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## Efficacy of herbal mixtures in childhood obesity control

### Authors' Contribution:

- A** Study Design
- B** Data Collection
- C** Statistical Analysis
- D** Data Interpretation
- E** Manuscript Preparation
- F** Literature Search
- G** Funds Collection

Mahin Hashemipour<sup>1ADEF</sup>, Roya Kelishadi<sup>2ADEF</sup>, Sedigeh Asgary<sup>3AF</sup>,  
Mojtaba Talaei<sup>4GB</sup>, Mehdi Salek<sup>1E</sup>, Nooshin Mohammadifard<sup>5AF</sup>,  
Naser Tavakoli<sup>6A</sup>, Mojgan Soghrati<sup>2E</sup>

<sup>1</sup> Department of Pediatric Endocrinology, Endocrine Research Center, Isfahan University of Medical Sciences, Isfahan, Iran

<sup>2</sup> Department of Preventive Pediatric Cardiology, Isfahan Cardiovascular Research Center, Isfahan University of Medical Sciences, Isfahan, Iran

<sup>3</sup> Basic Research Unit Isfahan Cardiovascular Research Center, Isfahan University of Medical Sciences, Isfahan, Iran

<sup>4</sup> Isfahan University of Medical Sciences, Isfahan, Iran

<sup>5</sup> Department of Nutrition, Isfahan Cardiovascular Research Center, Isfahan University of Medical Sciences, Isfahan, Iran

<sup>6</sup> School of Pharmacy, Isfahan University of Medical Sciences, Isfahan, Iran

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### Summary

The aim was to evaluate the efficacy of herbal mixtures on childhood obesity control.

### Background: Material/Methods:

In a double-blinded clinical trial, 120 children and adolescents aged 5–17 years were studied in four randomly divided groups. Similar physical activity and diet were recommended for all groups. Two groups received herbal drugs, one group placebo, and the fourth group received no medication. All subjects were visited by a physician at the beginning and after 6, 12, and 24 weeks. Their serum cholesterol, triglyceride, HDL-C, and LDL-C levels were measured at baseline and after 12 and 24 weeks. Data were analyzed by SPSS v. 10 for Windows software using ANOVA and the Friedman and Wilcoxon signed rank tests with  $P < 0.05$  as the level of significance.

### Results:

In the first follow-up visit (after 6 weeks), mean weight loss was higher in the fourth group than in the other three groups (30% vs. 16.6%, 10%, 10%, respectively,  $P < 0.05$ ). In the further follow-ups there was no significant weight loss compared with the first follow-up.

### Conclusions:

Since the fourth group (no medication or placebo) had better results in weight loss, it seems that those who received an herbal mixture or placebo gave up physical activity and diet recommendations. As there was no continuous weight loss in further follow ups, the role of family compliance and lifestyle modification should be emphasized rather than looking for medications for the control of childhood obesity.

### Key words:

childhood obesity • placebo • herbal mixture • diet • physical activity

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### Author's address:

Mahin Hashemipour, MD, Isfahan Endocrine Research Center, Sedigeh Tahereh Research Center, Khoram St., Isfahan, Iran, e-mail: [hashemipour@med.mui.ac.ir](mailto:hashemipour@med.mui.ac.ir)

## BACKGROUND

Childhood obesity is a cultural and medical problem. Although its prevalence is higher in developed countries, it is rapidly increasing in developing and even in Third-World countries as well [1-5]. According to World Health Organization (WHO) reports, the prevalence of obesity is 30% in the Middle East. Iran has been considered as one of seven countries with high prevalence of childhood obesity in 1998 [6,7]. Recent studies in our society have shown a rapid increase in the childhood obesity rate [8,9]. In addition to immediate complications, childhood obesity has many medical complications in adulthood. After 26 years of follow-up, the Framingham Study showed that the sequels of childhood obesity are independent of weight in adulthood [10].

The early and late complications of childhood obesity confirm the importance of weight control from childhood on. Lifestyle change is a very effective method in this regard, but it needs good training and support. In addition, after weight loss it is difficult to maintain proper weight. In many cases it is very difficult to attract the children's and adolescents' cooperation in weight-loss programs, so many families look for safe medication for weight control of their children. Several studies have been conducted on drug therapy for obesity, but considering the side effects, the present study aimed to evaluate the effect of some kinds of herbal mixtures on weight control in children.

## MATERIAL AND METHODS

In a double-blinded controlled trial, 120 children and adolescents aged 5 to 17 years who were referred to the Obesity Clinic of Preventive Pediatric Cardiology Department, Isfahan Cardiovascular Research Center (a WHO Collaborating Center), were randomly selected and then divided into four groups of equal number. The Ethics Committee of the Research Center approved the study design and the prepared herbal mixture. After an explanation of the whole procedure, written consent was obtained from the parents and oral assent from the children.

In the first visit, after recording age and birth date, weight (Wt) was measured to the nearest 200 grams with the subjects lightly dressed and barefoot. Height (Ht) was measured to the nearest 0.2 cm with the subjects standing and barefoot. As a measure of obesity, body mass index (BMI) was calculated by dividing weight (kg) by the squared height in meters. Physical examination was performed by the same physician and venous blood samples were obtained from the subjects after at least 12 hours of fasting. The blood samples were centrifuged for 10 minutes at 3000 rpm, and the frozen sera were kept at -20°C and analyzed at the Isfahan Cardiovascular Research Center laboratory, which meets the criteria of the National Reference Laboratory (A WHO Collaborating Center) and is under the external quality control of St. Rafael University, Department of Epidemiology, Leuven, Belgium.

Total cholesterol (T-Chol), high-density lipoprotein cholesterol (HDL-C) and triglyceride (TG) were measured by the enzymatic method using an Elan 2000 auto-analyzer (Ependorf, Germany). Low-density lipoprotein cholesterol

(LDL-C) was calculated (in serum samples with TG  $\leq$  400 mg/dl) according to the Friedwald formula [11]. Thyroid function tests were assessed in all participants, and in those with suspicious endocrine disorder, glucose tolerance and dexamethasone suppression tests were performed as well. Children and adolescents with simple obesity ( $85^{th} < \text{BMI} < 95^{th}$  percentile,  $\text{BMI} \geq 95^{th}$  percentile and no endocrine or other concomitant disorders) were included in this study, while those with proved endocrine disorder, abnormal faces, or mental retardation and/or with a positive history of chronic medication use were excluded from the study.

Two herbal mixtures, one with *Descurainia sophia* and *Lactuca sativa* and the other with *Plantago psyllium* and *Origanum marjorana*, were used in this study. *Origanum marjorana* was selected because of its probable effect of decreasing appetite, and the other herbal mixtures were used due to their high amounts of mucilage that cause high fecal bulk and increase excretion through defecation and reduce intestinal absorption [12,13]. A placebo was prepared in the form of a suspension. *Origanum marjorana* leaves were collected from the botanical garden of Isfahan University of Medical Sciences, *Descurainia sophia*, *Lactuca sativa*, and *Plantago psyllium* seeds were purchased. Each kind of plant was identified at the Botany Department of the Faculty of Science of Isfahan University. The leaves were dried at the room temperature, ground, and sieved. The plant seeds were ground and sieved.

The above two herbal mixtures as well as the placebo in suspension form were prepared by a pharmacognosist and an industrial pharmacist. All participants were referred with their parents to the same dietician who, besides the written diet, gave them oral explanations. The recommended diet consisted of all the essential food groups and the energy amount was calculated according to the ideal weight for height. In general, a low-fat diet and avoiding excess intake of highly refined starches and other carbohydrates were advised. In addition, all participants obtained written and oral recommendations for age-appropriate daily exercise of moderate intensity. Participants were advised to exercise 2-3 times a day, each time for 5-10 minutes, and to increase the frequency gradually.

The patients were divided into four groups of 30 members each as follows:

1. Group 1 received one herbal mixture (*Descurainia sophia* and *Lactuca sativa*) in addition to diet and exercise recommendations.
2. Group 2 received the other herbal mixture (*Plantago psyllium* and *Origanum marjorana*) in addition to diet and exercise recommendations.
3. Group 3 received the placebo in addition to diet and exercise recommendations.
4. Group 4 received only diet and exercise recommendations.

To perform the study in a double-blinded manner, the physician who prescribed the suspensions, the nurse who gave them to the patients, and the patients who received the medications were not aware of the kind of medications. Participants were visited at 6, 12, and 24 weeks after the first visit and their serum lipid levels were checked at 12 and 24 weeks after the first visit. The medications were prescribed

**Table 1.** Prevalence of obese children and adolescents according to gender.

Groups		Sex		Total
		Boys	Girls	
A	n	11	19	30
	Percent in group	36.7%	63.3%	100.0%
B	n	9	21	30
	Percent in group	30.0%	70.0%	100.0%
C	n	13	17	30
	Percent in group	43.3%	56.7%	100.0%
D	n	12	18	30
	Percent in group	40.0%	60.0%	100.0%
Total	n	45	75	120
	Percent in group	37.5%	62.5%	100.0%

**Table 2.** Prevalence of obese children and adolescents according to school level.

	School level		
	n	%	Cumulative percent
Preschool	30	25.0%	25.0%
Elementary school	68	56.7%	81.7%
Intermediate school	16	13.3%	95.0%
High school	6	5.0%	100.0%
Total	120	100.0%	—

for 12 weeks. Thereafter the patients were recommended to continue their diet and daily exercise at home and were visited again after 24 weeks.

Data (except weight, BMI, weight for height, and serum lipids) were analyzed by EPI info 2000 software. Weight, BMI, weight for height, and serum lipids were analyzed by statistical software SPSS v. 10 for Windows. ANOVA and the Friedman and Wilcoxon-signed ranks tests were used to analyze and compare the results of each group from the first to the fourth visit. The significance level was set at  $P < 0.05$ .

## RESULTS

Prevalence of obesity according to gender, school level, and BMI percentiles are shown in Tables 1, 2 and 3. Our results showed that after 6 weeks the mean weight loss of the subjects in the fourth group (receiving only diet and exercise recommendations) was more than in the other groups (Table 4). There was no significant difference in the mean value of weight loss among the four groups after 12 weeks (Table 5) and 24 weeks. There was no signif-

**Table 3.** Prevalence of obese children and adolescents according to BMI percentiles.

Groups		Percentile BMI		Total
		85 <sup>th</sup> ≤ BMI < 95 <sup>th</sup> percentile	BMI ≥ 95 <sup>th</sup> percentile	
A	n	11	19	30
	Percent in group	36.6%	63.4%	100.0%
B	n	6	24	30
	Percent in group	20.0%	80.0%	100.0%
C	n	9	21	30
	Percent in group	30.0%	70.0%	100.0%
D	n	7	23	30
	Percent in group	76.6%	23.3%	100.0%
Total	n	33	87	120
	Percent in group	27.5%	72.5%	100.0%

icant difference in the control of dyslipidemia among the four groups studied.

## DISCUSSION

The study suggests that the use of any kind of medication, even placebo, may lead to a decrease in the compliance of obese children and their families in following recommended changes in diet and physical activity. In the most comprehensive study that followed up obese children into adulthood, Whitaker et al. found that after 6 years of age, more than 50% of obese children remained obese into adulthood, and by the age of 10 to 14 years, 80% of obese children remained obese [14]. It is concluded that overweight should be controlled from an early age. Because of the complicated nature of childhood obesity, its treatment is very difficult and researchers have tried to find safe drugs to help control obesity. Many studies have shown the efficacy of herbal medications in the controlling obesity and hyperlipidemia in rats [15–20].

Many families often ask many questions about various herbal or over-the-counter medications for weight loss in their children. Nowadays there is a rapidly growing trend to use herbal remedies in many countries [21]. The studies by Sindler [22] and by Andersen and Fogh [23] showed herbal products may be effective in weight loss in obese adults. The study of Boozer et al. showed that a herbal mixture effectively promoted short-term weight loss [24]. In a randomized controlled trial, Heymsfield et al. compared the effects of a herbal medication with placebo (in addition to a

Table 4. Changes in weight 6 weeks after the first visit.

Weight change	Groups							
	A n %		B n %		C n %		D n %	
Decreased	5	6.16	3	10.0	3	10.0	9	30.0
Without difference	23	7.76	25	83.3	27	90.0	21	70.0
Increased	2	6.70	2	6.70	0	0.0	0	0.0
Total	30	100.00	30	100.0	30	100.0	30	100.0
P value in comparison to the first visit*	**(NS) 0.406		0.480 (NS)		0.083 (NS)		0.003	

\* Wilcoxon signed rank test;

\*\* NS - not significant.

Table 5. Changes in weight 12 weeks after the first visit.

Groups	Weight change				*P-value
	Decreased n %	No difference n %	Increased n %	Total n %	
A	7 23.3	23 76.6	0 0.0	30 100.0	0.011
B	8 26.7	20 66.6	2 6.7	30 100.0	0.145 (NS)**
C	6 20.0	23 76.6	1 3.3	30 100.0	0.059 (NS)*
D	9 30.0	21 70.0	0 0.0	30 100.0	0.004

\* Wilcoxon signed rank test;

\*\* NS - not significant.

high-fiber, low-energy diet) on weight loss in obese adults. Participants in both groups had significant weight loss during a 12-week treatment period; however, there was no statistically significant difference in weight loss between the two groups, so they concluded that in comparison with placebo, the herbal medication used failed to produce significant weight loss [25].

Consistent with the above study, our results did not show a significant difference between those who received a herbal mixture and placebo; however, in contrast with the above studies, the participants who received herbal medication or placebo did not lose weight. Overall, according to the results of our study, the fourth group (the group that received only diet and exercise recommendations) had considerable weight loss after 6 weeks compared with the other groups. It is suggested that the other groups, who received herbal medication or placebo in addition to the diet and exercise recommendations, only relied on medications for weight loss and did not followed the recommendations on diet and physical activity appropriately. In our study, the first group, who had significant weight loss after 6 weeks, did not have desirable weight loss in further follow-ups, which is suggested to be because of the low compliance of children and their families. It is well documented that a good weight-loss program needs appropriate training for both children and families to enjoy physical activity and healthy eating [26].

## CONCLUSIONS

Lifestyle modification and the family compliance have a key role in the control of childhood obesity. Relying on medication use may lower the compliance of the obese child as well as of the family in following the recommended diet and physical activity program.

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