF) [28, 29]. HPSF aims to improve the health and well-being of all children in the school
31
32 127 which should contribute to a healthier future generation and thereby offer perspective in the on-going
33
34 128 obesity epidemic [30]. HPSF includes top-down and bottom-up processes to create health-promoting
35
36 129 changes in the school. Two changes were initiated to create some form of positive disruption in the
37
38 130 school: 1) providing a free healthy lunch each day and 2) daily structured physical activity (PA) sessions
39
40 131 after lunch. While in other national school systems this may represent usual practice, these changes
41
42 132 are hypothesized as disruptive to the Dutch school system because the provision of school lunches and
43
44 133 structured PA sessions are not usual practice in Dutch schools. The two changes aimed to create
45
46 134 momentum to implement additional health-promoting changes in the school, such as a healthy school
47
48 135 policy or creating a PA-friendly schoolyard. All changes together should favourably affect the health
49
50 136 behaviours of all school children, which should lead to improved health and a more normal weight status
51
52 137 [28, 29].

53 138
54
55 139 The aim of the current study was to assess the effect of HPSF on children's BMI z-score after one and
56
57 140 two years' follow-up and to investigate whether HPSF has different effects within specific subgroups of
58
59 141 children. The current study is part of an overall study to investigate HPSF. The overall study has a broad
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1
2
3 142 scope and includes a multi-disciplinary research group, which focuses on many different outcomes, such
4
5 143 as children's health behaviours, educational achievements, and well-being. The studies that have been
6
7 144 published previously, focused on the implementation process of HPSF [31] and the effects of HPSF on
8
9 145 children's dietary and PA behaviours [32]. The current study explicitly concentrates on children's BMI z-
10
11 146 score to focus in much detail on the primary outcome as described in the study design of Willeboordse
12
13 147 et al. [28].

14
15 148

16 149 **Methods**

17 150 **Study design**

18
19
20 151 The current study had a longitudinal quasi-experimental design with four intervention schools and four
21
22 152 control schools, which maintained the school curriculum that is currently common practice in the
23
24 153 Netherlands. Ethical approval (14-N-142) was given by the Zuyderland Medical Ethics Committee
25
26 154 located in Heerlen (Parkstad, the Netherlands). Parents had to sign an informed consent form to
27
28 155 participate in all measurements for themselves and their child(ren). Measurements were conducted in
29
30 156 September-November of 2015 (T0), 2016 (T1) and 2017 (T2). A detailed description of the study and
31
32 157 the power calculation is reported in Willeboordse et al. [28].

33
34 158

35 159 **The Healthy Primary School of the Future**

36
37 160 Three collaborating organisations, i.e., the regional educational board 'Movare', the regional public
38
39 161 health services and Maastricht University, developed the idea for HPSF [28]. In March 2013, 12 out of
40
41 162 53 schools governed by the Movare educational board were informed about the initiative. Four schools
42
43 163 gave their initial consent and spent a whole school year (2014/2015) creating bottom-up support for
44
45 164 HPSF. Two of the four intervention schools decided to implement both the daily lunch and the structured
46
47 165 PA sessions and are referred to as the 'full HPSF'. The other two intervention schools decided to only
48
49 166 implement the structured PA sessions, and are referred to as the 'partial HPSF'. All schools could
50
51 167 implement additional health-promoting changes, that fit their school context [29, 31]. The full HPSF
52
53 168 improved their health policy, provided water bottles to all children, and provided an educational lunch
54
55 169 once a week. The partial HPSF did not implement additional health-promoting changes.

56
57 170 Implementation started in all four intervention schools in November 2015. The time for having
58
59 171 lunch (in the full HPSF) was increased to 20–30 min. The total lunch break time in these schools was
60

1
2
3 172 prolonged by about 60 min. For this reason, the school day was extended: children of the full HPSF
4
5 173 attend school to approximately 15:30/15:45 instead of 15:00. A dietician of the caterer developed a lunch
6
7 174 menu cycle that changed every 10 weeks, in which at least 80% of the products met the advice of the
8
9 175 Dutch Health Council [33]. A mid-morning snack, consisting of fruits and/or nuts, was also provided. The
10
11 176 lunch, a bread-based cold meal, was typically Dutch. During lunch break time, the children participated
12
13 177 several times a week in structured PA sessions; one or two times per week they could participate in
14
15 178 cultural activities. The PA sessions were carried out in the schoolyard and, when available and needed,
16
17 179 in parks, forest, and/or sports hall in the neighbourhood. All schools collaborated with sport clubs or
18
19 180 other external partners to offer specific activities as well. Since the two changes were contextualized
20
21 181 bottom-up, this resulted in some differences between schools in the form of the changes; the content
22
23 182 remained comparable.

24 183 The two changes, i.e. providing daily a free healthy lunch and structured PA sessions after
25
26 184 lunch, were both led by external pedagogical employees provided by childcare organizations to not
27
28 185 increase the workload of teachers even further. This integration of the childcare organization during
29
30 186 school hours is not to provide a temporary solution, but to change the school's organization in a
31
32 187 sustainable way. The aim for the future is to bring school and childcare more together and thereby create
33
34 188 an integrated day for children, whereby children are supervised by the same people prior, during and
35
36 189 after school hours. Employees of sports and leisure organizations supported the external pedagogical
37
38 190 employees during implementation when needed, and after a year they provided a training course (8
39
40 191 sessions of 2h) to supply them with additional tools for how to motivate children for active participation
41
42 192 during the PA sessions. A health promoter from the regional Public Health Services was assigned to
43
44 193 each school to provide support when needed. In this study, researchers from Maastricht University
45
46 194 monitored and fed back results to the schools to support the processes of change. Funding for
47
48 195 implementation of HPSF is provided by the provincial authorities until the end of 2019. However, the
49
50 196 four schools have committed to continued implementation after 2019 and make the changes sustainable
51
52 197 in their school.

53 198

54 199 **Patient and public involvement**

56 200 Public involvement was a key feature of HPSF. This intervention intended to establish a co-creation
57
58 201 movement in schools aimed at the systematic incorporation of health and well-being. The two top-down
59
60

1
2
3 202 changes and the additional health-promoting changes were developed and contextualized by bottom-
4
5 203 up involvement. Teachers and parents were involved from the start in the adoption decision and the
6
7 204 process of adapting the several changes into the school context. Moreover, all four schools used a
8
9 205 children voice group, with representatives from each class in school, to get insight into the opinion of
10
11 206 children regarding HPSF. In this way, the experiences of children were being heard and the changes
12
13 207 could be further contextualized to fit better to the children's needs and wishes. Each of the four
14
15 208 intervention schools selected a teacher as school coordinator, who managed HPSF in their school.
16
17 209 Overarching, HPSF was led by an executive board with representatives of the three collaborating
18
19 210 organisations: Movare, the regional public health services and Maastricht University. They discussed
20
21 211 the study design, the relevant outcome measures, and the interpretation of the results. The
22
23 212 representative of Movare advised explicitly on school and participant recruitment and the communication
24
25 213 to schools. A project team was created with representatives of all partners involved: the four schools,
26
27 214 Movare, regional Public Health Services, Maastricht University, the Limburg provincial authorities,
28
29 215 childcare organizations, the caterer, and sports and leisure organizations. No patients were involved in
30
31 216 this study.

32 217

33 218 **Study population**

35 219 All intervention and control schools are situated in the Parkstad region in the southern part of the
36
37 220 Netherlands. This region has a low average socio-economic status (SES), and unhealthy lifestyle
38
39 221 behaviours and overweight are highly prevalent compared with the rest of the Netherlands [34]. More
40
41 222 information on the recruitment of the schools has been described elsewhere [28]. All children (N=2326
42
43 223 at T0) and their parents in the eight schools were invited to participate in the study. This included children
44
45 224 from study year one to eight (age 4 to 12 years), which is comparable to two years of Kindergarten and
46
47 225 six primary school grades. Recruitment was done via information brochures for parents. In addition, the
48
49 226 research team visited the classrooms to inform children about the study and encourage them to ask
50
51 227 their parents for participation [28]. Due to the dynamic population in the schools (new children enter and
52
53 228 other children finish school each year), we focused in this study only on the children who were enrolled
54
55 229 in the schools at baseline till the end of this 2-year study. The population of children included in this
56
57 230 study were: at baseline (T0) children from study year one to seven, at T1 children from study year two
58
59 231 to eight, and at T2 children from study year three to eight. Children of these study years who joined the
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1
2
3 232 study at T1 or T2 were included, even though no baseline data was available. Even though these
4
5 233 children joined the study later, they were at baseline already participating in their school and thus also
6
7 234 exposed to HPSF during the full 2 years of this study. Children who switched to other schools between
8
9 235 2015 and 2017 were excluded.

10 236

11 237 **Measurements**

12 238 In each school, the data were gathered annually during one week of measurements. Inter-rater variability
13
14 239 was minimised by training researchers according to a strict protocol [28]. Children's age, study year,
15
16 240 and gender were collected via the database of the educational board Movare. A digital questionnaire for
17
18 241 parents was used to obtain information about the children's socioeconomic background and ethnicity.
19
20 242 SES was calculated as the mean of standardized scores on maternal education level, paternal
21
22 243 educational level, and household income (adjusted for household size) [35]. The mean scores were
23
24 244 categorized into low, middle and high SES scores based on tertiles. Children's ethnicity was determined
25
26 245 by the country of birth of both parents and divided into 1) Western background (including the
27
28 246 Netherlands) and 2) non-Western background [36]. If one of the parents was born in a non-Western
29
30 247 country, the child's ethnicity was assigned to non-Western. The distinction between Western and non-
31
32 248 Western was created because of differences in socio-economic and cultural position between the two
33
34 249 backgrounds [36].

35 250

36 251 *BMI z-score*

37 252 Anthropometric measurements, i.e., height, weight, hip and waist circumference, were conducted in
38
39 253 children from study year two to eight. The measurements were integrated in the school hours allocated
40
41 254 to physical education. Weight was measured to the nearest 0.1 kg (Weighing Scale 803, Seca,
42
43 255 Hamburg, Germany) and height was measured to the nearest 0.1 cm (Stadiometer 213, Seca,
44
45 256 Birmingham, United Kingdom). Hip and waist circumference were measured with a measuring tape to
46
47 257 the nearest 0.1 cm (model 201, Seca, Hamburg, Germany). Children were measured with light sports
48
49 258 clothing and no shoes. All anthropometric measurements were performed twice, and a third
50
51 259 measurement was conducted if the difference between the first two measurements exceeded a pre-set
52
53 260 limit (weight ≥ 0.2 kg, height ≥ 0.5 cm, hip and waist circumference ≥ 1.0 cm). Unfortunately, hip and
54
55 261 waist circumference were excluded from further analyses due to measurement errors. BMI was
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1
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3 262 assessed by height and weight; age- and gender-specific BMI cut-off points were used to define
4
5 263 overweight and obesity [37]. BMI z-scores were calculated by using Dutch reference values [6].
6

7 264

8 265 **Statistical analyses**

9
10 266 Data were analyzed using IBM SPSS Statistics for Windows (version 23.0. Armonk, NY: IBM Corp).
11
12 267 Pearson's chi-square tests and ANOVA tests were conducted to analyze the comparability of the
13
14 268 observed participant characteristics among the full HPSF, the partial HPSF, and control schools at
15
16 269 baseline. Linear mixed model analyses were used to assess the longitudinal intervention effects on the
17
18 270 children's BMI z-score. Since measurements were repeated within participants, we used a two-level
19
20 271 model with repeated measurements as the first level and participants as the second level, where an
21
22 272 unstructured covariance structure was considered for the repeated measures. The fixed part of the
23
24 273 model consisted of group (full HPSF, partial HPSF, and Control), time (T0, T1, T2) and the interaction
25
26 274 terms of group with time. We were not able to include class as a level in the model, because often
27
28 275 several divisions of one class existed, e.g. 4a or 4b, and children often did not have fixed class divisions
29
30 276 for all years. All analyses were adjusted for gender, study year at baseline, SES, and ethnicity. Missing
31
32 277 covariates and BMI z-scores were imputed using multiple imputation method with fully conditional
33
34 278 specification (FCS) and 10 iterations, generating 50 complete datasets. Gender, study year at baseline,
35
36 279 school type, ethnicity, SES score, and BMI z-score were used to impute the missing data. We performed
37
38 280 two sensitivity analyses. First, we replicated the analyses by only selecting the children who had no
39
40 281 missing BMI z-score at all three time points (complete-case analysis). Second, we replicated the
41
42 282 analyses while excluding children with an extremely low BMI z-score at baseline (BMI z-score ≤ -2), to
43
44 283 study the effects only in children for which a decrease in BMI z-score is favourable.
45

46 284

47 285 To study whether the intervention effects were similar for all subgroups of children, the following potential
48
49 286 effect modifiers were considered: gender (boys/girls), study year at baseline (lower (1-4)/higher (5-8)
50
51 287 grades), SES (low/middle/high) and baseline weight status (non-overweight/overweight). To assess this
52
53 288 potential effect modification, the interaction term group*time*effect modifier, with all corresponding two-
54
55 289 way interactions, was added to the above mentioned model. If this interaction term was significant (here
56
57 290 we used a significance level of 0.10 to deal with the fact that the power of a test for interaction is relatively
58
59 291 low and we did not want to miss any effect-modification), the intervention effects were reported for all
60

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

296

297 Results

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

310

311 Figure 1. *Flowchart*

312

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

314

315 Observed data at T1 showed a decrease in BMI z-score compared with baseline in all three groups,
316 with the full HPSF (Δz -score: -0.074) and the partial HPSF (Δz -score: -0.098) having the largest
317 decrease, and control schools a smaller decrease (Δz -score: -0.018). At T2, a decrease in BMI z-score
318 compared with baseline was observed in the full HPSF (Δz -score: -0.039) and the partial HPSF (Δz -
319 score: -0.012), and an increase in the control schools (Δz -score: +0.058) (Figure 2). The extent of
320 observed increase or decrease at T1 and T2 compared with baseline of individual children in the three
321 different groups is visualized in Figure S1 (Supplementary file 1). This figure shows that compared to

1
2
3 322 the control schools, in the full and partial HPSF a higher percentage of children had decreased BMI z-
4
5 323 scores. This was particularly visible after one-year follow-up. The figure also indicates that, on an
6
7 324 individual level, mostly minimal to moderate changes ($-0.6 \leq \Delta z\text{-score} \leq +0.6$) were realized. The
8
9 325 variation in changes increased over time, i.e. the percentage of large and extreme decreases and
10
11 326 increases was larger after two years' follow-up compared with one-year follow-up.

12
13 327

14 328 *Figure 2. Observed change in children's BMI z-score at one year and two years' follow-up*

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16 329

17
18 330 Mixed model analyses were conducted to study the differences in effect among the three groups. The
19
20 331 intervention effect was, compared with control schools, significant after one-year follow-up in the partial
21
22 332 HPSF (ES=-0.05), not significant in the full HPSF (ES=-0.04) (Table 2). After two years' follow-up a
23
24 333 significant intervention effect on children's BMI z-score was found in both versions of HPSF. Children's
25
26 334 BMI z-score had decreased significantly more in the full HPSF (ES=-0.08) and the partial HPSF (ES=-
27
28 335 0.07), compared with children of the control schools, whose estimated mean BMI z-score increased
29
30 336 from baseline to two years as reported above. No significant difference in effect was found between the
31
32 337 full and partial HPSF at T1 and T2. Both complete case analyses (N=759) and the sensitivity analyses
33
34 338 in which children with an extremely low BMI z-score at baseline were excluded (N_{excluded}=14), resulted
35
36 339 in comparable effect sizes. None of the interaction terms of the potential effect modifiers, i.e., gender,
37
38 340 study year, SES and weight status, was significant (Table S1 in Supplementary file 1).

39
40 341

41 342 *Table 2. One- and two-year estimated intervention effects on children's BMI z-score*

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43 343

44 344 **Discussion**

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46
47 345 This study assessed the effects of HPSF on children's BMI z-score after one and two years' follow-up
48
49 346 compared with children of control schools. The findings showed a favourable decreasing effect at T2 on
50
51 347 children's BMI z-scores in both the full HPSF (standardized effect size (ES) =-0.08) and the partial HPSF
52
53 348 (ES=-0.07) compared with control schools, where the BMI z-score actually increased at T2 compared
54
55 349 with baseline. According to Lipsey's guidelines [39], these findings can be indicated as a small effect
56
57 350 (effect size between 0 and 0.32). These small intervention effects are promising for three reasons: 1)
58
59 351 they are already visible after two years of implementation, 2) they indicate a change in the increasing

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2
3 352 BMI trend observed in the control schools, and 3) they are slightly higher than the effect sizes found in
4
5 353 several meta-analyses regarding school-based interventions [19, 20, 40]. The decrease in BMI z-score
6
7 354 found in this study in the full and partial HPSF can therefore be considered as a favourable and
8
9 355 promising intervention effect. No significant differences were found between the full and partial HPSF.
10
11 356 The main distinction between them was the provision of a healthy lunch. However, the process
12
13 357 evaluation of Bartelink et al. has shown that providing this lunch led to the implementation of additional
14
15 358 health-promoting changes (e.g. health promoting policy, educational lunch) [31]. Additional health-
16
17 359 promoting changes were not implemented in the partial HPSF [31]. However, since no significant
18
19 360 differences were found between the full and partial HPSF, this might indicate that the differences
20
21 361 between the two versions of HPSF did not have an additional favourable effect on the children's BMI z-
22
23 362 score.

24 363
25
26 364 The favourable effects on children's BMI z-scores seem to indicate that the children improved their
27
28 365 health behaviours. Indeed, significant favourable intervention effects were found after one- and two-
29
30 366 years' follow-up for the full HPSF on children's dietary behaviours for, among others, school water
31
32 367 consumption and lunch intake of vegetables and dairy products [32]. Children's sedentary time and light
33
34 368 PA significantly improved after two years' follow-up. Almost no significant favourable results on
35
36 369 children's health behaviours were found in the partial HPSF. Since it is the co-existence and interaction
37
38 370 of several nutrition and PA behaviours that results in a positive (or negative) energy balance and weight
39
40 371 gain (or loss) [41, 42], the results suggest that many small improvements on several different health
41
42 372 behaviours have occurred in the children of the partial HPSF, leading to the favourable effects on their
43
44 373 BMI z-score.

45 374
46
47 375 Even though the effects of HPSF on children's BMI z-score seem promising, it is important to realize
48
49 376 that two years' follow-up is too short to conclude that HPSF has led to sustainable changes. A longer
50
51 377 follow-up period is needed to study whether the results found are not only due to the children's
52
53 378 enthusiasm for and cooperation with the new changes in school, which might result in intervention
54
55 379 effects that diminish after longer follow-up periods. This can be the reason for the smaller observed
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57 380 change scores after two years' follow-up compared to after one year, shown in Figure 2. On the other
58
59 381 hand, the favourable results that are still found after two years' follow-up might indicate that new habits

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3 382 and routines have developed in children's health behaviours. The latter is not easy to change and
4
5 383 requires a shift in the social norms of all people in the school regarding 'normal' health behaviours.
6
7 384 Therefore, further research into HPSF should investigate its long-term effects on children's BMI z-score.
8
9 385 Other outcomes should also be investigated to study the effects of HPSF, including children's
10
11 386 educational achievements and well-being and the cost-effectiveness of the intervention. This broader
12
13 387 scope of the effects of HPSF is included in the overall study design and will be investigated by our multi-
14
15 388 disciplinary research group [28]. The specific focus in the current study enabled us to investigate the
16
17 389 effects of HPSF on children's BMI z-score in much more detail.

18 390
19
20 391 The second research question investigated whether HPSF has different effects within specific
21
22 392 subgroups of children. Effect-modification analyses showed no significant interactions at T1 and T2.
23
24 393 However, effect sizes give a better indication since the big difference in group sizes in the subgroups
25
26 394 of, for example, children's weight status, influenced the p-value. All effect sizes showed similar patterns
27
28 395 to the overall analyses. These results seem to indicate that no specific subgroups of children were found
29
30 396 to benefit more from HPSF, which is promising as often school-based interventions only seem effective
31
32 397 for specific subgroups [19, 27]. These results are especially promising when related to health
33
34 398 inequalities, because even when interventions are successful in improving children's health, they may
35
36 399 still increase health inequalities. This can happen when an intervention is of greater benefit to
37
38 400 advantaged groups, e.g., high SES, than to disadvantaged groups, e.g., low SES [43]. Given the results
39
40 401 of the effect modification analyses, HPSF can be seen as an example of an intervention that does not
41
42 402 seem to increase health inequalities among children. Further research with longer follow-up periods
43
44 403 should investigate whether HPSF contributes to reducing the health inequalities.

45 404

47 405 **Limitations and strengths**

48
49 406 The longitudinal quasi-experimental design can be seen as a limitation of this study, since we were
50
51 407 unable to (cluster-) randomize schools. However, due to this design, we were able to test the
52
53 408 effectiveness in terms of differences in children's BMI z-scores between the three school groups over
54
55 409 time, and were also able to enroll schools on the basis of motivation, which reflects the real-life situation
56
57 410 of school health promotion. Moreover, participants did not significantly differ from non-responders in the
58
59 411 participating schools and other children in the region with regard to health and lifestyle [44]. The lack of
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3 412 randomization could, however, have resulted in confounding bias. Therefore, we controlled for baseline
4
5 413 BMI z-score, gender, study year at T0, SES score, and ethnicity in all analyses. The significant
6
7 414 differences in children's BMI z-scores at baseline between the three groups could indicate that children
8
9 415 in the control schools are less open to change: their habits in unhealthy behaviours are stronger as they
10
11 416 have already led to overweight or obesity. On the other hand, this difference, which we controlled for,
12
13 417 may have resulted in an underestimation of the effect: more room for improvement existed for the
14
15 418 children in the control schools compared with the full and partial HPSF.

16 419 Next, HPSF seemed to affect all children in the intervention schools. However, a decrease in
17
18 420 BMI z-score might not be favourable for all of them, for example when they already have an extremely
19
20 421 low BMI z-score. Therefore, to ensure that the findings reflected the children for whom a decrease in
21
22 422 BMI z-score is favourable, we conducted extra sensitivity analyses in which we excluded the children
23
24 423 with extremely low BMI z-scores at baseline. These analyses showed comparable results. The high
25
26 424 number of children enrolled in the measurements, the low drop-out rate, and the objectively measured
27
28 425 BMI were other strengths of this study. There were missing data because some participants did not
29
30 426 participate from the start, other participants finished school before the last measurement period in 2017,
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32 427 the parental questionnaire was not completed, respondents skipped questions, or data could not be
33
34 428 obtained due to the absence of the child. To deal with the missing data, multiple imputations were used,
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36 429 and a sensitivity analysis, in which only complete cases were included, was conducted. Complete case
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38 430 analysis showed similar results to the original analysis, which increased the reliability of the findings in
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40 431 this study.

41 432

43 433 **Conclusions**

44
45 434 Taking all the results and limitations into account, it can be concluded that HPSF was effective in
46
47 435 lowering children's BMI z-scores after one and two years' follow-up and no specific subgroups of children
48
49 436 were found to benefit more from the intervention. Even though longer follow-up periods are needed to
50
51 437 draw hard conclusions, both versions of the initiative seem promising in offering perspective in the on-
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53 438 going obesity epidemic in young children.

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2
3 **442 Acknowledgements**
4

5 443 We are grateful to all of the schools, the children and other collaborating partners participating in the
6
7 444 project. We thank the PhD students and research assistants for their help in data collection.
8

9 445

10
11 **446 Competing interests**
12

13 447 The authors declare that they have no competing interests.
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17 **449 Ethics approval and consent to participate**
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19 450 Ethical approval was given by the Medical Ethics Committee Zuyderland located in Heerlen (MEC 14-
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21 451 N-142). All participants were required to complete an informed consent form, signed by (both) parents.
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24
25 **453 Data sharing**
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27 454 The data that support the findings of this study were collected as part of the 'Healthy Primary School of
28
29 455 the Future' quasi-experimental study. Data collection will take place until 2019 to study the effects after
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31 456 4 years of exposure. Data on the 4-year effects and potential other comparative studies in the
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33 457 Netherlands will become available following article publication.
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36
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49 **465 Authors' contributions**
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51 466 NB, PvA, SK, HS, MW, OvS, and MJ were part of designing the intervention. NB, MO, MW collected the
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53 467 data for the manuscript. NB and BW analysed the data. NB drafted and revised the manuscript. PvA,
54
55 468 SK, HS, MO, MW, OvS, BW, and MJ critically reviewed the manuscript during the writing process. All
56
57 469 authors have read and approved the final manuscript.
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60 **471 Supplementary Information**

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3 472 Supplementary file 1 (PDF): A graphical presentation of individual changes in BMI z-scores at one year
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5 473 (T1) and two years' (T2) follow-up compared with baseline. A table with potential effect-modifiers of the
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7 474 intervention effects on children's BMI z-score.
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10 476 **License statement**

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595 **Figure 1. Flowchart**

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 597 * Reasons for drop-out T1: switched to other included school (n=2), other reasons, e.g., moved away or actively
 598 stopped participation (n=62).
 599 ** Reasons for drop-out T2: finished school (n=228), switched to other included school (n=17), other reasons e.g.
 600 moved away or actively stopped participation (n=45).
 601 ***Selection for effect study: at baseline (T0) children from study year one to seven, at T1 children from study year
 602 two to eight, and at T2 children from study year three to eight.

604 **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 ^c	.006

605 ^a Observed N, missing data was due to later participation in the study, incomplete parent questionnaire, or because
 606 no height/weight was measured in study year 1.

607 ^b Study year 1-8 in Dutch system is comparable to two years of kindergarten followed by grade 1-6.

608 ^c Chi-square test.

609 Bold p-value = significant (<.05) difference

610 Abbreviations: SD = standard deviation; C.I. = confidence interval; ES = Effect size.

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

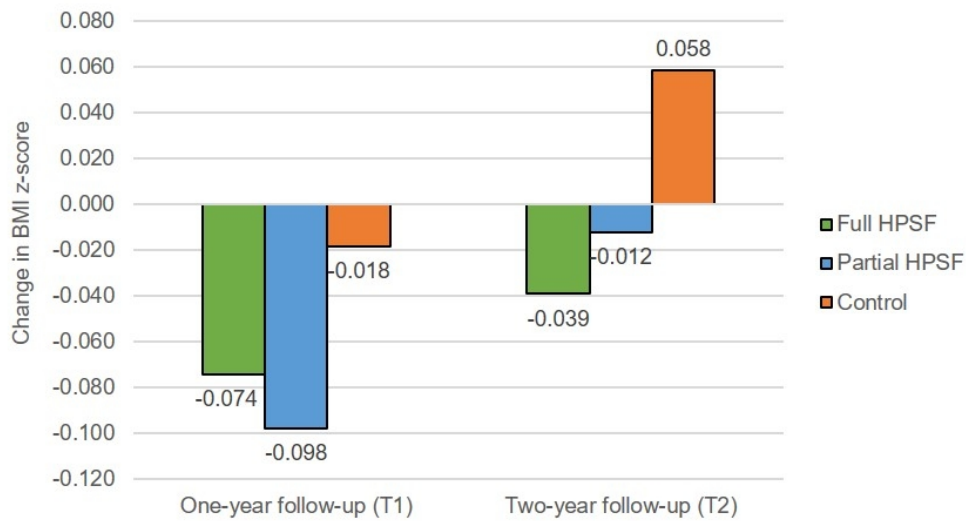
620 **Table 2. One- and two-year estimated intervention effects on children’s BMI z-score^a**

		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

621 ^a Adjusted for baseline, gender, study year at T0, SES, and ethnicity.

622 Bold p-value = significant (<.05) difference

623 Abbreviations: C.I. = confidence interval; ES = Effect size.



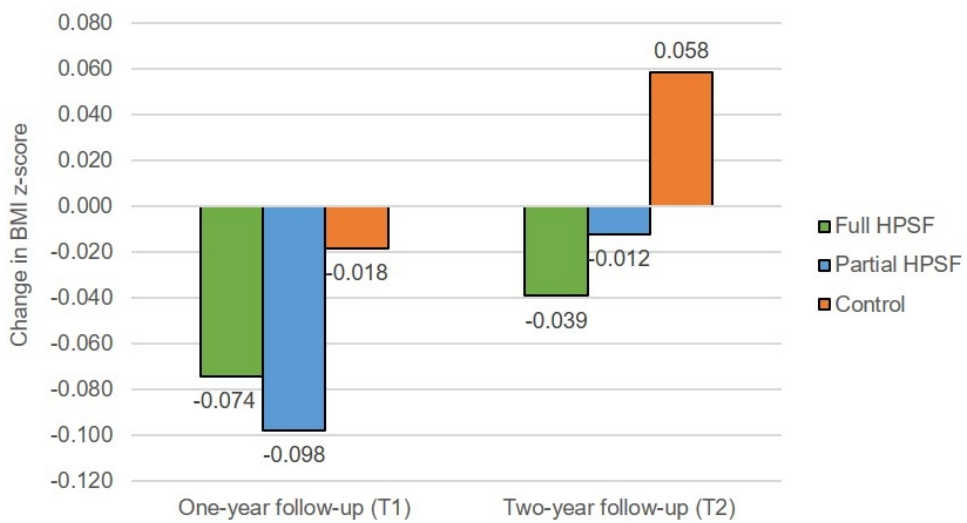
* Reasons for drop-out T1: switched to other included school (n=2), other reasons, e.g., moved away or actively stopped participation (n=62).

** 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.

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Supplementary file 1

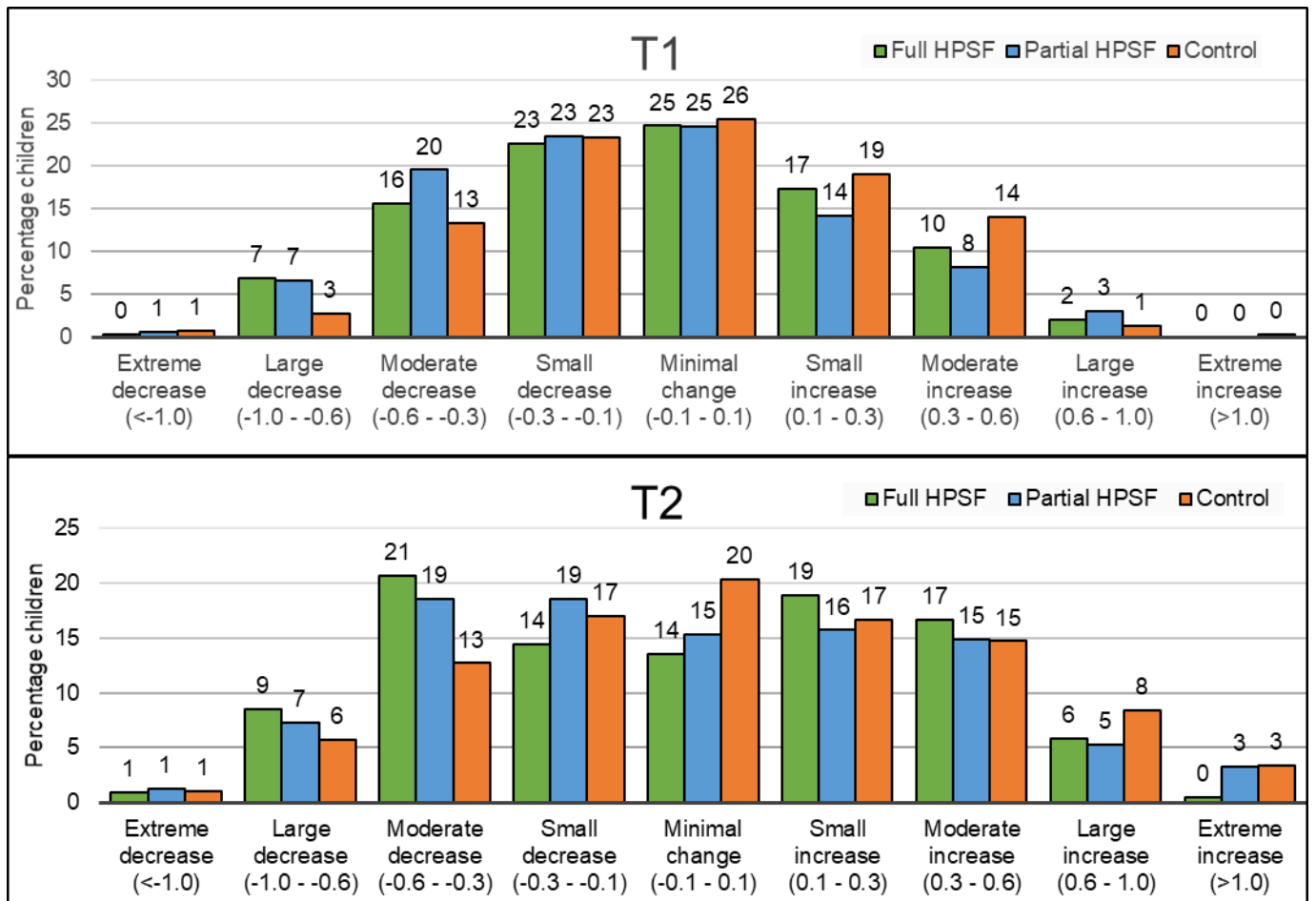


Figure S1. Graphical presentation of individual changes in BMI z-scores at one year (T1) and two years' (T2) follow-up compared with baseline

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

	N ^b	Full HPSF vs. control			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
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
165-8	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.