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Long-term Effect of an Excess-Weight-Reduction Intervention among Iranian School Children: A 13-month Follow-up of a Cluster Randomized Controlled Trial

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ABSTRACT

Background: Childhood obesity and overweight have become major public health problems worldwide. To combat this problem, effective, sustainable, and consistent strategies are needed. In this study, the long-term effect of a school-based intervention for weight reduction was evaluated in primary school students in Tehran, Iran. **Methods:** This was a cluster randomized controlled trial (RCT) conducted in 12 primary schools in a low- to middle-class district in Tehran, Iran. The participants were 334 overweight or obese primary school students (girls =164) based on World Health Organization standards, equally distributed in the intervention (n=167) and comparison (n=167) groups. It was a multi-component intervention and included nutrition education and increased physical activity (PA), a lifestyle modification program for parents, and changing the food items sold in canteens of the schools. Body mass index Z-score [BMI-Z] was determined as the primary outcome and measured at baseline, three months after baseline, at post-test (after 18 weeks), and follow-up (13-month). In total, 205 students (59.5%) completed the follow-up. Analyses were carried out based on the intention-to-treat principle using linear mixed models. **Results:** After 13 months, the BMI Z-score decreased in both intervention and comparison groups. However, the change was more significantly observed in the intervention group (adjusted change: 0.098, 95% CI: (0.03-0.16) compared with comparison group (P=0.003). The intervention had a more significant effect on BMI Z-score among girls (adjusted change: 0.36, 95% CI: (0.27-0.45) compared with the comparison group (P<0.001))than among boys (adjusted change: -0.14, 95% CI: (-0.23- -0.05) compared with the comparison group (P=0.002). **Conclusion**: The intervention was an effective way to reduce BMI in the girls and the effect lasted for a relatively long time.

Keywords: *Schools; Obesity; Child; Education; Physical activity*

Introduction

Childhood obesity is an epidemic health problem worldwide (Di Cesare *et al.*, 2019). Over 340 million children and adolescents aged 5-19, globally, reported to be overweight or obese in 2016 (World Health Organization, 2020). Middle-income countries are experiencing a 'nutrition

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transition' leading to a rapid rise in obesity in adults and children in the last two decades; this is in contrast to high-income countries where the prevalence has plateaued (Singhal *et al.*, 2021).

Risk of being obese for adults who were obese in childhood is five times as much as normal-weight counterparts (Simmonds *et al.*, 2015). Obesity in children increases the risk of asthma, type 2 diabetes mellitus, orthopedic disorders, and is associated with reduced academic performance (Deal *et al.*, 2020). Excessive fat accumulation in childhood is mentioned as a predisposing factor of cardiovascular and hepatic abnormalities (Faienza *et al.*, 2020).

Although some interventions to reduce excessive weight gain in children have proved to be effective (Pan *et al.*, 2020), in some cases, the impact has not lasted for a long time (Norman *et al.*, 2019). Some considerations on the interventions such as a combination of diet and physical activity, parental involvement, and behavioral change may reduce body mass index (BMI), body mass index z score (BMI-Z) and weight of children in a short-term (Mead *et al.*, 2017, Psaltopoulou *et al.*, 2019, Singhal *et al.*, 2021). However, the sustainability of the outcomes in the real-world setting is a key consideration (Mead *et al.*, 2017).

Iran is experiencing a growing trend of childhood overweight (Heidari-Beni and Kelishadi, 2019). Although several school-based interventions aimed to slow down weight gain of children in Iran (Bagherniya *et al.*, 2018, Kelishadi *et al.*, 2014, Marandi *et al.*, 2014, Rezapour *et al.*, 2017), their effect was evaluated in a short term. In addition, none of them managed to significantly reduce BMI in experimental groups.

Therefore, to reduce weight gain in obese and overweight primary school children, the authors designed a multi-component intervention in a district of Tehran, in 2012-13 (Amini *et al.*, 2016). The intervention was based on a model previously developed by the authors to focus on individual behaviors; however, the role of the environment in shaping the childrens' obesogenic behaviors was taken into account (**Figure 1**) (Amini, 2014).To assess the long-term effect of school-based intervention eight months after its termination, children's body weight and height were measured again. In this paper the findings of the follow-up are reported.

Materials and Methods

Study design and participants: This was a follow-up study conducted in Tehransar, a low- to middle-class district in the west of Tehran. It was a cluster randomized controlled trial (RCT) aiming to reduce excess weight in primary school children. The intervention was initiated in the academic year 2012–2013. Designing, conducting and reporting of this trial adhered to the CONSORT statement. The procedure and the rationale of the trial have been described in detail in a previous study (Amini *et al.*, 2016). Overweight and obese children from 12 primary schools were screened according to World Health Organization (WHO) standards in which overweight and obesity were defined as BMI-for-age>+1SD and >+2SD, respectively (World Health Organization, 2021). Children with a metabolic illness, on a diet, participating regularly in supervised sports or exercise programs, or those taking appetite-depressing drugs were excluded from the study.

The intervention had four main components, namely, nutrition education; increased physical activity (PA) for children; lifestyle improvement program for children's parents; and improvement of canteens in schools. The schools' health instructors were paid to provide nutrition education to children in a 12-week course; two members of the research team with a master's degree in nutrition were in charge of educating parents in the selected schools; parents were requested to report progress regarding the objectives of the study in a month; regarding PA, the schools' coaches were hired to work with children. Canteen keepers were requested to stop selling high-calorie food items and encouraged to provide healthier food. The intervention was planned in line with routine activities of the schools.

The children in the comparison group received no intervention; however, after the end of the

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intervention period, a summary of all the topics discussed in the intervention schools was presented to the parents in comparison schools.

To ensure of the coherence, similar lesson plans and teaching materials were given to the health instructors and PA coaches in schools. At the same time, the lead researcher regularly supervised educational sessions. The original intervention took approximately 18 weeks. A total of 334 eligible children (girls and boys) among 4^{th} to 6^{th} graders within the age range of 9 to 13 were recruited in the study. Following baseline data collection, randomization occurred at the school level. Through simple random sampling, schools were selected as intervention or control groups by chief investigator, and 167 children were equally assigned to each group.

To calculate sample size, the primary outcome variable was BMI-Z score. Assuming a two-sided α of .05, power of 80%, a δ of 2, ρ=0.17, m=12, $\mu1-\mu2=1$, and a design effect of 2, 166 children were assigned for each group. Considering a 10% dropout rate, the authors chose 30 children in each school, making up a total of 360 children.

$$N= ((Z1-\alpha/2+Z1-\beta)^2(\delta)^2(1+(m-1)\rho))/((\mu1-\mu2)^2)$$

Measurements: Baseline data collection began in October 2012. At this stage, socio-demographic, anthropometric (including weight, height, waist and hip circumferences, and triceps skinfold fold), PA, dietary intake, and self-esteem data were collected. Body weight was measured by a digital scale; height, by a stadiometer; waist and hip, by a nonelastic measuring tape; and triceps skin-fold thickness was measured using a caliper. PA was evaluated by a questionnaire with 29 items categorized into nine metabolic equivalent (MET) groups which was validated in Iran (Kelishadi *et al.*, 2004). Dietary intake data, namely energy and macronutrient, were measured by three 24-hr dietary recalls, including 2 weekdays and 1 weekend. The authors asked the students about what they had eaten or drunk during the previous day(s). Self-esteem was evaluated by a valid Persian version of the 10-item Rosenberg self-esteem scale.

The primary outcome variable was BMI-Z scores from baseline to the end of the follow-up (after 13 months). To evaluate the effect of the intervention, due to financial constraints, only weight and height of the children were remeasured.

Children's weight and height were measured four times: (1) at baseline; (2) three months after baseline assessment, which was just before the Iranian New Year vacation (New Year or Nowrouz vacation in Iran is usually about two weeks for children); (3) at the end of the intervention (18 weeks after baseline assessment); (4) follow-up (13 months after baseline assessment). The results of the original intervention were reported by Amini *et al.* (Amini *et al.*, 2016).

To maintain consistency, in this phase, only one member of research team measured all weights (kg) and heights (cm) using a Seca 813 digital floor scale and a Seca 217 stable stadiometer. Weight and height were measured with light clothing and no shoes, and BMI-Z was calculated by AnthroPlus (WHO, 2013).

Data analysis: The participants were described using means and standard deviation (SD) for interval variables, and frequency (%) for categorical variables (Amini *et al.*, 2016). Intergroup differences were tested using independent t-tests for continuous variables with normal distribution. Statistical analyses of the first phase were explained in detail by Amini (Amini *et al.*, 2016). Since data loss in the second and fourth stages of data collection was considerable and the time intervals between data collection were not equal, the authors used a linear mixed model to seek the effect of the intervention over a 13-month period. The model included the groups (i.e., intervention and comparison groups), time (baseline, after three months, post-test, and follow-up), and the interaction between the group and time. The data was controlled for education of the mother, family size, and grade of the children.

Intention-to-treat analyses were conducted using the available data, and assuming that data were missing randomly. Models were specified with a between-subject factor of group, a within-subject

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factor of time, and a group × time interaction. The statistical significance of the group × time interaction effect in the model indicated differential intergroup changes in the outcome from baseline to 13 months. P-values were for two-sided tests with statistical significance at P-value < 0.05. For data analyses, the SPSS version 22 (SPSS, Inc., Chicago, IL, USA) was used.

Ethical considerations: The trial was registered to the https://clinicaltrials.gov/study/NCT02082080 10/03/2014. Written informed consent was obtained from all the parents or the children's guardians; the students, however, gave their consent verbally. The proposal of the study was approved by Ethics Committee (ethical code: 92, D, 130, 51) which follows the guidelines of the Declaration of Helsinki.

Results

Since the school year was over, almost one third of the older children had started high school and could not be tracked anymore. In addition, 129 children were lost to the study because they either went to other schools or were not contactable. The reasons for withdrawal are explained in the **Figure 2**. Therefore, 59.5% completed the follow-up (66% of intervention group and 57% of comparison group). Almost half (49%) of the children were girls. Flowchart of the study procedure is shown in **Figure 2**. 205 children (95 in the comparison and 110 in the intervention group) completed the follow-up.

Since the rate of dropout was relatively high (>40%), dropout data were compared with follow-up data to ensure if the remaining follow-up data was representative of all the participants. There were significant differences between those who completed the study (WC, HC and zinc intake) and those who dropped out in the intervention group, not the comparison group. However, the differences between the two groups in terms of other variables, especially BMI-Z score, which was the primary outcome, were not significant.

As **Figure 2** shows, the height and weight of 121 (67 in the comparison and 54 in the intervention group) children were unavailable for the follow-up measurements. One hundred four children had finished primary school and started high school, and 17 children had changed their schools. The demographic characteristics of the children can be found in the study by Amini *et al.* (Amini *et al.*, 2016).

Table 1 displays estimated means and standard deviations of BMI Z-scores in the four measurement time-points. Among girls, boys, and total population in the intervention group, BMI Z-score had a descending trend. However, the difference between two groups was significant in three months, and only among girls; in the follow-up, a significant difference was observed among girls and the total population.

Based on **Table 2**, statistically significant effects on BMI Z-score were observed, especially among girls. In other words, girls in the intervention group demonstrated significant reduction in BMI Z-score over time (baseline to follow-up; BMI Z-score change=0.36, *P*= <0.001). However, boys showed a significant increase in BMI Z-score (BMI Z-score change=-0.14, *P*= 0.002). The total study population showed a significant reduction of BMI Z-scores over time (baseline to follow-up; BMI Z-score change=0.098, *P*= 0.003).

None of the children became underweight by the end of the follow-up. The intervention was not related to unhealthy outcomes in height (Mean ± SD of height for the intervention group at base line: 148.8±0.5 cm, and at follow-up:152.7±6.8 cm)

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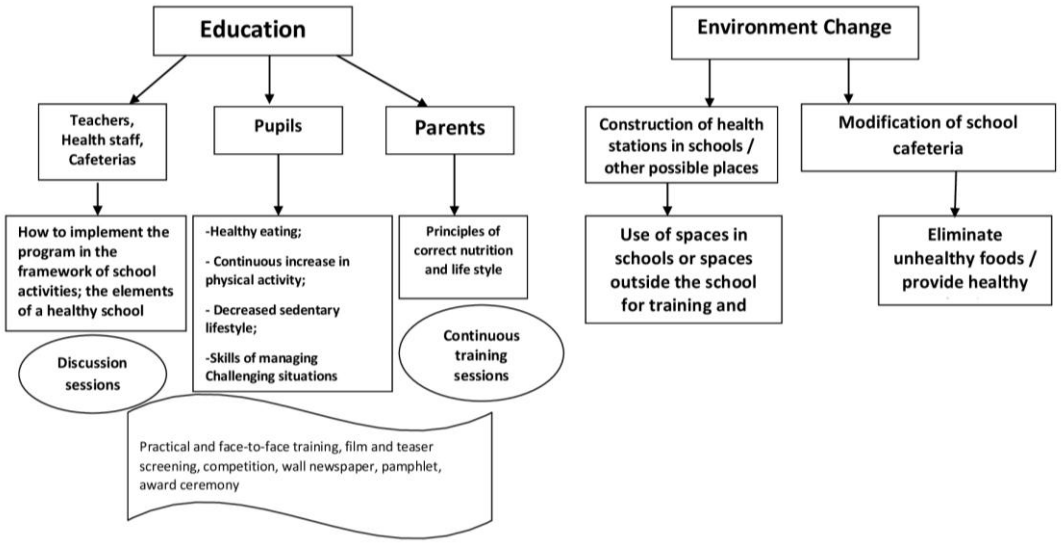

Figure 1. Proposed model for prevention and control of obesity in primary school students in District 9 of Tehran.

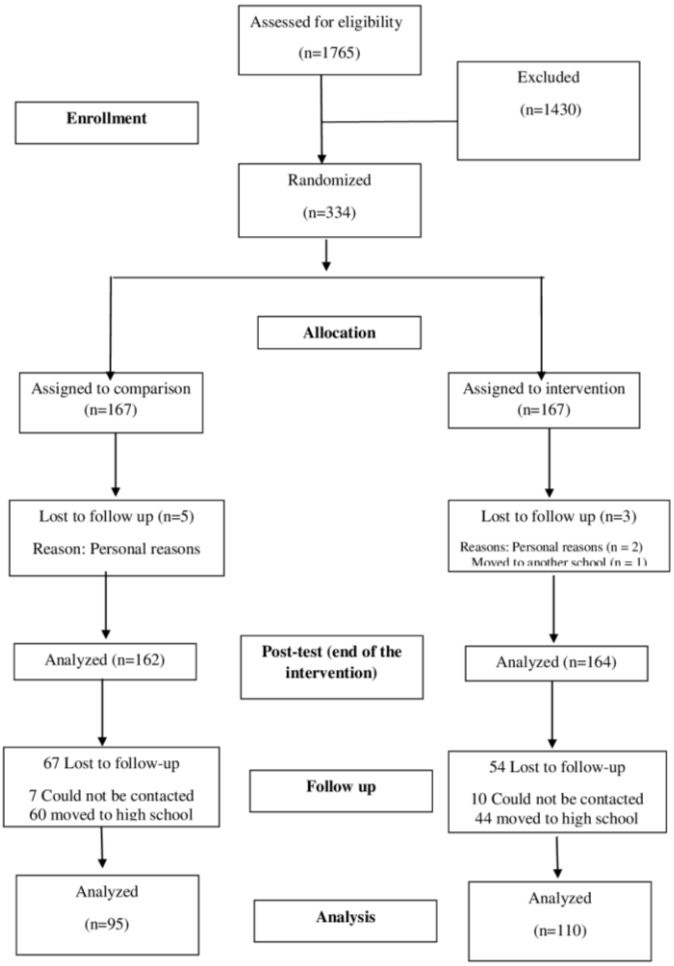

Figure 2. Flowchart of the study.

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Table 1. Comparison of body mass index Z-score regarding the four measurements in the intervention and comparison groups.

Variables	Baseline[a]	After 3 months[b]	Post-intervention[c]	Follow-up[d]
Girls				
Intervention	1.88 ± 0.60[e]	1.88 ± 0.58	1.79 ±0.61	1.54 ± 0.68
Comparison	1.72 ± 0.62	1.64 ± 0.65	1.70 ± 0.65	1.87 ± 0.66
P-value[f]	0.09	0.02	0.34	0.001
Boys				
Intervention	2.15 ± 0.70	2.10 ± 0.68	2.08 ± 0.69	1.95 ± 0.75
Comparison	2.18 ± 0.64	2.0 ± 0.62	2.11 ± 0.61	1.92 ± 0.77
P-value	0.73	0.74	0.82	0.96
Total				
Intervention	2.0 ± 0.66	1.99 ± 0.63	1.93 ± 0.66	1.72 ± 0.74
Comparison	1.96 ± 0.67	1.86 ± 0.66	1.91 ± 0.66	1.90 ± 0.72
P-value	0.57	0.10	.86	0.2

[a]: n =334, 167 intervention, 167 comparison; [b]: n=290, 144 intervention, 146 comparison; [c]:n = 326, 164 intervention, 162 comparison; [d]: n =205, 110 intervention, 95 comparison; [e]: Mean±SD; [f]: independent sample t-test.

Table 2. Mean differences from repeated measures of mixed models regarding BMI Z-score change by sex

	Boys			Girls			Total		
Groups	**B**	**L-U**	**P value**	**B**	**L-U**	**P-value**	**B**	**L-U**	**P-value**
Intervention	0.07	-0.14-0.30	0.48	-0.21	-0.42- -0.01	0.034	-0.04	-0.19 -0.09	0.51
Comparison	0	--	--	0	--	--	0	--	--
Time									
Baseline[a]	0.26	0.20-0.32	<0.001	-0.08	-0.14- -0.01	0.014	0.11	0.06-0.15	<0.001
After 3 months[b]	0.18	0.11-0.24	<0.001	-0.12	-0.19- -0.05	<0.001	0.05	0.001-0.09	0.042
Post-intervention[c]	0.18	0.12-0.24	<0.001	-0.10	-0.16- -0.03	0.003	0.06	0.01-0.11	0.009
Follow-up[d]	0	--	--	0	--	--	--	--	--
Group×Time[e]									
Baseline[a]	-0.14	-0.23- -0.05	.002	0.36	0.27-0.45	<0.001	0.09	0.03-0.16	0.003
After 3 months	-0.13	-0.23- -0.04	.004	0.34	0.25-0.43	<0.001	0.09	0.02-0.15	0.008
Post intervention	-0.14	-0.23- -0.05	.001	0.29	0.20-0.38	<0.001	0.06	-0.003-0.12	0.063
Follow-up	0	--	--	0	--	--	--	--	--

B: BMI Z-score change; L-U: Lower-Upper bounds; [a]: n =334, 167 intervention, 167 comparison; [b]: n=290, 144 intervention, 146 comparison; [c]: n = 326, 164 intervention, 162 comparison; [d]: n =205, 110 intervention, 95 comparison; [e]: Mixed models analysis was used to assess the effect of intervention over time adjusted for mother's education, family size, and student's grade

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Discussion

In the present study, the trend of BMI reduction in a sample of overweight and obese primary school children was followed after termination of the intervention under real-life conditions. Overall findings indicated that the effect of intervention lasted for almost eight months.

In a study on Chinese children, three years after termination of the RCT, the odds of developing obesity or overweight in the intervention group were lower than those in the control group. BMI z-scores in the intervention group were also lower than those in the control group for both normal-weight and overweight or obese students compared with baseline (Cao *et al.*, 2019).

A cluster RCT conducted in UK primary schools assessed the effectiveness of a 12-month intervention. The mean BMI-Z scores were lower at two time-points of 15 and 30 months in the intervention group compared with the comparison group; however, none of the measures were significant (Adab *et al.*, 2018).

Although results of follow-up indicated that the intervention affected the total population, however, it was more effective among girls. In other words, girls and boys responded to the current intervention differently. The study's original intervention was not as practical for the boys as it was for the girls; the boys could not be reached as efficiently as the girls. PA coaches in the girls' schools were motivated and supportive, however, PA was hardly observed in the boys' schools. Although the authors were not generally successful to change unhealthy food items sold in school canteens, the situation seemed worse in the boys' schools. The nutrition education sessions in the two girls' schools were directly observed by the chief researcher and feedback was given. On the other hand, in the boys' schools, only one educational session was observed and the authors had to be briefed by the instructors. Therefore, it was not clear whether the material was based on the desired protocol. It can be assumed that the boys did not change their PA level as much as the girls because of higher baseline values, and consequently, had a smaller potential for change. Furthermore, the girls were less satisfied with their body and more concerned about their health and beauty. In a school-based obesity prevention program in Argentina, girls were more willing to improve their dietary intake (Rausch Herscovici *et al.*, 2013).

A 20-month school-based intervention in Norway targeted PA, sedentary, and dietary behaviors on anthropometric outcomes of 11-year-old children. The intervention had a beneficial effect on BMI and BMI-Z score in adolescent girls, but not in boys (Grydeland *et al.*, 2014). It was stated that interventions based on social learning may be more appropriate for girls, while boys responded better to environmental modifications with the possibility of doing PA (Kropski *et al.*, 2008). However, some researchers believed female target groups responded better to an intervention irrespective of its components (Yildirim *et al.*, 2011).

The long-term follow-up can be acknowledged as the strength of the study. Although the rate of dropout in the follow-up was high, the characteristics of the subjects who did not complete the study did not vary significantly. This intervention was implemented in Tehran; however, it can be generalized to similar settings.

The authors did not examine which parts of the intervention continued in schools. Furthermore, it was not specified if the educational materials were adopted by parents or students in their lifestyles. Although onset of puberty could impact the children's growth, it was not taken into account for both girls and boys.

Conclusions

Overall, the effect of intervention on girls could be observed for almost eight months. The original study was a multi-component intervention for primary school children, which included nutrition education and increased physical activity for the children and lifestyle improvement education for the parents, as well as improvement of the schools' canteens. Since we did not measure adherence of the schools, students, and their parents to whole or part of the intervention we are not able to judge

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which part(s) of it might have brought about relative success. The intervention can be copied in similar settings.

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Authors' contributions

Amini M contributed to conception and design; conducted the research; contributed to data analyses; drafted the manuscript; and agreed to be accountable for all aspects of work ensuring integrity and accuracy. Djazayery A contributed to analysis and interpretation; contributed to writing and critically revised the manuscript; and agreed to be accountable for all aspects of work ensuring integrity and accuracy. Majdzadeh R contributed to the conception and design; contributed to data analyses; critically revised the manuscript; and agreed to be accountable for all aspects of work ensuring integrity and accuracy. Karimi M contributed to analysis and interpretation; and agreed to be accountable for all aspects of work ensuring integrity and accuracy. All authors read and approved the final manuscript.

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