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Original Article

Design and Pilot Testing of an Intervention for the Management of Overweight/Obesity in Primary School Children (7-8 years old) Through the Primary Health Care System in an Urban Setting in Iran

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ABSTRACT

Background and Objectives: In Iran, childhood obesity is an emerging problem that the primary health care (PHC) system is not well equipped for yet. The purpose of this study was to design and evaluate the effect of a PHC-based behavioral management intervention to control overweight and obesity in children.

Materials and Methods: This quasi-experimental trial was performed on 200 overweight or obese 6-8 yr. old children, in 5 urban PHC centers (3 interventions and 2 controls) for 12 months. A convenient sampling frame was applied from elementary schools of districts 7 and 8 (as intervention and control groups, respectively) in the northeast of Tehran city, the capital of Iran. Mothers were trained on parenting style and healthy lifestyle behaviors through a 5-session training workshop. Anthropometrics (Weight, Height, Body Mass Index (BMI), and Waist Circumference) , as well as blood pressure of children were measured at the beginning, 3rd, 6th, and 12th months, thereafter. Physical activity, sedentary behaviors, and dietary habits of children were also assessed.

Results: Of the total, 20.8% (n=41) of children were overweight and 79.2 % (n=156) were obese. Compared with controls, the intervention group had smaller BMI-Z scores. The slope of BMI-Z score reduction was more impressive in the intervention group compared to the control group. The systolic and diastolic blood pressure of the intervention group was significantly lower compared to the control group in all three measurements. In the intervention group, a significant decrease in the frequency of fast-food consumption and sedentary behaviors time was observed (p-value= 0.022 and 0.055, respectively). There was no significant difference between the two groups in waist circumference, fruit, vegetable, and breakfast consumption, calorie intake, and physical activity at the end of the study.

Conclusions: The protocol of the study is being used as a basis for developing childhood obesity management programs within the health system in Iran.

Keywords: School-age children, Obesity, Chronic Care Model, Primary Health Care, Iran

Trial registration: The trial was registered in the Iranian Registry of Clinical Trials (IRCT2013062213740N1).

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Highlights

- Childhood obesity is an emerging problem in Iran for which the primary health care (PHC) system was not well equipped.
- In this quasi-experimental trial, in 3 urban PHC centers, health workers and mothers were trained in behavioral management intervention to control the overweight and obesity in 6-8 y old children in Tehran.
- The slope of BMI-Z score reduction was more impressive in the intervention group compared to the controls.
- A significant decrease in the frequency of fast-food consumption and sedentary behaviors time was observed in the intervention group.

Introduction

Childhood obesity is a worldwide public health problem. According to the last report of the world health organization, in 2020, 39 million children under the age of 5 were overweight and obese [1]. Obesity is associated with an increased risk of chronic diseases, metabolic syndrome, psychological co-morbidities and all-cause mortality in children [2-4]. The major increase in the prevalence of childhood obesity and its comorbidities is associated with significant health and financial problems. Therefore, developing strategies for the prevention and management of overweight and obesity within the health system is essential.

In Iran, based on the fifth survey of childhood and adolescence surveillance and prevention of adult non-communicable disease, the prevalence of overweight and obesity among school-age children is 9.4 and 11.4 percent, respectively [5]. Several interventional studies have been conducted on Iranian children to control childhood overweight and obesity. However, almost all of these trials were designed and conducted as office-based, private interventions.

In response to the increasing prevalence of childhood obesity, the nutrition department of the Ministry of Health and Medical Education, with a fund from the UNICEF office in Tehran developed the first national guideline on the management of overweight and obesity in children and adolescents in Iran in 2011 [6]. Based on a request from the same office, this study was designed and performed to develop and evaluate a pilot intervention to manage overweight/obesity in children through the primary health care system.

Theoretical Framework: Chronic Care Model for Childhood Obesity

The long-term success of child obesity control efforts depends on the efficacy of the selected approaches, as well as the strategies through which they are applied and sustained. Although multidisciplinary approaches are considered the best solutions to tackle childhood obesity [7], providing a supportive environment in which families have access to health services and can have effective interactions with health providers is of great importance. Based on such assumption, the present study adopted Chronic Care Model (CCM), described by Wagner [8], as its framework. CCM is a well-established organizational framework for chronic care management and practice improvement. Its main assumption is that improvement in care requires an approach that incorporates patient, provider, and system-level interventions [9, 10]. It has been used to control diabetes [11], obstructive pulmonary diseases [12], obesity [13, 14], and other chronic illnesses. Also, it has been adopted in controlling childhood obesity in several interventions, including "High Five for Kids" [14], and Eat Well, Live Actively [15] trials. To our knowledge, this study is the first health system research based on CCM to control childhood obesity in Iran.

Based on Wagner, CCM is composed of 6 components (Figure 1), including**:**

(I) **Health System-Organization of Healthcare**: Program planning that includes measurable goals for better care of chronic illness.

(II) **Self-management support:** Emphasis on the central role of patients or their families in managing their care.

(III) **Decision support for providers**: Integration of evidence-based guidelines into daily clinical practice.

(IV) **Delivery-system redesign:** Focus on teamwork and integrating related specialties to support chronic care.

(V) **Clinical Information System** (CIS): Developing information systems based on patient populations to provide relevant client data that provides alerts and follow-up information.

(VI) **Community Resources and Policies:** Develop partnerships with community organizations that support and meet patients' needs.

Considering new pieces of evidence on the efficacy of CCM in obese children [16, 17], their parents, and health workers, it was adopted as the proper framework for developing and evaluating such interventions.

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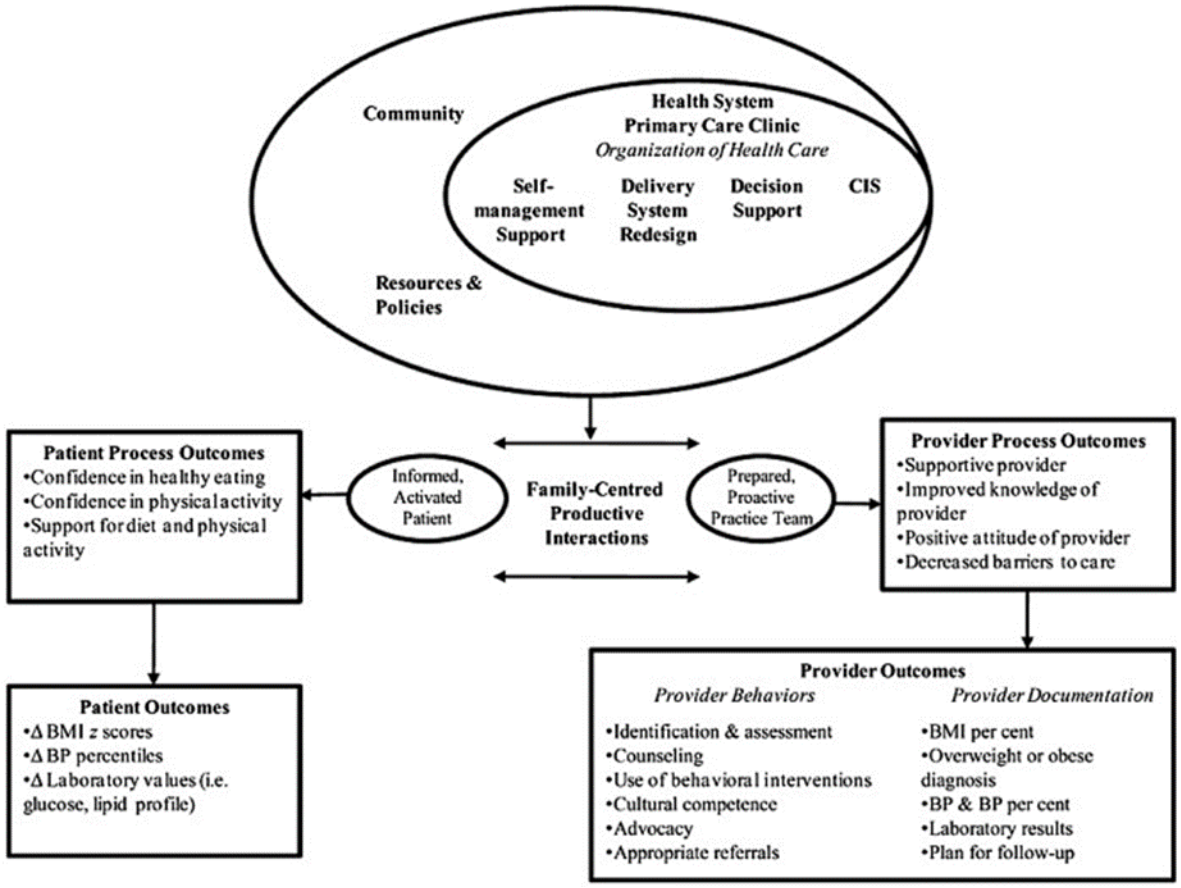


Fig1. CCM components, 2010 Jacobsen and Gance-Clevend [30]

Materials and Methods

Study Design and Setting: This study was performed over two years from June 2013 to May 2015. In this quasi-experimental trial, 257 children who were in first grade of primary school (6-7 years old) were selected from those who had been screened for health profiles at enrollment for the first grade and identified as overweight or obese. A convenient sampling frame was applied from elementary schools of districts 7 and 8 (as intervention and control groups, respectively) in the northeast of Tehran city, the capital of Iran. Three health centers from each district were selected as intervention and control centers. In each health center, a physician (program coordinator in the center) and 2 health workers were recruited as responsible persons for the implementation of the intervention.

The protocol of the intervention was developed based on the "Iran national guideline on management of overweight and obesity in children and adolescents"[6], and considering elements of CCM.

Sampling and study groups: According to previous studies [18], to compare the average changes in BMI in the two groups and considering the significance of one unit differences in BMI between the two groups, with the statistical power of 80%, Z_β =0.84, 95% confidence interval, and Z $\alpha/2$=1.96, the sample size was calculated as 74. By taking into account 20% dropout, 89 subjects in each group were assigned.

Study protocol

This study was performed through the following steps (corresponded with CCM):

A. Training of trainers: At the first step, to develop a training program, a multidisciplinary team, consisting of a pediatrician, a physician, a psychologist, a nutritionist, and a health promotion specialist, was initiated. After selecting intervention and control centers, health workers, physicians, and nutritionists within the centers were trained separately. In the intervention centers, through an eight-hour workshop for health workers and a four hours workshop for physicians and nutritionists, the national guideline on management of overweight and obesity [6] was introduced and discussed. Also, they were trained on the intervention protocol and measurements in each phase by the study team. In addition, health workers were trained on behavior modification techniques by a health psychology specialist. To examine the efficacy of the training workshops, pre and post-tests were conducted.

In the health centers of the control group, a one-day workshop was also held to provide a general orientation of the study without any details on the intervention and to introduce the application of BMI Z-score which was new to the centers.

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B. Subject Enrollment: Schools' health workers (SHW) and principals in both intervention and control health centers (usual care), were invited to an introductory meeting in the district office of the department of education. Through this meeting, they were requested to refer overweight/obese 6-7 years old students who were assessed by SHW at school enrollment to the defined health centers.

At the health center, the referred child's weight status was re-assessed and those confirmed to be overweight/ obese, based on WHO 2007 cutoffs, and those with at least one educated parent (both are inclusion criteria) were enrolled in the study. After describing the project protocol, informed consent was obtained from the parents. During this assessment, children with systemic disease, multiple endocrine disorders, epilepsy, psychosocial and orthopedic diseases, history of medication affecting weight, glucose, and lipid profile (based on a biochemical assessment), or those diagnosed with congenital or acquired hypothyroidism, as well as those on a special diet or participating in other interventions were excluded. Also, students with fractures or any other disease affecting physical activity at any stage of the study were excluded.

C. Intervention

The intervention included three phases:

C.1. Intensive phase: After initial screening, mothers of students who did not have any of the exclusion criteria and their parents had signed the informed consent were invited. Over 2 months, mothers attended a 5-session (3 in the first month and 2 in the second month) training program held in each intervention health center. Each session lasted 45-60 minutes. During the sessions, a workbook entitled: "How to have a healthy weight child" was used that was given to all mothers. This booklet included information, as well as activity sheets on three behavior modification techniques, including goal setting, enforcement, and self-assessment about target behaviors.

Recommendations emphasized within the training were based on a literature review done by the study team. In this regard, a wide range of studies, including descriptive, analytical, and experimental, as well as systematic reviews in which the most common behaviors associated with overweight and obesity in children were identified. Table 1 presents a summary of the training program content. At the end of each session, each mother according to her child and family's condition selected one behavior to focus on and noted a behavioral goal for the week in her booklet. She reported her progress/failure in achieving the selected goal in the next session. Mothers received a certificate of training completion as a reinforcement, at the end of the training sessions

After the 2-month training, a post-test was conducted to evaluate the classes and booklets (picture quality, applicability, teaching methods, …) from the mothers' perspective. Finally, they were asked to rate their level of satisfaction with the training program from one to ten. In addition, in all sessions, one of the research members attended as an observer.

C.2. Maintenance Phase: Children were followed in the third to the sixth month, for any weight change. If the child gained weight (after ensuring full compliance with recommendations by children and mothers), they were referred to a nutritionist for counseling. All the measurements, including dietary assessment and physical activity, were repeated at the beginning and end of this phase.

C.3. Follow-up Phase: To assess the stability of the effects of the intervention on anthropometric, physical activity, dietary habits, as well as blood pressure, children were measured in the 12th month.

Table 1. Summary content of the training sessions

Session	Title	Instructor
1	What is obesity, its causes, complications, and cures	Trained health worker
2	Understanding the correct communication techniques with children Parenting styles Encouragement Goal setting Self-monitoring	Psychologist
3	Importance of regular meals (especially breakfast) and snack consumption, reducing sweetened beverages consumption, Giving booklet on "Healthy cooking"	Trained health worker
4	Increasing fruit and vegetable consumption, appetite control	Trained health worker
5	Increasing physical activity at least 1 hour/day, reducing sedentary behaviors to 2 hours /day Sleep setting	Trained health worker

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Considering the components of CCM, the following actions were carried out:

I. Organization of Healthcare: The organization of the weight management team was based on the periphery healthcare team in Iran PHC.

II. Self-management support: To ensure self-management support, we used relationship-focused methods through motivational-based education by health workers. Mothers were trained via educational sessions to increase child and family skills and confidence, mothers' self-efficacy about the lifestyle behaviors of children, as well as their cooking abilities, understanding of the correct communication techniques with children, and proper parenting styles. Through the educational sessions, mothers practiced how to do goal setting and documented their lived experiences in a booklet they were given, to track their progress.

III. Decision support for providers: Healthcare teams were trained in a one-day workshop using evidence-based practice guidelines. The workshop aimed to help them understand the decision support options in different cases with different characteristics.

IV. Delivery-system redesign: Defining a weight management team within the health delivery system and improving it with the addition of a psychologist were elements of the re-design. It should be noted that at the time of the study, no defined behavioral intervention for management of childhood obesity within the health system was in place and it was limited to a routine physician or nutritionist counseling with no defined protocol.

V. Clinical information system (CIS): Proper forms to provide relevant client data and follow-up information were designed and added to the information systems.

Community Resources and Policies: The schools were contacted and sensitized regarding childhood obesity. Also, in the intervention group, if a mother did not participate in the training sessions, schools were informed to follow up and encourage them.

C. Control group (usual care)

In the control group, routine care by health workers was continued. In the first visit, health workers assessed weight, height, and waist circumference and calculated BMI. If the overweight/ obesity of the child were confirmed, they referred him/her to the physician. Blood pressure was measured by the physician. After confirmation of being overweight or obese, the children were recommended to refer to the nutritionist. In months 3, 6, and 12 all of the measures were repeated by health workers and physicians, although these follow-up sessions were not routine in the health care program.

Ethical Considerations: All subjects signed written informed consent. The study protocol was approved by the ethics committee of the National Nutrition and Food Technology Research Institute (approval code: 4965-521 date: 10/24/2013). The trial was registered in the Iranian Registry of Clinical Trials (IRCT2013062213740N1).

Outcome measures

Anthropometric Measures: The primary outcome of the study was the child's BMI Z-score. Weight was measured on a Seca robusta 813, digital floor scale and standing height by Seca stadiometer with an accuracy of a tenth of a centimeter while each subject bared feet and was in a light dress. Body mass index (BMI) and Z scores of BMI for age were calculated by WHO AnthroPlus2007 software [19]. Overweight was defined as BMI Z score ≥1 SD <2 from the median and obesity as BMI Z score ≥ 2 SD more than the median for age and sex group based on WHO criteria. [20] To measure WC, the subjects were asked to stand relaxed with arms at the sides, feet positioned close together, and weight evenly distributed across feet. WC was measured midway between the lowest rib and the superior border of the iliac crest at the end of normal expiration with a stretch-resistant measuring tape.

Blood Pressure assessment: Blood pressure was measured by a trained physician using a standard sphygmomanometer (Aneroid, HS-20C, made in China) on the right arm of children in the seated position, after at least 5 minutes rest.

Dietary assessment: At the first visit, a 24-hour diet recall was completed for each child through interviewing the mother by a trained nutritionist. Also, mothers were provided with a food record form and oral and written instructions on how to complete the questionnaire. The food record questionnaire was completed by mothers. Nutritionist IV software, modified for Iranian foods, was used to analyze the dietary data. In addition, a questionnaire on dietary habits, including frequency consumption of sugar-added beverages, fast foods, and breakfast intakes was completed to assess changes in main behaviors that were focused on during the training sessions.

Physical Activity: Physical activity was assessed by a classified validated questionnaire on physical activity based on metabolic equivalent (MET) data containing 9 levels of activity from sleep and rest (METs 0.9) to vigorous activity (more than 6 METs). The validity and reliability of the questionnaire in Iran have been previously confirmed by Kelishadi et al. [21]. For assessing sedentary behaviors, we asked about playing with computer, laptop or tablet and watching TV on usual and weekend. Finally, the mean time of sedentary behaviors of the child was calculated.

We considered parents' job, education, housing situation, and area of the residence as markers of the

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socioeconomic status of families and as shown in Table 2. There was no difference between the two groups in these variables. The socioeconomic status of distinct 7 and 8 is almost similar.

All the measurements were overseen by a member of the study team.

Table 2. Baseline Characteristics of Participants

Variable		Intervention group (n=99)	Control group (n=98)	P-value
Age (month) * mean ± sd		79.58±4.42	81.38±3.92	0.007
Sex, n (%)***	girls	52 (52.5)	54 (55.1)	0.71
	boys	47 (47.5)	44 (44.9)	
BMI Z score Median (IQR)**		2.44 (1.92-3.21)	2.59 (2.17-3.24)	0.081
Weight status***	overweight	27 (27.3%)	14 (14.3%)	0.03
	obese	72 (72.7%)	84 (85.7%)	
Waist circumference (cm)* mean ± sd		68.1±7.61	70.37±6.74	0.089
Mother employment status, n (%)***				
Housewife		79 (82.3)	73 (79.3)	0.87
Worker		15 (15.6)	17 (18.5)	
Fathers' employment status, n (%)***				
Employed		30 (31.9)	35 (37.6)	0.67
Self-employment		59 (62.8)	55 (59.1)	
Other		5 (5.3)	3 (3.3)	
Mothers' education, n (%)***				
Under diploma		16 (16.7)	14 (15.2)	0.81
High school diploma/ associate degree		62 (64.6)	58 (63)	
Bachelor and higher		18 (18.8)	20 (21.7)	
Fathers' education, n (%)***				
Under diploma		22 (23.7)	23 (24.8)	0.86
High school diploma/ associate degree		52 (55.9)	46 (49.5)	
Bachelor and higher		19 (20.4)	24 (25.8)	
Housing situation, n (%)***				
Leased		45 (46.4)	40 (45.5)	0.69
Owner		50 (51.5)	44 (50)	
Other		2 (2.1)	4 (4.5)	
Area of the house (m^2) * mean ± sd		73.4±29.01	76.43±22.01	0.07
Family size * mean ± sd		3.74±0.67	3.69±0.64	0.65

* Independent samples t-test
**Mann Whitney U test
***Chi-square

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Statistical Analysis:

Statistical analysis was conducted using SPSS software, version 21 (SPSS Inc., Chicago, Illinois) at the significance level of P< 0.05. The normal distribution of variables was confirmed by the Kolmogorov-Smirnov test. To compare data, T-test or Mann-Whitney for quantitative variables and the Chi-square test for qualitative variables were used. To analyze the efficacy of the intervention, because of missing data, we used a data set derived from multiple imputations for the analyses, and the Markov-chain Monte Carlo method was applied to impute missing values, in other words, we used Intention to Treat (ITT) analysis. Each missing value was replaced 5 times to generate 5 complete data sets. Each complete data set was analyzed with a **piecewise linear** mixed-effects model with knot at time 2 (sixth month). As there is a change at the second time point, (time-2)+ is included in the model and results were combined to provide inferential test statistics. The model can be parameterized as follow:

$$E(Y_{ij}) = \beta_1 + \beta_2\, time_{ij} + \beta_2\, (time_{ij} - 2)_+ + \beta_4\, group_i \times time_{ij} + \beta_5\, group_i \times (time_{ij} - 2)_+ + b_i ,$$

where i and j indicate individual and measurement respectively. Y_{ij} indicates the response for subject i at measurement j. β_1, β_2, β_3, β_4, β_5 represent the estimated effect of intercept, time, (time-2), and the interaction of time and (time-2) with group, respectively. The knot at time 2 is defined as $(time_{ij} - 2)_+$ which is equal to $(time_{ij} - 2)$ when time> 2 and is equal to zero when time < 2, and b_i represents random intercept. We considered the 6th month as knot point, since there was a 6-month intervention phase and a 6-month follow-up phase. In some previous studies, it has been shown that variable changes in the intervention phase are more impressive, however, in the follow-up phase, positive effects were less persistent, so we decided to consider the two sections separately and compare them. Analyses were conducted using proc mixed in SAS, version 9.4, SAS Institute Inc, Cary, NC. Data were adjusted for sex and age (except Z score of BMI-for-age).

Results

Baseline characteristics: A total of 257 children were referred to centers while 57 did not have the inclusion criteria for entering the study. Of the children who were included in the study, 20.8% (n= 41) were overweight and 79.2% (n=156) were obese. Table 2, presents the baseline characteristics of the children in the two study groups. Most of the mothers were housewives and fathers were mostly self-employed. According to Table 2, most children were from households with 3-4 members. The two study groups were broadly similar at baseline, except for age. The mean age of the children was 80.48 months. Since the children in the control group were significantly older, age was considered a confounder in the analysis. There were no differences in socioeconomic variables of the two groups.

Figure 2, shows participants throughout the trial. Twenty-nine (28%) subjects in the intervention group and nineteen (19%) in the control group were not visited at 6 months. A total of 59 (57%) subjects in the intervention group and 28 (28.5%) subjects in the control group were not visited at 12 months. Due to loss of follow-up, missing data were imputed and finally, 99 in the intervention and 98 children in the control group completed the study.

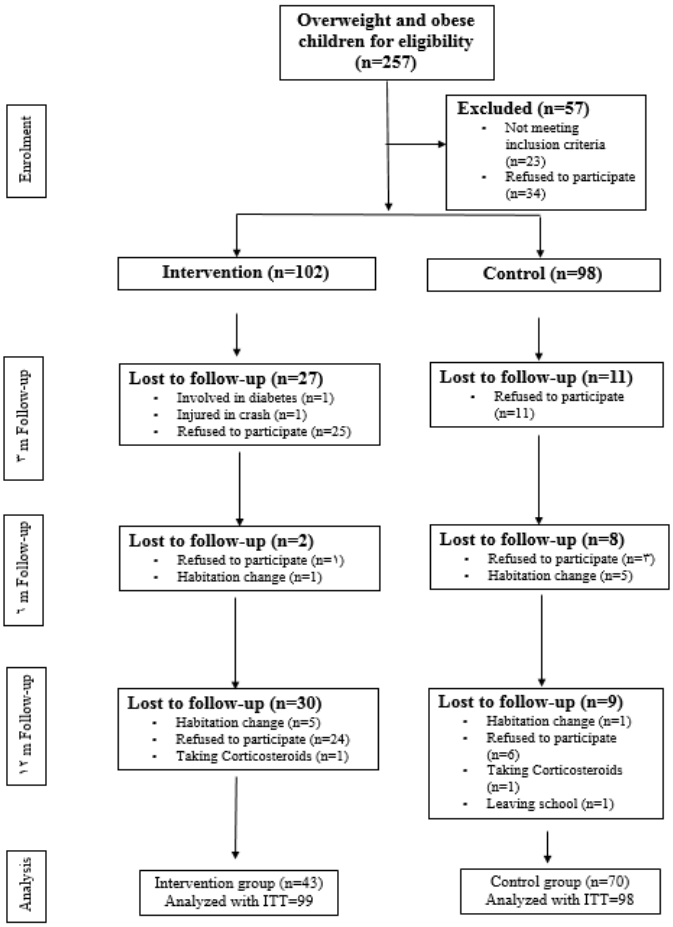


Figure 2. Recruitment and retention in the intervention and control groups

Effect of intervention

Table 3, reports participants' mean ± SE of BMI, BMI Z-score, and waist circumference at baseline, 3, 6, and 12 months thereafter. In comparison with the control group, BMI and BMI Z- scores were lower in the 3rd, 6th, and 12th months in the intervention group. The slope of BMI-Z score reduction was more impressive in the intervention group compared to the control group (Figure 3). The biggest difference of BMI-Z score between groups was seen in the 6th month (-0.39). There was no significant difference in WC in the three measurements between the groups, nor were any significant differences during the follow-up phase in comparison with the intervention phase in the intervention group.

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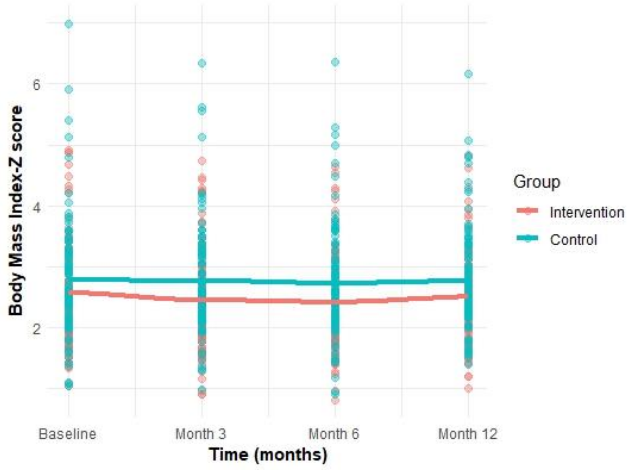


Figure 3. Graphical representation of BMI-Zscore

The systolic and diastolic blood pressure of the intervention group was significantly lower compared to the control group in all three measurements. During the follow-up phase, the mean systolic blood pressure was 4.13 mmHg lower in comparison to the first six months in the intervention group (Table 4).

There was no significant difference in biochemical variables during the time in any of the groups and between groups (data are not shown).

Table 5 presents information on the lifestyle behaviors of the children. Compared with the controls, fast food and sweetened beverages consumption in the intervention group were significantly lower in the 3rd, 6th, and 12th months. However, there were no significant differences in calorie intake, breakfast, fruit and vegetable consumption, and physical activity between the groups. It should be noted that the mean breakfast consumption and physical activity in both groups slowly increased during the intervention phase and decreased in the follow-up; however, not significantly. In the intervention group, during the six-month intervention period, a remarkable increase in vegetable and breakfast consumption was observed compared to the controls; however, in the follow-up phase, it again reduced (Figures 4 and 5) and as it is obvious, in the 12th-month compared to the baseline, we cannot see impressive change in physical activity and sedentary behaviors. In other words, we can declare that the present study was more effective in vegetable consumption rather than fruit consumption.

Sedentary behaviors in the intervention group in all three measurements were lower compared to the controls. During the follow-up phase, the sedentary behaviors time reduced significantly in comparison to the first six months in the intervention group.

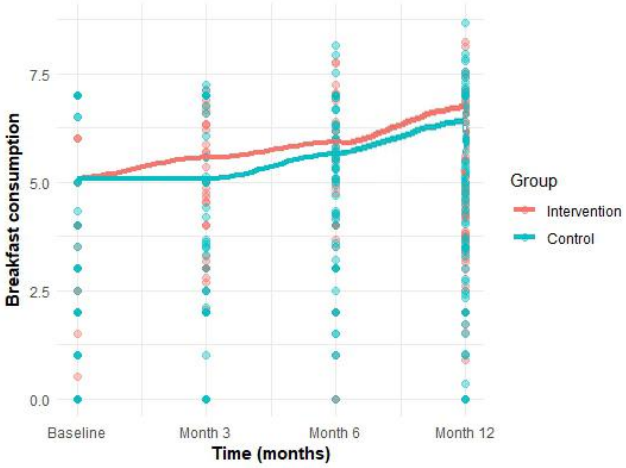


Figure 4. Graphical representation of Vegetable intake

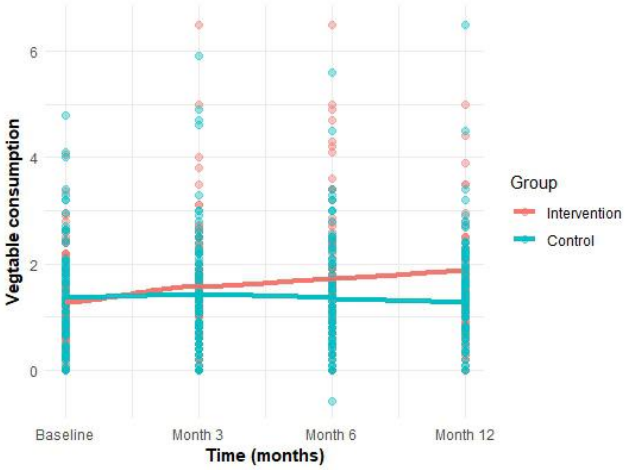


Figure 5. Graphical representation of Breakfast consumption

Discussion

This paper outlines the protocol and results of a pilot study aimed at managing childhood obesity in the primary healthcare setting in the city of Tehran. Through this theory-based study, the chronic care model was used to consider different related factors to manage obesity. Also, behavior change techniques were used to reinforce mothers 'self-efficacy. To our knowledge, this study is the first PHC and theory-based intervention to control childhood overweight and obesity in Iran. Based on the findings, the 6-month intervention was able to control overweight and obesity in school-age children; however, this change was not permanent in the follow-up phase. Among lifestyle behaviors emphasized, fast food intake and sedentary behaviors time reduced significantly.

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Table 3. Changes in the anthropometric indicators in intervention and control groups

Variable	**group**	**Baseline** Mean ± SE	**3rd month** Mean ± SE	**6th month** Mean ± SE	**12th month** Mean ± SE	**Group** (p-value)	**Time** (p-value)	**(Time- 2)+** (p-value)	**Group* time** (p-value)	**group*(time-2)+** (p-value)
*BMI (Kg/m^2)	intervention	20.88±2.28	20.69±2.30	20.88±2.28	21.59±2.23	0.75 (0.037)	-0.23 (0.11)	0.72 (0.004)	0.22 (0.013*)	-0.30 (0.052)
	control	22.06±2.71	21.84±2.54	22.06±2.71	22.77±2.73					
	Δ	-0.75	-0.97	-1.20	-1.65					
BMI Z score	intervention	2.57±0.87	2.45±0.84	2.41±0.80	2.5±0.74	0.25 (0.045)	-0.15 (<.0001)	0.26 (<.0001)	0.07 (0.013*)	-0.12 (0.022*)
	control	2.78±0.96	2.78±0.89	2.72±0.92	2.76±0.85					
	Δ	-0.25	-0.32	-0.39	-0.29					
*Waist circumference (cm)	intervention	68.1±7.61	68.14±7.09	69.01±6.79	73.89±6.50	2.26 (0.02)	0.00 (0.99)	3.02 (0.02)	0.44 (0.240)	-0.96 (0.188)
	control	70.37±6.74	71.87±6.41	72.23±6.36	76.63±6.41					
	Δ	-2.26	-2.70	-3.14	-2.10					

*Adjusted for age and sex
Mixed effects model
Δ = μ(T)- μ(C), indicates the difference of estimated marginal mean between treatment and control groups.
(Time- 2)+ is equal to (time_- 2) when time> 2 and is equal to zero when time < 2. The number 2 indicates the sixth month.

Table 4. Changes in blood pressure indicators in intervention and control groups

Variable	**group**	**Baseline** Mean ± SE	**3rd month** Mean ± SE	**6th month** Mean ± SE	**12th month** Mean ± SE	**Group** (p-value)	**Time** (p-value)	**(Time- 2)+** (p-value)	**Group*time** (p-value)	**group**(time-2)+** (p-value)
*Systolic BP	Intervention	106.8±10.52	109.66±9.23	109.52±11.59	109.73±9.39	10.54 (<.0001)	5.91 (0.001)	-11.02 (0.009)	-4.39 (<.0001)	7.43 (0.014)
	Control	116.95±11.09	114.25±8.21	113.01±8.83	108.84±8.18					
	Δ	-10.54	-6.15	-1.75	-7.82					
*Diastolic BP	Intervention	64.59±10.91	66.54±10.07	68.39±9.64	68.66±7.79	10.82 (<.0001)	7.14 (<.0001)	-10.25 (<.0001)	-5.20 (<.0001)	7.57 (0.0003)
	Control	74.99±7.62	72.15±6.43	69.63±6.74	75.01±5.26					
	Δ	-10.83	-5.63	-0.43	-5.18					

*Adjusted for age and sex
Mixed effects model
Δ = μ (T)- μ(C), indicates the difference of estimated marginal mean between treatment and control groups.
(Time- 2)+ is equal to (time_- 2) when time> 2 and is equal to zero when time < 2. The number 2 indicates the sixth month.

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Table 5. Changes in the lifestyle behaviors in intervention and control groups

Variable	group	Baseline Mean ± SE	3rd month Mean ± SE	6th month Mean ± SE	12th month Mean ± SE	Group (p-value)	Time (p-value)	(Time- 2)+ (p-value)	Group*time (p-value)	group**(time-2)+ (p-value)
*Fruit consumption (serving/day)	intervention	1.81±1.14	1.53±1.14	1.52±1.25	1.54±0.97	-0.023 (0.90)	-0.12 (0.59)	0.10 (0.84)	0.02 (0.898)	0.04 (0.879)
	control	1.74±1.28	1.6±1.24	1.5±1.16	1.71±1.23					
	Δ	0.02	0.00	-0.02	-0.14					
*Vegetable consumption (serving/day)	intervention	1.26±0.85	1.56±1.06	1.69±1.22	1.71±0.89	0.09 (0.61)	0.47 (0.04)	-0.90 (0.05)	-0.25 (0.076)	0.53 (0.073)
	control	1.35±0.99	1.41±1.1	1.36±1.04	1.35±0.95					
	Δ	-0.09	0.16	0.41	-0.14					
*Fast food consumption (freq/month)	intervention	3.26±3.86	1.63±3.39	1.64±3.31	1.53±1.43	-0.19 (0.04)	-0.33 (<.0001)	0.42 (0.01)	0.13 (0.022)	-0.20 (0.071)
	control	2.55±2.34	1.69±1.51	1.95±1.61	1.46±0.85					
	Δ	0.19	0.06	-0.08	-0.34					
*Sweetened beverages (freq/week)	intervention	2.97±3.8	1.13±1.32	1.9±1.9	0.94±1.2	-0.45 (0.27)	-1.25 (<.0001)	0.95 (0.09)	0.64 (0.005)	-0.62 (0.106)
	control	2.5±3	2.02±3.43	2.6±2.95	1.65±2.11					
	Δ	0.45	-0.18	-0.82	-2.09					
*Breakfast consumption (freq/month)	intervention	5.07±1.02	5.55±0.77	5.91±0.71	6.08 ±0.76	-0.13 (0.72)	0.49 (0.12)	-0.43 (0.53)	-0.08 (0.704)	-0.13 (0.777)
	control	5.06±1.03	5.07±1.00	5.64±0.74	6.01±0.88					
	Δ	0.13	0.21	0.29	0.71					
*Physical activity (Met.h/d)	intervention	33.93±2.85	34.78±2.89	38.15±4.98	39.55±2	1.44 (0.01)	2.68 (0.06)	-2.98 (0.28)	-0.40 (0.628)	-0.68 (0.686)
	control	34.97±2.72	36.24±3.65	39.37±5.95	40.28±2.26					
	Δ	-1.44	-1.04	-0.65	1.50					
*Calorie intake (Kcal)	intervention	1468.25±401.54	1331.48±461.45	1438.33±412.8	1387.63±293.23	50.55 (0.42)	-0.23.05 (0.77)	-45.38 (0.78)	5.07 (0.921)	20.31 0.852)
	control	1475.15±431.45	1351.64±435.59	1452.19±372.25	1417.3±270.59					
	Δ	-50.55	-55.62	-60.69	-111.45					
*Sedentary behaviors	intervention	152.8±90.86	124.88±67.16	237.911±115.88	260.39±94.07	18.70 (0.28)	-4.00 (0.82)	21.11 (0.56)	38.38 (0.001)	-76.93 (0.002)
	control	172.71±103.25	171.78±128.38	304.4±142.2	327.59±120.54					
	Δ	-18.70	-57.08	-95.46	-18.35					

*Adjusted for age and sex
Mixed effects model
Δ = μ(T)- μ(C), indicates the difference of estimated marginal mean between treatment and control groups.
(Time- 2)+ is equal to (time_- 2) when time> 2 and is equal to zero when time < 2. The number 2 indicates the sixth month.

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In Esfarjani's study on 7-year-old obese children in Tehran [22], BMI increased in both groups but the trend was slower in the intervention group. By considering the effect of age and sex on weight status, it is better to report BMI Z-score which was not reported in that study. Croker also reported that a six-month intervention on 8-12 years of age, overweight or obese children in the UK significant reduction in BMI SDS (Standard Deviation Score) in both groups. In the intervention group, after 6 months of follow-up, BMI SDS did not change significantly. [23] The results are in contrast with the present study since BMI Z-score increased in the follow-up phase. As mentioned before, in comparison with the control group, BMI and BMI Z-score were lower in the intervention group in all three measurements. One of the reasons behind the tangible decrease in BMI Z-score during the earlier phases of the study in the intervention group, and the significant increase in the follow-up phase can be the more intense follow-ups by the health workers. In addition, the reduction in BMI Z-score may be due to an increase in physical activity as well as a decrease in fast food and sweetened beverages intake in the intervention phase. Although the intervention did not result in reducing calorie intake, the consumption of fast foods and sweetened beverages was reduced significantly.

Unexpectedly there was no significant change in waist circumference, calorie intake, physical activity, breakfast, fruit and vegetable consumption, and biochemical variables. Similarly, studies by Croker [23], Fulkerson [24], McCallum [25], and Taveras [14] reported no significant change in the WC of children. It should be noted that the mentioned studies varied in the length of time of intervention, which ranged from 3 months (30) to 12 months (29).

Regarding the measurement of WC in children and effective ways to decrease it, there is no consensus. Family-based studies show that a combination of behavioral modification and exercise can reduce WC. [26] In the present study, the intervention did not have a significant effect on the children's WC and there was not adequate funding to support free sports classes.

Although the mean of sedentary behaviors was still higher than the standard (2 hours/day) at the 12th month compared to the beginning of the study, the intervention could slow down the trend over the first six months in comparison with the control group, especially in the first 3 months. In Taveras's study [14], total television and video viewing time decreased significantly over a year in the intervention group compared to the control group. However, the meantime of sedentary behaviors was still higher than standard. The results are in disagreement with the present findings.

The consumption of fruits and vegetables was lower than standard in all the measurements and despite the training of mothers, it did not increase. The results are similar to Gerards [27] and in contrast with Esfarjani [22] and Garipagaoglu [26]. Factors such as the price of fruits and vegetables and children's preferences about different types of fruits and vegetables can affect this finding [28].

After 6 months of intervention, consumption of breakfast increased in both groups; however, it decreased after six months of follow-up. Part of the second 6 months of follow-up coincided with summer when children spend more time with their families and may have more food consumption due to school closure.

Physical activity increased in the first six months and decreased in the follow-up phase (not significantly) in both groups. In the present study, the third measurement was during summer when schools were closed and children had enough time to play and be more active, but in the fourth measurement, which was in the next academic year and they were going to school MET of physical activity was decreased again. Therefore, the intervention couldn't change physical activity level and the changes were mostly due to changes in schools' closure. It should be considered that maybe due to the Hawthorn effect mothers in the control group paid more attention to the physical activity of their children, which may have resulted in a non-significant difference between groups [29]. Because students spend most of their time in school, promoting after-school programs can be a good strategy for increasing physical activity in this age group. In an urban setting, air pollution, specifically in polluted cities like Tehran can be an obstacle to increasing children's physical activity.

Overall, the present intervention was effective in controlling weight gain in school-age children. Although the reduction in BMI Z- score was not persistent in the follow-up phase. Therefore, it can be concluded that the intervention was effective in preventing the increase in overweight. The most dramatic change observed was a reduction of sweetened beverages intake in the intervention group which remained even in the follow-up phase. Younger children eating behaviors are mainly affected by their family's eating habits; however, in older children, more focus on their nutrition education and peer pressure effect can be promising. It is proposed to run continuous and multiple interventions via different settings to control the overweight and obesity of children. As it is clear in the Table 3, there is no obvious change in BMI-Z score in 12 month compare to the baseline in both groups, so, it is proposed to conduct cost-effectiveness studies in Iran to select the most cost-effective interventions through health care system.

One of the outputs of the present study is a set of educational materials that were developed to be used in the healthcare system to address childhood obesity and reinforce counseling skills in health workers. Similar materials were not available within the health system before. The study protocol, integrating family, school, and health care system as stakeholders of childhood obesity through the CCM framework could serve as a useful model to control obesity

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in school-age children. However, the present study had some limitations that need to be taken into account. Too many ongoing programs within the health system overwhelmed the providers and as a result, limited their interest in cooperating with the study. The shortage of health workers in some health centers was another restriction that may have affected the results.

According to the working hours of health centers and schools, some parents were less likely to bring their children to health centers for measurements. In future studies, using the Integrated Health System of Iranians can offer and provide faster service to diagnose, control, and accurate referral or follow-up intervals.

It should be noted that at the time of the present study, only children up to 8 years in health care centers were assessed, but after the health reform plan, all age groups were covered by the health care system. This can be a great opportunity in the control and follow-up of overweight/obese children. Since school-aged children do not usually come to health centers and there is no guarantee for intervention based on the health care system, multilevel interventions that involve schools, sports clubs, and municipalities can have more effective and persistent effects.

Conclusion:

This study shows that the use of an evidence-based protocol, well-trained healthcare teams, and medical oversight, as well as engaging main stakeholders of childhood obesity, are components to ensuring effective delivery of high-quality care and achieving clinically meaningful weight management outcomes. Using the chronic care model and considering different aspects of managing childhood obesity can lead to better results and provide stable conditions for the management of obesity.

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Ethics approval and consent to participate

All subjects signed written informed consent. The study protocol was approved by the ethics committee of the National Nutrition and Food Technology Research Institute (approval code: 4965-521 date: 10/24/2013). The trial was registered in the Iranian Registry of Clinical Trials (IRCT2013062213740N1).

Consent for publication

All the authors agreed to submit the manuscript.

Availability of data and material

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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The authors declare that they have no competing interests.

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