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D7.3: Report on the effectiveness of the Healthy Lifestyle Intervention

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Dissemination Level

PU	Public	☒
PP	Restricted to other programme participants (including the Commission Services)	
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Glossary of terms

Abbreviation	Definition
BMI	Body mass index
NCDs	Non-communicable diseases
OB	Obesity
OW	Overweight
PA	Physical activity
PE	Physical Education

Contents

1. Summary

Introduction: Efficacy trials of Physical activity (PA) intervention programs during childhood have repeatedly shown favourable effect on obesity (OB) prevention. On the other hand, in order to change population health these programmes need to be up-scaled; yet many challenges feature translating interventions to real-world settings and delivering programmes to large population groups.

Methods: The present study examines the effects of a real-world, population-based, long-lasting PA intervention on OB prevalence in children aged 6-14 in Slovenia, called "Healthy Lifestyle". It was derived from previous successful small-scale PA interventions in single Slovenian schools that provided above-standard programme of one physical education (PE) lesson per day, delivered by PE specialist teachers also in lower classes of primary school. Healthy Lifestyle was a nation-wide intervention, introduced in Slovenia in the period 2011-2018. The intervention provided two (grades 1 to 6) to three (grades 7 to 9) additional lessons of PE per week, and one PE lesson per day to children aged 6 to 14. Although the focus of Healthy Lifestyle programme was the improvement of physical fitness and encouragement of healthy lifestyle, we examined its effects on OB prevalence. We included 30 000 participants in Healthy Lifestyle and a similar number of non-participants with measured Body mass index, and employed Logistic Generalised Estimating Equations to estimate the effects of different durations of the programme on OB prevalence (from one up to 5 consecutive years of participation).

Results: The analysis showed that the control group had significantly higher odds of OB than intervention group in all five temporal scenarios. In the first monitored group of children (participating or not participating for one year), the odds of OB were 10% higher in controls compared to the intervention group, then doubled in the next three groups (2,3 and 4 years of participation), and more than tripled among children who participated or did not participate for 5 consecutive years. Next, in the school-level analysis, we found that when comparing to the year before joining the intervention, Slovenian schools that were running PA intervention showed a decrease in the prevalence of OB, but only if they joined before 2016. Also, schools that joined the intervention in the first five years (2011-2015) achieved lower OB rates than other non-participating schools despite higher OB prevalence at baseline, but the decline of OB prevalence was stopped or even reversed after 2016 (when the programme was disrupted by the lack of funds).

Conclusion: We found that a large-scale, population-based PA intervention delivered in real-world conditions targeting children and adolescents aged 6 to 14 years was effective in reducing the odds of OB. Conversely, we observed to what extent temporary disruptions in long-lasting interventions might attenuate their long-term effectiveness, as a reduction in effectiveness was evident in the year the programme was hindered by the lack of funding, but also after this point. This might be particularly relevant given the current public health crisis and related barriers to PA for children which translate to dramatically reduced physical activity levels and impaired physical fitness.

2. Background

Childhood obesity (OB) is among leading public health problems worldwide with consequences even among younger age groups.[1] Strikingly, the prevalence of overweight (OW) and OB in children has increased far and wide, and notably also in economically advanced countries.[2] Over the last 40 years, childhood OB increased worldwide, with more rigorous, eightfold rise in 5-19-year old individuals compared to children under the age of five.[3] Moreover, this global prevalence developed at a startling rate from 0.7% to 5.6% in boys and 0.9% to 7.8% in girls between 1975 and 2016.[4]

The present global OB pandemic makes groundwork for numerous non-communicable diseases (NCDs),[5] which are no longer exclusively related to adults but are becoming more frequent among younger populations as well. Growing sedentary behaviour of children which includes increased screen time with an excess caloric intake, causes energy imbalance and contributes to the accumulation of adipose tissue.[6] Additionally, current individual's adipose condition increases propensity towards behaviours which contribute to a fat-mass accumulation in the future.[7]

The number of children living with OB globally is rising, reaching 124 million in 2016[8]. Also, the projections for future incidence of OB-related morbidity and mortality are very high as well as are the anticipated costs for health care and economic losses.[8] It is, therefore, of great importance to implement convenient and controlled approaches on global scale and surveil their effectiveness in order to slow down and reverse this epidemic. It has been established that OB pandemic is a consequence of changed dietary habits and reduced physical activity (PA),[9] often on behalf of increased sedentary time,[10] while strong evidence support favourable upshot of OB prevention programs that include PA on BMI, especially in children aged 6 to 12.[11]

Schools can serve as one of the most appropriate settings to implement interventions aimed at preventing and controlling OB. Children and adolescents go to school on daily basis, which means that school-based interventions have a possibility of reaching large number of children simultaneously, including hard-to-reach groups, such as ethnic minorities or migrants. Schools also provide a convenient setting for synergistic implementation of physical and health education accompanied by a noticeable influence from teachers, peers, and parents.[12] Compellingly, interventions are more effective in childhood then later in life due to higher sensitivity of children to external influences.[13]

Numerous systematic reviews have shown that school interventions involving physical activity had the largest effect on body mass.[14-16] This is why school-based programs which include physical activity as a health component positively affecting well-being, can serve as an important tool in childhood OB management. Interventions that increase physical activity can simultaneously improve children's functioning also in other domains. Beside the increase in energy expenditure and reduction of energy imbalance,[17] it has positive effects on cardiovascular, metabolic and bone health,[18] as well as on cognitive development, psychological wellbeing and academic performance.[19]

Longer-lasting interventions usually result in better and larger effects in comparison to shorter ones, and World Health Organization (WHO) suggests programs to last at least one year involving many forms of movement, an optimal caloric intake and parental involvement.[20] Moreover interventions that are fitness-oriented are showing greater potential improving body composition compared to other types of PA interventions.[21] An hour of daily PA, accompanied by reduced high-fat, high-sugar, high-salt foods, and healthy caloric intake can effectively prevent a further unnecessary accumulation of fatty tissue.[22]

Although beneficial effects of PA intervention programs during childhood are well documented, most of the evidence comes from small to medium scale studies in well-controlled settings, without implementing a large scale, population-based approach. However, the researchers are opting for PA interventions to scale-up[23] and in this sense encompass wider masses of children in different strata of society.[24-29] The deficit of the institutionalisation of school-based physical activity interventions in real social settings can—as a consequence—impede the fight against childhood OB epidemic.[30,31]

Nevertheless, even if a PA intervention is put in place and scaled-up it can be susceptible to poor performance accuracy depending on the adequate competencies of stuff that ensure a higher quality of implementation,[32] and it can be affected also by external factors such as discontinuous funding or poor political decisions.[33,34]

In the last decade the research community started emphasising the need for larger and smarter approaches to get people moving but also the need for more systematic documentation and investigation of already scaled-up PA interventions.[23] In this regard, the present study is an attempt to examine the effects of a population-based, long-lasting PA intervention *Healthy Lifestyle* on OB prevalence in children aged 6-14 in Slovenia, which was derived from previous successful small-scale PA interventions in individual Slovenian schools that provided above-standard programme of one physical education (PE) lesson per day, delivered by PE specialist teachers also in lower classes of primary school.

3. Methods

3.1 Intervention

Healthy Lifestyle was a nation-wide intervention, introduced in Slovenia in the period 2011-2018. The intervention provided two (grades 1 to 6) to three (grades 7 to 9) additional lessons of PE per week—thus providing one PE lesson per day—to children aged 6 to 14. In grades 1 to 5, in which predominantly classroom teachers are delivering PE lessons, the PE specialist teachers were delivering additional PE lessons, thus improving quality along quantity of PE.

The intervention was financed by the European Social Fund with the aim to increase the first employment opportunities of recently graduated physical educated teachers. Schools were granted funds for half-time employment per teacher but had to provide sports facilities and equipment. The additional lessons were organised immediately after school. Schools were allowed to include children of two consecutive grades in one class (e.g. children from grade 1 and grade 2) and they had to adhere to legislative demands regarding the maximum number of children per class, which meant between 16 and 30 children per class. The intervention was available to all children and was organised in the form of elective course. The involvement in Healthy Lifestyle was therefore voluntary and accessible to all but it especially encouraged the inclusion of children who were not yet exercising in the local sports clubs or who had been experiencing difficulties in somatic and motor development.

The focus of Healthy Lifestyle programme was the improvement of physical fitness and encouragement of active lifestyle. The programme required from teachers to provide at least twelve different sports per triennia but they had to prioritise the three most established sports in the local environment. It also included the presentation of urban sports, currently not specifically covered in the physical education curricula at the time, and they had to provide also basic information on healthy dietary and lifestyle habits. Classes, that specifically included children with difficulties in somatic and motor development had to be organised as separate classes in which the maximum number of children was limited to ten in order to provide more individualised approach. Childhood OB was not a specific target of the intervention, but increased PA due to two or three additional PE lessons helped maintaining optimal weight and to improving the energy imbalance in the participating children with OB.

The funding of the intervention was administered by the Ministry of Education, Science and Sport of the Republic of Slovenia through European Social Fund. The national coordinator of the intervention programme was the Slovenian Sports Agency Planica which has been publishing annual public calls for inclusion of new schools in the programme and was responsible for administration and surveillance of its organisational functioning. This meant that new schools were joining the programme yearly: the first round comprised 78 schools in school year 2010/11, included additional 32 in 2011/12, 19 in 2012/13, 17 in 2013/14, 16 in 2014/15, 33 in 2015/16, 8 in 2016/17 and 13 in 2017/18. In the final year of implementation, the total number of involved schools was 216. The intervention was facing a serious challenge in the school year 2015/16 when the financing was suspended for several months due to administrative reasons that were not resolved timely by the Ministry of Education, Science and Sport. In this period the schools had to provide funds for teacher's salaries and this resulted in considerable reduction of delivered lessons in comparison to previous year (Table 1). Finally, the intervention was temporarily terminated in 2018 due to inability of the Ministry of Education, Science and Sport to assure regular funding from the national budget.

Table 1. Quantitative description of the Healthy Lifestyle intervention

School year	2010/11	2011/12	2012/13	2013/14	2014/15	2015/16	2016/17	2017/18
Newly included schools (N)	78	32	19	17	16	33	8	13
Included children (N)	18,993	24,202	26,000	27,600	30,261	29,549	35,640	32,245
Lessons (N)	33,190	60,505	68,306	70,866	72,054	53,527	69,613	51,893
Annual costs (EUR)	1,156,322	1,754,087	2,007,291	2,026,940	2,070,681	1,752,964	2,618,384	2,341,557
Annual costs per child (EUR)	60.88	72.48	77.20	73.44	68.43	59.32	73.47	72.62

3.2 Study design and sample

In Slovenia there are 451 primary schools, 216 of which have been involved in the intervention for at least one school year (Figure 1). The participating schools did not differ from non-participating schools in proportions of regional distribution, size, or urbanisation level, but the participating schools did show higher levels of baseline OB, which could have contributed to their decision to implement the intervention. Between 18,000 and 35,000 children have been included in the intervention in a single year and the number of their anthropometric measurements in the period between 2011 and 2018 was 221,646.

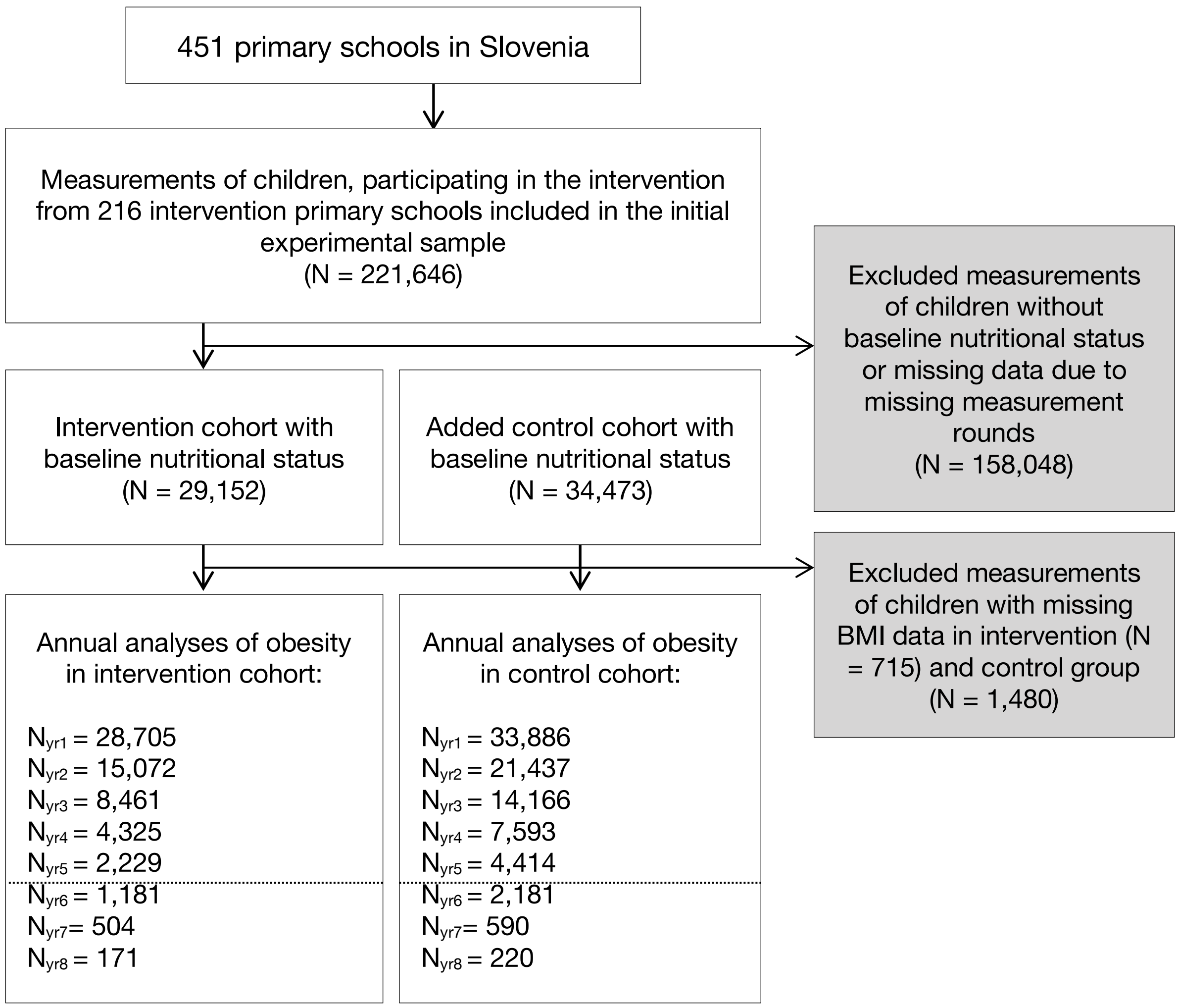


Figure 1. Study design and flowchart of the study sample

Due to the complexity of the intervention with schools entering in different years and children entering, exiting and re-entering the intervention in different grades, there were numerous scenarios of individual participation. In terms of analysis we had to choose an approach that would give the most straightforward insight into possible effects of the intervention on the prevalence of OB. In order to observe possible changes in OB prevalence, the information on OB prevalence prior to the intervention is essential. In terms of analysis, this was translated to considering only children who were enrolled in a participating school already a year before school's first inclusion in the intervention. The quasi-experimental design of the study limited the possibilities for controlling numerous environmental effects that potentially influence childhood OB, but in order to reduce the number of these effects, we sampled the control group of children from the participating schools by including only children who never participated in the intervention.

The analyses were based on the comparison of the intervention and control group by the number of consecutive years of participation or non-participation in the intervention. Since the number of children was decreasing steadily with longer participation duration, resulting in less than 10% of the original sample in the cohort that participated for six consecutive years, we decided to restrict the analyses to five consecutive years of participation.

At baseline, there were some differences between the intervention and control group (Table 2). The average baseline age of children in intervention group was lower in all five analysed participation scenarios and declined in groups with longer participation scenario of intervention. In all five participation scenarios, control group had lower percentile of subcutaneous fat. The average difference between intervention and control group was 1.5 percentile and the baseline difference among both groups was increasing with longer duration of intervention. The largest baseline difference was observed between intervention and control group in scenario of five consecutive years of participation or non-participation in intervention, in which the triceps skin fold percentile of intervention group was 3.9 percentile ranks higher. There was no significant difference in baseline body height between the intervention vs. the control group in any of the scenarios. In all five participation scenarios, at the baseline the schools from intervention group had more obesogenic environment than the control group.

Table 2. Baseline characteristics of the intervention and control cohort according to consecutive years of participation or non-participation in the intervention programme

	N (boys, girls)	Age (SD)	Triceps skinfold (SD)	Height (SD)	Obesogeneity (SD)
1 yr control	33,886 (16,816, 17,070)**	10.37 (2.26)*	54.65 (28.84)*	52.42 (28.79)	7.13 (2.80)*
1 yr intervention	28,705 (15,398, 13,307)**	9.06 (2.24)*	55.16 (28.63)*	52.32 (28.73)	7.66 (3.11)*
2 yrs control	21,437 (10,414, 11,023)**	9.99 (1.96)*	54.48 (28.77)*	52.57 (28.77)	7.06 (2.75)*
2 yrs intervention	15,072 (8,407, 6,665)**	8.56 (1.96)*	55.32 (28.75)*	52.32 (28.61)	8.00 (3.28)*
3 yrs control	14,166 (6,738, 7,428)**	9.42 (1.70)*	54.10 (28.91)*	52.05 (28.78)	7.05 (2.76)*
3 yrs intervention	8,461 (4,919, 3,542)**	8.20 (1.70)*	55.20 (28.71)*	55.20 (28.71)	8.23 (3.35)*
4 yrs control	7,593 (3,573, 4,020)**	8.81 (1.44)*	53.52 (28.85)*	51.40 (28.72)	7.04 (2.78)*
4 yrs intervention	4,325 (2,655, 1,697)**	7.87 (1.46)*	54.71 (28.77)*	51.63 (28.59)	8.45 (3.46)*
5 yrs control	4,414 (2,057, 2,357)**	8.19 (1.20)*	52.08 (29.07)*	50.43 (28.65)	7.06 (2.76)*
5 yrs intervention	2,299 (1,447, 852)**	7.61 (1.20)*	55.97 (28.25)*	51.11 (28.53)	8.51 (3.56)*

Legend: N - number of children, Age - baseline age in years, truncated to integer, Triceps skinfold - baseline age- and sex-specific percentile value of triceps skinfold, Height - baseline age- and sex-specific percentile value of height, Obesogeneity - baseline obesity prevalence in individual school in %. * significant difference between intervention and control group, $p < .005$, ** significant difference between intervention and control group, $p < .005$

3.3 Anthropometric measurements

Anthropometric measurements of body height, body weight and triceps skin fold thickness were obtained through the SLOfit system—the Slovenian national surveillance system of children's somatic and motor development—in accordance with the standardised and uniform protocol.[35] The SLOfit measurements are organised in all Slovenian schools every

April, assuring identical time interval between measurements in all schools with standard equipment. The measurements in schools are performed by the PE teachers with the support of classroom teachers. PE teachers have been thoroughly trained for this task in various courses during their study at the Faculty of Sport, University of Ljubljana which is the only institution in Slovenia, educating PE teachers in a five-year study programme.

Following the SLOfit system protocol, during the anthropometric measurements children are barefoot and wearing only light clothes—typically shorts and t-shirt. Body height is measured in the standing position with stadiometer to the nearest mm, and body weight with medical scale to the nearest 0.1 kg. Triceps skinfold thickness is measured at the mid-point on the posterior surface of the left upper arm to the closest mm with Holtain calliper. The measurements of children whose parents provide positive consent are sent to the Laboratory for Diagnostics of Somatic and Motor Development at the Faculty of Sport, where the data is checked for logical errors, eventual errors are communicated back to teachers for correction. Schools receive feedback for every individual child and class after the age- and sex-specific national percentile ranks of 8 fitness indicators and 4 anthropometric indicators (height, weight, triceps skinfold, and BMI) are calculated. The participation rate of children in the studied period 2010-2018 has been above 94% in all years.

3.4 Statistical methods

Chi-square test was used to check to baseline differences in number of boys and girls in intervention and control group and independent sample t-test to check the baseline difference in age, triceps skinfold, height and environmental obesogeneity between intervention and control group.

Logistic Generalised Estimating Equation (GEE) was used to analyse the possible effect of the intervention on the prevalence of OB in the intervention and control group. GEE[36] is a multilevel regression method that adjusts standard errors to account for correlated data, such as the correlation of repeated measurements in a longitudinal study. A working correlation structure is specified before the analysis and defines the hypothesised relationship between repeated observations of individual subject. Regression parameters in GEE are first estimated through a generalised linear regression that initially ignores whether the data are longitudinal and—in the next step—the standard error estimates are adjusted according to the hypothesised correlation between different time points of the outcome. This adjustment then updates the standard errors in the analysis to account for repeated observations within the same subject.[37]

The OB outcome was analysed using a logit link function. We specified a first-order autoregressive correlation structure (AR-1) for the main GEE models. This assumption is appropriate in the context of our balanced longitudinal data in which measurements closer in time are more correlated than measurements further apart in time. Balanced data occurs when subjects are assessed at the same intervals, which was the case in our study. In a first-order autoregressive structure, the correlation of the outcome between any two points in time is a mathematical power of their distance in time. For example, nutritional status a year apart would be correlated by r_1 (i.e., r raised to the power of one), nutritional status two years apart would be correlated by r_2 (i.e., r raised to the power of two), and so forth.

The outcome variable in the model was nutritional status, determined by the sex- and age-specific BMI percentile of the Slovenian population of children between 1989 and 2020. We decided to use the national percentiles because a population-specific reference is more representative of a country's children than any other international reference and because international BMI cut-offs are not recommended for assessment of individual child's growth,[38] which is the case when analysing the cohort data with GEE. The choice of population-specific percentile references was further substantiated by the recent evidence that contemporary Slovenian children are taller than the WHO growth references core sample for almost 4 cm which can lead to high rates of misclassifications of nutritional status.[39]

Time—as within-subject variable—was categorised into five categories, contrasting baseline versus 1st, 2nd, 3rd, 4th, and 5th year of children's participation or non-participation in the intervention.

Five different models were produced to assess the intervention effects by comparison of control and experimental group who were exposed to 1-, 2-, 3-, 4-, and 5-year consecutive participation or non-participation in the intervention. Predicted category of nutritional status (z-test with Bonferroni adjusted p-values) and odds ratio of OB of control versus intervention group (Wald test) were calculated for each model.

The intervention was evaluated by the participation in individual year, interpreted as the odds of non-participation versus participation (0 vs. 1).

As observed in published evidence on intervention effects on OB, a common limitation is the ignoring of micro-environmental settings[40] and individual biological factors that can have a strong positive or negative influence on the effectiveness of the intervention. One of the most important micro-environmental factors is environmental obesogeneity, which was first described in 1999 when Swinburnet et al.[41] described it as the sum of environmental influences on promotion of OB in individuals or populations. Each school in the intervention had its distinctive prevalence of baseline OB that could be considered as an indicator of childhood obesogeneity in the local environment. In any environment—even in markedly obesogenic—not all children suffer from the same level of OB. Some children with OB have less body fat than others, but the ones that have more, have lower odds of becoming non-obese than the ones who have less of it. To account for this intervention effect handicap we took into consideration also the baseline triceps skinfold percentile value of an individual. Furthermore, if the intervention is longer—as was the case with the Healthy Lifestyle intervention—individual growth cannot be ignored. The timing and tempo of growth spurt are characterised by big differences among peers, but also by sex-related differences with girls mostly it sooner than boys.[42] Growth spurt is preceded by increased energy accumulation in the form of body fat which can result in temporary rise of BMI that normalises afterwards. To account for these differences, we considered also sex and body height percentile to adjust for individuals whose speed of growth deviates from their peer group. Lastly, the own life of an intervention is mostly not considered in the analyses although the effectiveness of an intervention can be severely impaired by external factors such as discontinued funding, staff changes, policy changes or other unexpected events. Since Healthy Lifestyle intervention suffered from temporarily discontinued funding which in some cases resulted in six-month total or partial suspension of intervention, we also decided to control for this effect by including it in the model.

Each model was, therefore, adjusted for sex, baseline environmental obesogeneity (baseline OB prevalence in individual school), individual risk of OB (baseline percentile of triceps skinfold thickness of an individual), individual maturation rate (body height percentile rank of an individual in certain year), and intervention disruption (designation whether an individual was exposed to disturbance of intervention in 2016). All five models were adjusted by the same covariates that were considered potential moderating variables, although only participation, environmental obesogeneity and individual risk of OB were found significant in all five models. Sex was significant only in the one-year participation scenario in which boys had 10% less odds for OB in comparison to girls (OR=0.90, 95%CI=0.84, 0.96). Body height percentile rank was significant only in the 1-, 2- and 3-year participation scenario, while intervention disruption was not significant in any of the scenarios but had a moderating effect and improved the model and reduced confidence intervals.

All statistical analyses were performed with IBM SPSS 26.0 and statistical significance was set at $\alpha = 0.05$.

4. Results

Before performing GEE analysis and calculating model-predicted values of OB prevalence, we estimated the unadjusted prevalence of OB to assess the trends of OB in intervention schools and compare them to the general trends in other Slovenian schools, which were never included in the intervention (Figure 2).

The schools that decided to join the intervention typically had higher prevalence of OB at baseline compared to other schools, with the exception of schools joining in 2016. The prevalence of OB—in comparison to the year before joining—declined in schools that joined the intervention before 2016. It also declined in the schools that joined the intervention in 2017. However, in the schools that joined the intervention in 2016, when the intervention was disrupted due to delayed and reduced financing, and in the last year 2018, when the uncertainty regarding its future emerged, the joining of the intervention was not accompanied by the decline of OB.

In schools that joined the intervention from 2011 to 2015, we detected a visible increase of OB prevalence in 2016, whereas in the schools joining in 2013 the trend of decline temporarily decelerated in that year. With exception of schools who joined in the first and in the last year of the intervention, an increase of OB prevalence was observable after 2018 when the intervention was terminated. The schools that joined the intervention in the first five years, managed to achieve lower OB rates than other non-participating schools but after 2016, the OB prevalence in schools, joining in 2015 rose above the non-participating schools again.

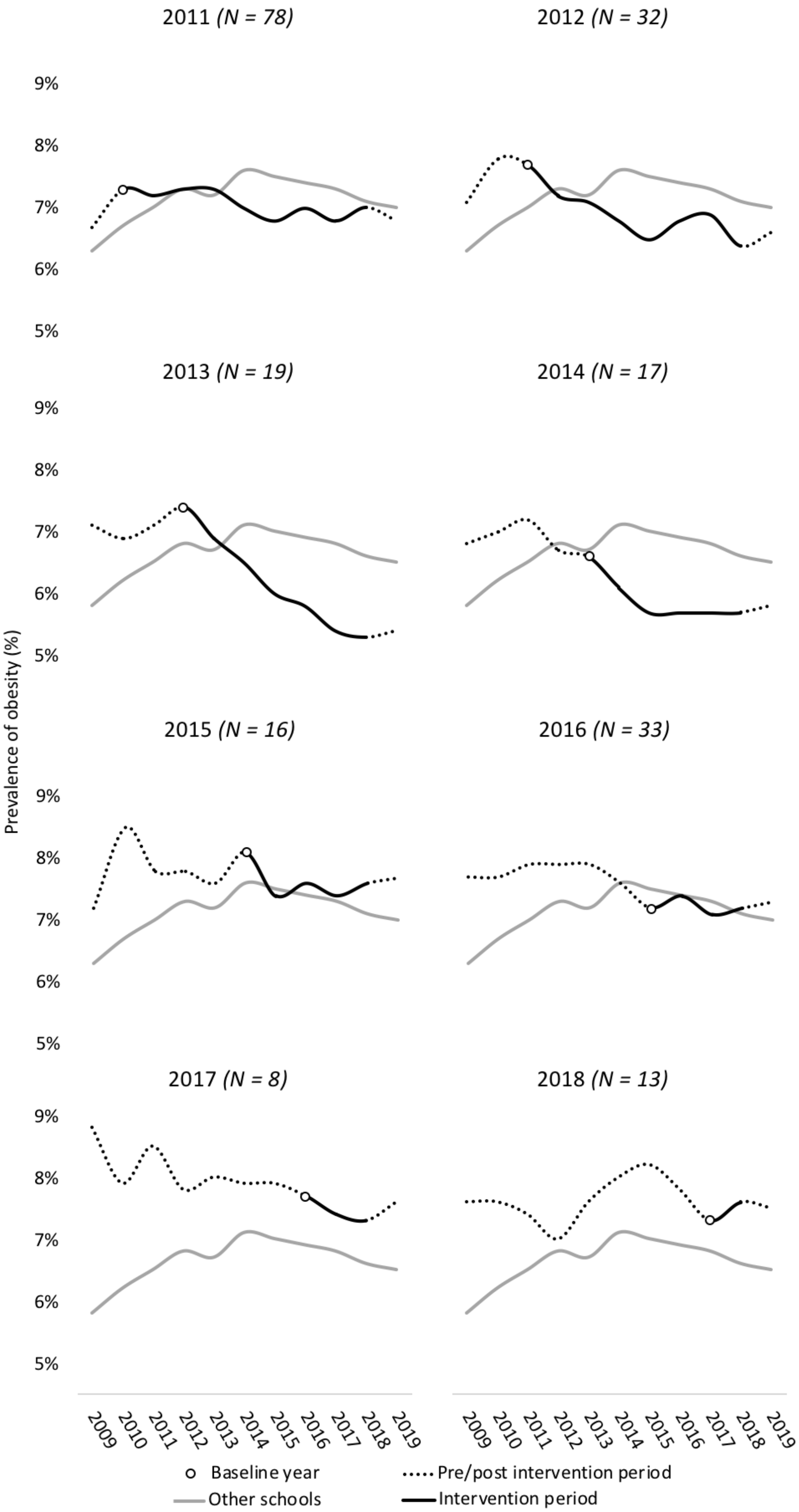
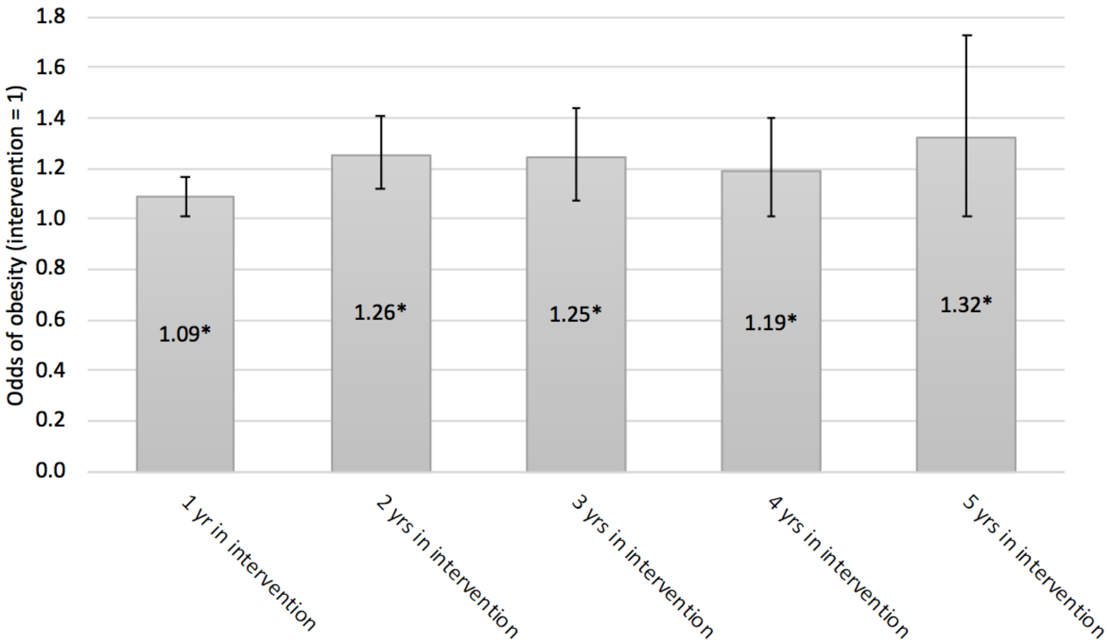


Figure 2. Comparisons of obesity trends between intervention schools according to the year of their inclusion and other schools in Slovenia



*Error bars indicate lower and upper 95% Wald CI, * $p \leq .05$*

Figure 3. Odds of obesity in control group vs. intervention group according to consecutive years of participation or non-participation in the intervention programme

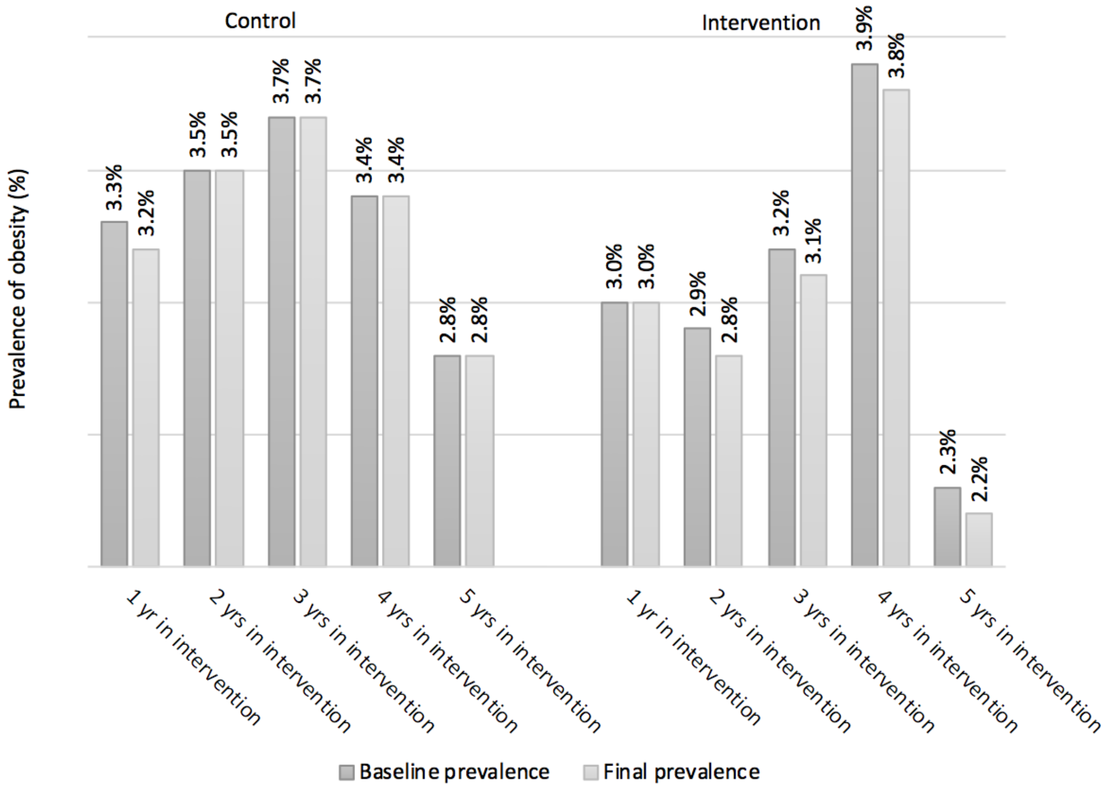


Figure 4. Model-adjusted changes between baseline and final prevalence of obesity in intervention and control group according to consecutive years of participation or non-participation in the intervention programme

The GEE analysis (Figure 3) showed that the control group had significantly higher odds of OB than intervention group in all five intervention scenarios. In the first monitored group of children who were participating or not participating for one year, the odds of OB in the control group was below 10% in comparison to intervention group, but the odds more than doubled in the next three groups and more than tripled among children who participated or not participated for five consecutive years. The 95% confidence interval also increased with every additional year of intervention but remained very similar in second, third and fourth group and doubled in the last group.

The analysis of model-predicted values of OB prevalence (Figure 4) showed that among the controls there were no visible changes in OB prevalence in any of the groups except the first one while the situation was exactly opposite in the intervention group. The model-adjusted decline of OB prevalence between the baseline and final year did not exceed 0.1% in any of the intervention five groups.

5. Discussion

In this study we examined the effect of a large-scale, population-based PA intervention delivered in real-world conditions on OB in children and adolescents aged 6 to 14 years. The intervention group had higher odds of OB in comparison to the control group in all participation scenarios, with odds increasing as intervention duration increased. After one year of intervention, the odds of OB in the control group was 10% higher compared to intervention group, then doubled in the next three groups and more than tripled among children who participated or not participated for five consecutive years. This has to be interpreted in light of baseline differences in obesogenic environment between the groups. Hence, the results also showed that—despite more obesogenic baseline environment of children belonging to intervention group and higher levels of baseline subcutaneous fat—the risk of becoming obese grew significantly higher in control group than in the intervention group. This clearly indicates that additional exposure to physical activity in the intervention group, partly neutralised or altered the environmental obesogeneity and individual biological factors that moderated OB. Next, we found that when comparing to the year before joining the intervention, Slovenian schools that were running PA intervention showed a decrease in the prevalence of OB, but only if they joined before 2016. In schools involved in 2016 and 2018, when the intervention was disrupted and not running smoothly, positive changes regarding childhood OB were lacking, with no visible decline. Similarly, the schools that joined the intervention in the first five years (2011-2015) managed to achieve lower OB rates than other non-participating schools despite higher baseline OB prevalence, but the decline of OB prevalence was stopped or even reversed after 2016 disruption. This indicates that temporal disruptions in long-lasting interventions may attenuate their effectiveness, which might be particularly important given the current public health crisis and related barriers to physical activity for children.

The effects of the intervention studied here are in line with the recent near-census analysis of secular trends in childhood OB in Slovenia, that showed a decreasing OB prevalence among 6-14-year-olds during the last decade.[43] It is noteworthy that the former study used IOTF classification[44] and our study used national reference values. Although the analysis presented in this report is based exclusively on 30,000 children who were continuously included in the intervention, Healthy Lifestyle programme has involved about 30% of the entire population of children in the country during its life course. Thus, Healthy lifestyle is probably one of the main drivers of the decrease in childhood OB in Slovenia observed since 2010.

Further, we did use BMI percentile of the Slovenian population of children as reference value because it is the most appropriate for this population due to its larger average height compared to international standards.[39] Nevertheless, BMI is still not the most accurate estimate of adiposity due to a well-known limitation of its inability to distinguish between fat and muscle mass.[45] A systematic review that has examined resistance training and showed that those interventions have effect on body fat % and skinfolds, without changing body mass, BMI, fat-free mass, fat-mass or lean mass, or waist circumference.[46] Furthermore, a study which conducted an eight week (three times per week) program using resistance stimulus in children with excess body weight, aged 7-12, showed a significant increase in lean body mass (5.3%, $P< 0.05$), and decrease in percent body fat (2.6%, $P< 0.01$). However, no significant change in weight was observed.[47] Hence the effect of Healthy lifestyle programme on adiposity could be even larger if we had used body fat as the outcome instead of BMI. On the other hand, growth during maturation period can also contribute to weight gain during intervention, especially if the program is long lasting. In girls, higher prevalence of excess body mass correlates with maturation. Further, higher stature is visible in both sexes,[48] and results based on girls build on previous cross-sectional studies.[49,50] This indicates that even if the change in weight is missing, positive alternations in body composition are still present with modification of body fat %. Although we adjusted for maturation effect in our models, we cannot rule out the residual effect of growth that could have resulted in the underestimation of the true effect of the intervention.

The PA program studied here had similar impact on both boys and girls. This is in line with a recent review that showed that fitness-oriented programmes, such as the one studied here, have similar effects on BMI in both genders, although the effect on % body fat is larger in boys compared to girls.[21]

Our results indicated that the longer children participated in the intervention, the larger were the effects. More specifically, the effects were more than double in the group that was involved for two years compared to their peers involved for only one year, and participating in the intervention for five consecutive years produced the largest effect on OB prevention. This goes hand in hand with WHO suggestion which emphasises interventions lasting a longer period of time with usually better and larger effects in comparison to shorter ones.[20] In contrast to our results, another five-year, school-based PA intervention program, which included six PE sessions per week, and incorporated the improvement of children's diet at school, and lasted longer period of time—while improving fitness level—did not manage to affect BMI although it did result in the decline of waist circumference.[51] Similarly, a childhood OB prevention program focusing on diet, physical activity and stress-related lifestyle factors, over a two-years observation period did not successfully reduce the prevalence of OW/OB in children up to the age of 10.[52] In line with this, even a longer PA intervention, lasting four-years, found no difference in the prevalence and incidence of OW/OB between the intervention and control schools before and after the implemented program.[53] The Healthy Lifestyle intervention was a population-based, nation-wide programme, delivered in the real-world conditions. Consequently, the effect size of the programme observed here has to interpreted in light of the challenges associated with scaling-up OB prevention initiatives. A recent meta-analysis[54] has observed minor effects in scaled-up OB prevention intervention trials compared to pre–scale up efficacy trials and that scaling-up OB prevention efficacy trials of does not provide significant benefit relative to a control group for BMI. Expanded interventions usually have 75% less of the effects of pre-scale-up efficacy trails.

Although this analysis focused on weight change, there are a number of other benefits incurred by a fitness-oriented PA programme such as the one described here. Unhealthy weight status is associated with increased risk for almost every chronic problem including diabetes, cardiovascular impairments, osteoarthritis and others.[55] OB is one of the main adjustable risk factor for insulin resistance in children and adolescents,[56] where excess body mass serves as a strong predictor of adult insulin resistance and type II diabetes.[57-59] In addition, childhood OB negatively affects social and emotional aspects of life, as well as academic performance and a quality of life,[60] with observational evidence suggesting that PA promotion and sedentary behaviour reduction may support mental health in children and adolescents.[61] It has to be noted that PA in children and adolescents has a wide range of benefits beyond weight loss, including beneficial metabolic changes and positive psychosocial outcomes. Self-esteem and cognitive capacities are enhanced and mental health problems are reduced, while evidence on improved mood is also promising but remains interrogative.[62] For instance, systolic blood pressure was higher in inactive children with OB compared to sufficiently active children having OB. Also, in children with OB, adequate PA as well as appropriate fitness level represent a favourable cardiovascular predictor despite excess adiposity, where good cardiovascular health can serve as a protective component from heart-related disease even in childhood.[63] Next, it has been shown that regular PA can serve as an important reducer of systemic inflammation,[63] and that children and adolescents with OW, when subjected to an aerobic exercise process lasting eight weeks, improved their fitness, HDL cholesterol levels and endothelial function.[64] All in all, PA is beneficial for children having normal weight, as well as for youth with overweight or OB irrespective of weight loss.

6. Strengths and limitations

This study has several strengths. First, our study is not a clinical trial, but a population-based study delivered in real-word settings, which contributes to higher generalisability of our findings. Generalisation of the results of a study represents an important element in translational research and is accompanied by ecological validity.[65] The latter can be examined as a correlation between results from an intervention and results obtained from everyday life where it stands for more as an estimate and not as exact data. Thus, ecological validity examines whether experimental results can be translated to a non-experimental, real-life setting. Second, while most prior interventions were restricted to one academic year or less, our study used a longitudinal design implemented over a very long, five-year period, which allows us to infer causal relationship between the intervention and obesity-related outcomes, while also examining the sustainability of the effects over a longer intervention period. Third, we adjusted our models for several important confounders, including obesogeneity of the environment, initial OB severity and maturation. Traditionally the intervention-effectiveness studies only considered the baseline differences in personal characteristics of intervention and control groups, or used only an indirect environmental indicators of OB risks, such as socio-economic indicators, whereas our study used an actual OB prevalence in certain environment to control for environmental obesogeneity. In contrast to existing studies, we also controlled for effects of individual's baseline subcutaneous fat which can hide the actual interventions' effects due to slower or less pronounced improvement of nutritional status. Through this approach we were also able to examine changes over time together with controlling factors which contribute to these transformations along with the intervention itself. Lastly, the study controlled also for the maturation effects which can blur the actual decline in body mass due to increased accumulation of subcutaneous fat before the growth spurt and due to increased gaining of muscle mass in boys and fat mass in girls entering puberty.[66,67]

However, this study also has several limitations that need to be addressed. First, the data did not allow for estimation of body composition, but relied on BMI as an indicator of adiposity. It is, namely, well documented that among children the BMI prediction ability varies across different body fat levels. Amongst individuals having higher amount of fat, the BMI is a good indicator of excess adiposity. However, differences in the BMIs of lean children can occur also due to fat-free mass.[68] Around the age of 12, fat free mass begins to plateau in girls while—on the contrary—it starts to increase notably in boys and stabilises much later than in girls. This process is accompanied by an increase in bone mineral density and height as well. Furthermore, during puberty girls gain more fat mass than boys, and have 5-6 kg higher absolute fat mass with an average gain of 1.14 kg/year. Conversely, absolute fat mass during maturation period does not change in boys.[69] Taking into account all these changes, evaluating efficacy of a long-lasting intervention based only on BMI represents a complex task. However, we made an effort to adjust for biological development of children in our models. Also, it should be noted that PA, alongside with fat mass reduction, typically increases lean mass, which leads to smaller changes in weight and an underestimation of the true effects on OB when BMI is used as the main outcome. Second, we were unable to collect information about dietary habits, physical activity outside the intervention and screen time, which represent important factors in childhood OB management.[70,71] There are also several other important determinants of OB (other than diet and physical activity) affecting OB which were not recorded in this study, and thus not included in analyses. Examples are genetic variation, epigenetics, endocrine disease, central nervous system pathology, sleep, infection and socio-economic and cultural factors.[72] Third, we are aware of possible sampling bias due to non-random voluntary enrolment used in the intervention. Thus, there is a possibility that some children and adolescents who had been more prone to behaviour change wanted to be a part of this intervention, omitting children with opposite characteristics. Lastly, while horizontally scaling up the intervention, we have not been able to collect other indicators on the quality of implementation across different schools and years of participation apart from the fact that it was delivered by specialist PE teachers rather than by less competent classroom teachers or other professional profiles.

7. Implications for future research

As using BMI as an outcome can result in the underestimation of the effects on PA on OB due to muscle mass accumulation, we urge future studies to include body composition measurement. Next, the sustainability of changes should be further examined in future studies by including follow-up assessments at different time points after the end of the intervention.

8. Ethical approval

The protocol, measurement procedures and data management of the SLOfit surveillance system were approved by the National Medical Ethics Committee of the Republic of Slovenia (No. 52/03/14) and is in accordance with the Helsinki Declaration. Healthy Lifestyle intervention did not require ethical approval since it was not an experiment and was independently evaluated by the SLOfit system.

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