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The impact of a lifestyle promotion program on anthropometric and clinical manifestations in adolescents with polycystic ovarian syndrome: a randomized controlled trial

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Abstract

Background Lifestyle modification can have beneficial effects on improving symptoms of ovary syndrome and anthropometric changes, particularly in obese individuals… However, it is not clear whether these affects in obese adolescents with PCOS are the same as non-PCOS adolescents. We had a study question" Can lifestyle promotion programs, which focus on changing behavioral habits, have an effect on anthropometric parameters and the manifestation of polycystic ovary syndrome (PCOS) in adolescents?"

Methods This was a cluster randomized trial (CRT) that started from January 2021 and follow-up ended in March 2022. 128 participants included adolescent girls (from 14 to 18 years old). The status of PCOS was determined for the participants, following which both the PCOS-afflicted and non-PCOS cohorts were subjected to randomization to either partake in a lifestyle promotion program or to proceed without it. This program included eight sessions that were designed to be implemented for two months. This intervention provides recommendations for a balanced diet and regular exercise, as well as advice on behavior change for adolescents, including those with PCOS, regardless of their weight. All participants were followed up for 12 months and were evaluated at three time points: baseline, 6 and 12 months. Outcomes included changes in the anthropometric indices (weight, hip and waist circumstance), regularity of menstrual cycle, hirsutism score by the modified-Ferriman-Gallwey scale, acne score by the Investigator's Global Assessment Scale, hair loss scores by the Sinclair Graphic Instrument and then physical activity by the Caspian tool and dietary intake status by the Food Frequency Questionnaire. Data was analyzed using the non-parametric Mann-Whitney test for variables with two-time point assessments and generalized estimation equations (GEE) for variables with three time point assessments.

Results In the study, the intervention group of girls with PCOS exhibited a significant reduction in weight and waist circumference, with an average decrease of 3.14 kg and 4.68 cm, respectively ($P < 0.001$), compared to the PCOS control group. Similarly, the non-PCOS intervention group showed a decrease in these factors by 2.60 kg and

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4.95 cm ($P < 0.001$) when compared to the non-PCOS control group. After 12 months of intervention, the odds ratio (OR) for menstrual regularity in the PCOS intervention group increased to 3.30 (95% CI: 2.06, 5.25), and the acne score significantly decreased with an OR of 0.46 (95% CI: 0.31, 0.70). In contrast, the non-PCOS intervention group experienced an increase in the OR for menstrual regularity to 2.45 (95% CI: 1.33, 4.25) and an improved in acne score with an OR of 0.44 (95% CI: 0.28, 0.69). No notable differences were observed in the nutritional status among all groups post-intervention. However, a significant increase in physical activity levels, measured in metabolic equivalent minutes per week (met/min/week), was recorded in both intervention groups ($p < 0.05$).

Conclusion Manifestations of PCOS in adolescents are improved by a lifestyle promotion program and high schools are considered an appropriate setting to identify those with PCOS and the implementation of a lifestyle modification program. This program was also shown to promote healthy lifestyles for non-PCOS adolescents.

Trial registration Trial registration number: irct.ir number: IRCT20200114046123N1.

Keywords Life style, Nutrition assessment, Physical activity, Polycystic ovarian syndrome (PCOS), adolescents, health promotion health evaluation

Introduction

Polycystic ovary syndrome (PCOS) is one the most common endocrine disorders among reproductive-aged females worldwide, mainly beginning during adolescence [1]. This multifaceted disorder may occur in 8–13% of adolescences [2, 3]. Absence or irregularity of menses, hirsutism, acne, and male-pattern baldness or alopecia are the main clinical presentations of PCOS in adolescents [4]. Adolescents with PCOS and healthy adolescents share a significant overlap in hyperandrogenism (HA) and oligo-anovulation symptoms. This overlapping of adolescent-specific symptoms with PCOS-specific symptoms may result in challenges in accurate diagnosis and its management [5].

The International Evidence-based Guideline for the Assessment and Management of Polycystic Ovary Syndrome (IEBG) 2018 recommends lifestyle management as first-line intervention for women with PCOS [6] due to the increased prevalence of obesity in PCOS subjects from 51% in the 1990s to 74% in the following decade. It has been shown that insulin resistance affects 75% of lean women and 95% of overweight women with PCOS, and their associated complications are exacerbated with increasing weight [7]. Therefore, all patients, regardless of their weight, could be considered for lifestyle education courses.

Adolescents with PCOS are confronted with PCOS symptom-related challenges; they also have to deal with changes to physical appearance related to puberty. It has been shown that some physiologic changes during the adolescence period including HA or menstrual irregularities may be associated with some emotional distress and social and psychological issues, regardless of PCOS status [8]. The negative impact of PCOS on physical appearance may increase psychological distress among adolescents, potentially diminishing the effectiveness of interventions that have proven successful in other populations [9]. Nevertheless, it is unclear, among adolescents, whether lifestyle modification affects the features of PCOS similar to those physiological features of puberty [10]. It is supposed that a higher rate of similarity of physiological changes of puberty with PCOS-specific symptoms may make adolescents with PCOS feel that they are not much different from their peers and could possibly help them adapt a health promotion program [11], especially when these programs are implemented in a common environment such as school [12]. School health promotion programs have demonstrated efficacy in areas such as sexual and reproductive health [13], obesity and physical activity [14], and self-care for chronic health conditions [15]. In Iran, adolescent girls with PCOS engage with healthcare providers, particularly gynecologists, for evaluation and management of the disorder.

Although plenty of studies have investigated lifestyle modifications in adults with PCOS [16], there is scarce evidence in adolescents with PCOS [17]. One meta-analysis study among adults have reported that there are several beneficiary effects of lifestyle modification as a therapeutic option for clinical and metabolic aspects of PCOS [18]. It has been shown that high intensity interval training for ten weeks improved insulin resistance and body composition without weight loss [19], or 12 weeks aerobic training changed the levels of weight, BMI, and LH [20].

Studies on lifestyle promotion in adolescents are limited and have inconclusive results [17]. It has been shown that a one-year lifestyle intervention based on nutritional education, exercise training, and behavior therapy was effective to treat menses irregularities, and normalize androgens in obese adolescent girls with PCOS [21].

The first and most important treatment for adults and adolescent with PCOS is a healthy lifestyle promotion. A healthy lifestyle can decrease the waist-to-hip ratio with a direct effect on visceral fat that leads to an increased response to the anti-lipolytic effects of insulin [22]. Increased intake of refined foods through many

molecular mechanisms such as insulin-I growth factor, β-growth factor, fibroblast growth factor, keratinocyte growth factor, and bone morphogenic proteins are involved in increasing hair thickness [23]. Also, obese people complain of hirsutism due to the production of androgen hormones by fat cells [24]. Since foods with a high glycemic index can cause acne [25], by following a healthy diet and lowering blood insulin, androgens are reduced and their clinical manifestations are improved [26]. Also, eliminating nutritional deficiencies by consuming omega, zinc, vitamin A, and antioxidants can improve the condition of acne [27].

Lifestyle modification programs that been implemented in the adolescence period have the advantage of being less challenging, since the severity of symptoms is not as high as in adults, and they are not yet involved with infertility issues [28]. Additionally, since the prevalence of obesity increases with age from childhood to adulthood, the challenge of losing weight in adolescents is less than adults.

This cluster randomized trial aimed to assess: can lifestyle promotion programs based on changes in behavioral habits affect the anthropometric parameters and manifestation of polycystic ovary syndrome (PCOS) in adolescents? Furthermore, whether these effect anthropometric indices in obese adolescents with PCOS are similar to non-PCOS adolescents.

Materials and methods

Trial design

This was a cluster randomized trial (CRT) that started from January 2021 and follow-up ended in March 2022. This study trial was designed based on the requirements of the Consolidated Standards of Reporting Trials (CONSORT) and registered in the Iran Registry of Clinical Trials (Registration number: IRCT20200114046123N1, date: 23/01/2020). This study was done in Tehran girl high schools for training lifestyle promotion program.

Ethics approval was obtained from the ethics committee of the Shahid Beheshti University of Medical Sciences, Tehran, Iran. (Ethics Code: IR.SBMU.PHARMACY. REC.1397.100).

Participants

Adolescents aged 14 to 18 years, born in Iran with Farsi as their mother tongues, and residing in Tehran, were recruited for this study. Eligible participants had no history of sexual relations, had at least 2 years since their juvenile menarche, and were free from liver, adrenal, kidney, thyroid, mental, heart, and skeletal diseases. Additionally, they had not used any medications, smoked, consumed alcohol, engaged in professional exercise [29], or adhered to a specific diet in the past three months [30].

We obtained written informed consent from parents of all eligible participants after the study content was clearly explained to the subjects by the trial assistant. Moreover, all research tools, including questionnaires, were completely anonymous. The study protocol was previously published [31].

All of the participants were evaluated for PCOS diagnosis based on their history of regularity of menstrual, hyperandrogenism signs and symptoms, and their clinical ultrasound or blood test reports. PCOS adolescents based on the American Society for Reproductive Medicine criteria (two out of the following criteria: oligomenorrhea, Clinical and/or biochemical evidence of hyperandrogenism (hirsutism, acne, raised testosterone, androstenedione, DHEAS, and FAI), and Polycystic ovaries (>10 cc and more than 12 follicles of 2–9 mm) were diagnosed by one gynecologist [32].

Finally, non-PCOS and PCOS adolescents, regardless of body mass index, were included in the four groups (PCOS intervention, non-PCOS intervention, PCOS control, and non-PCOS control). Adolescents who, for any reason, failed to attend the study or were affected by a specific illness or needed to take a particular drug after entering the plan were excluded from the study.

Randomization

Allocation done by stratified cluster randomization method, and the unit of randomization was a school group. Based on the geographical distribution and sociodemographic and economic status of the population of Tehran- Iran, a region was selected from the north, south, east, and west regions of the city. Based on a random table according to girls' high school code, schools were allocated to intervention or control group. In each of the four selected areas, one high school was selected for the intervention and one high school was selected for the control. In each school, tenth and eleventh-grade students were examined, and healthy cases were distinguished from those with PCOS based on the diagnosis of a gynecologist.

Participants were divided into two subgroups, including PCOS and non-PCOS intervention at school for the intervention and PCOS and non-PCOS control at school for the control.

Intervention

Eight sessions of the lifestyle promotion program, consisting of one session for parents and seven for the adolescents, were provided for those assigned to the two intervention groups. The content of this program was provided based on National Institute for Health and Care Excellence guidelines (NICE guidelines) by the research team and one trainer (S.A: a PhD candidate in reproductive health) who prepared it for teaching. In designing

this training program, the social, cultural, and economic factors affecting students in Tehran were taken into consideration. The psychological experts on the research team selected motivational interviewing as the method for teaching. More details of these sessions have been reported previously [31].

During this program, mothers were informed about the role of positive lifestyle promotion in adolescent health. Adolescents were trained regarding the physiology of the reproductive organs, a healthy lifestyle, diet, food groups, the food pyramid, healthy eating patterns, food labels, physical activities and their importance in health, obesity and its consequences, and psychological aspects of the adolescent period.

These training sessions were held for the intervention group with two subgroups (PCOS intervention and non-PCOS intervention). For the non-PCOS group, general information about lifestyle promotion topics was presented (table 1), but for the PCOS intervention group, additional training was given about PCOS, such as which physical activities or diet were recommended for PCOS.

All these sessions were designed to be implemented in participatory meetings for 45 min every week for 8 session, but due to the Covid-19 pandemic the last five sessions were held online. All these sessions were interactive and the girls who had a positive experience in terms of the lifestyle promotion program shared their experiences with their peers. In training sessions, the adolescent were advised to increase their physical activity and follow a healthy diet. Physical activity refers to any bodily movement that engages muscles and expends energy, such as housework, transportation, gardening, sports, and more [33]. Healthy diet defined Balanced meals with foods from all food groups: fruits, vegetables, grains, protein foods, and Fat-free or low-fat dairy products or calcium-rich alternatives [34]. The virtual space of WhatsApp was utilized for educational purposes. Teachers recorded educational videos and posted them in the WhatsApp group, with online classes conducted the following day. If a student missed the online class, the teacher addressed the absence through their parents, requesting the student to watch the educational video sent on WhatsApp To ensure that all youth had access to educational materials, a special CD containing eight learning sessions was produced and distributed to all students in the intervention group along with an educational notebook produced by the research team. "After the study concluded the training CD and educational notebook prepared for the intervention groups were provided to the control groups. They were encouraged to ask the researcher any questions through WhatsApp.

Outcomes

The primary outcomes included anthropometric indices, menstrual regularity, hirsutism, acne, and hair loss. These outcomes were assessed at three time points including baseline, 6, and 12 months after enrollment. The physical activity and dietary patterns of participants were assessed at baseline and 12 months after intervention. Evaluation of blood biomarkers and ultrasound factors were omitted from secondary outcomes because of financial problems and the restriction during Covid-19 pandemic.

Measurements

Body weight and height were measured while subjects wore light clothing and stood barefoot, with eyes directed straight ahead, and body mass index (BMI) was calculated and categorized (BMI < 18.5: underweight, BMI = 18.5-24.99: normal, BMI = 25-29.99: overweight, and BMI > 30: obesity) The waist circumstance was obtained by an inelastic tape measure, directly on the skin at the umbilicus level. Hip circumference was measured at the point yielding the maximum circumference over the buttocks using a tape measure to measure the nearest 1 cm at the widest part of the hips [35].

Table 1 Headlines of eight lifestyle promotion training sessions

session	
1ST	Parents were informed about a healthy lifestyle, the importance of diseases such as diabetes, obesity and PCOS and recommendations about prevention methods.
2nd	Students were informed about the physiology of women's bodies during puberty, the importance of related diseases (PCOS) and ways of prevention.
3rd	Students were informed about: their physical condition (anthropometric parameters, menstrual cycle, skin, and hair) and its relationship with lifestyle
4th	Students learned about the five main food groups and the food pyramid. Adequate amounts are needed by the body
5th	Students were informed about healthy eating patterns, my healthy plate, and how to read food labels
6th	Students were informed about the importance of daily physical activity to control weight and ways to increase it, along with expert recommendations for affected people
7th	Students were informed about obesity and the importance of weight management with energy balance through good behavioral habits in nutrition and physical activity
8th	Students were informed about behavioral factors affecting eating, especially creation changes and life skills. Investigating barriers to implementing a healthy lifestyle and Psychological and sleep disorders.

Clinical symptoms, including regularity of menstrual cycle, hirsutism, acne, and hair loss, were assessed through a face-face interview. All patients were evaluated for menstruation. An irregular menstrual cycle was defined as <21 or more than 45 days for those within 2–3 years post menarche or as <21 or >35 days or <8 cycles per year for those>3 years having passed since their menarche [36].

The standardized scoring system of the modified-Ferriman-Gallwey(m-FG) score was used to determine the density of terminal hair at nine different body sites (i.e., upper lip, chin, chest, upper back, lower back, upper abdomen, lower abdomen, arm, and thigh). A total score>8 indicates hirsutism, a score of 9–15 indicates mild hirsutism, and a score>15 indicates moderate or severe hirsutism [37]. The IGA (Investigator's Global Assessment Scale) tool, was used to assess the acne status of adolescents based on four scores: 0 and 1 for clear or unchanged skin, 2 for mild, 3 for moderate, and 4 for severe acne status [38]. To evaluate the severity of hair loss, a 5-point Sinclair Graphic Instrument was used that assesses hair loss based on the width of the hair part. Grade 1for Normal hair density, Grade 2 for Slight thinning of hair on the crown Grade 3 for Noticeable thinning and decreased hair density, Grade 4 for Advanced hair thinning with more scalp visibility, Grade 5 for The severe stage [39]. The tools used to investigate the symptoms of hyperandrogenism are all pictorial and based on Likert and have appropriate accuracy and sensitivity and takes very little time from study participants [40]. For assessment of dietary intake (secondary outcomes), the Food Frequency Questionnaire (FFQ) tool with 147-items was used and has appropriate accuracy and sensitivity [41]. Physical activity status was assessed using the Caspian tool, this questionnaire had previously been modified and validated among Iranian young people, and was found to be significantly associated with the results obtained using the International Physical Activity Questionnaire and has appropriate accuracy and sensitivity (IPAQ) [42].

Sample size

To show that the intervention was clinically effective, we used the following formula:

We considered 80% power, 0.05 type I error, and Θ=0.50, where Θ is defined as the difference of the mean of BMI of individuals with PCOS in the intervention group versus individuals with PCOS in the control group. The sample size was calculated from the table introduced by sample size calculations in clinical research [43]. Considering 5% loss to follow-up, we estimated 64 samples were needed for each group.

$$n \geq 2\frac{(z_\alpha + z_\beta)^2\sigma^2}{(\mu_1 - \mu_2)^2}$$

$$n = 2(1.96 + 0.85)^2\left(\frac{1}{0.50}\right)^2 = 64$$

Implementation

(F.N), (D.GH), and (M.J) prepared the training program, (S.A) generated the allocation sequence, another researcher (F.R.T) in endocrine research enrolled the participants and assigned participants to the intervention groups, and finally, S.A held a lifestyle promotion program. In this study, the data analyzer (H.A) was blinded only after the subjects were assigned to the intervention groups. All students in four groups were coded by a ID number.

Statistical methods

Data were analyzed using SPSS software (version 25). Since the statistical results showed that the excluded individuals in the follow-up study were randomly deleted and had no effect on the study results, the analysis approach used was Intention to Treat (ITT); as a result, no sample was excluded. The generalized measurement equations (GEE) were used to evaluate the primary efficacy outcomes that were measured for follow-ups thrice (onset, 6 months and 12 months). The Kruskal-Wallis and Mann Whitney tests were used to evaluate the secondary efficacy outcomes that were measured for two-time follow-ups (onset and 12 months).

Result

Sample recruitment was performed in January 2021, and 128 samples from eight high schools were included in the study. Implementation of the promotion program was for two months and the follow-up duration started April 2021 for 6 and 12 months. We recruited 66 adolescent girls for the intervention groups and 62 adolescent girls for the control groups, which were divided into four groups: intervention groups (35 PCOS+31 non-PCOS) and control groups (29 PCOS+33 non-PCOS). (Fig. 1). Out of 128 students enrolled in the study, nine were excluded at the 6-month follow-up (two girls from the PCOS intervention group and two from the non-PCOS control group were excluded due to non-cooperation in completing the questionnaires, and five from the PCOS control group were excluded due to the initiation of drug treatment). Additionally, seven were excluded at the 12-month follow-up (four girls from the PCOS control group due to the start of drug treatment, two from the non-PCOS control group, and one from the non-PCOS intervention group, all due to non-cooperation in

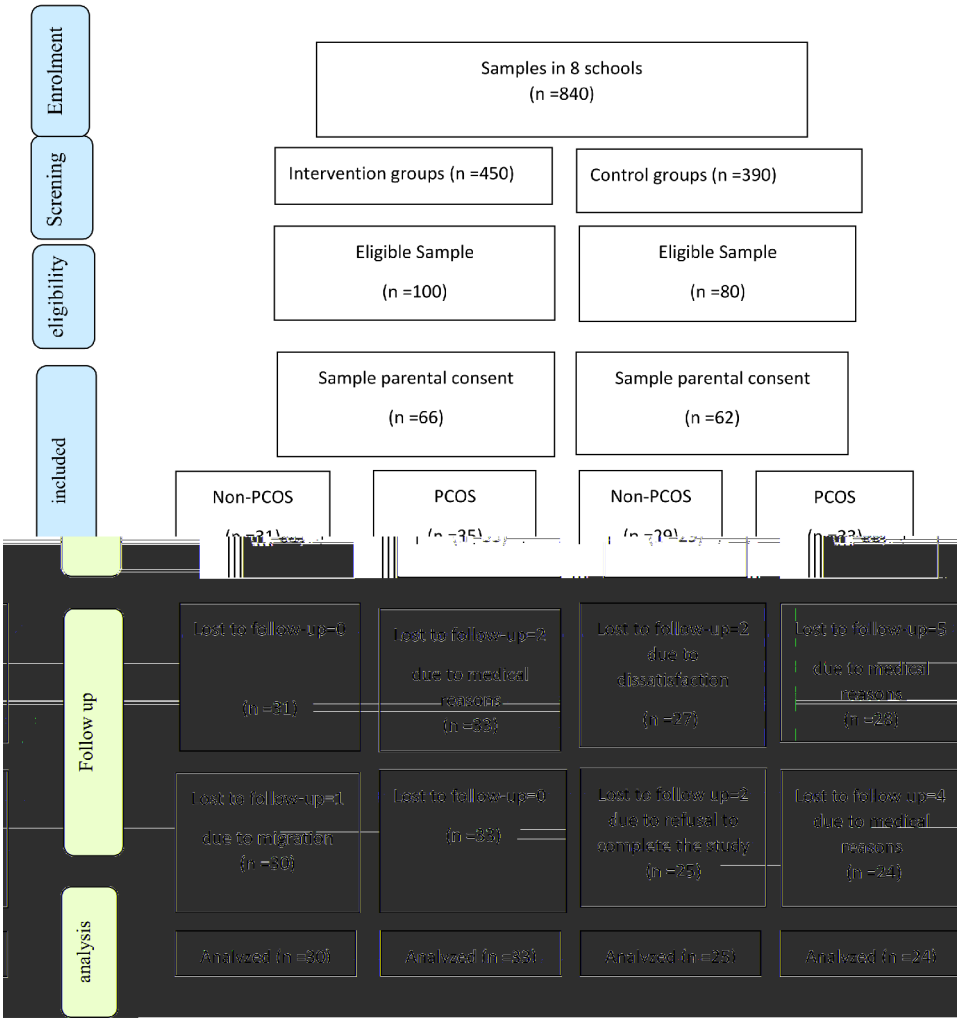

Fig. 1 Sample selection steps based on the consort flow diagram

completing the questionnaires). Ultimately, 112 subjects completed the study.

The results of general and demographic characteristics along with the baseline of primary outcomes are shown in Table 2. Mean age of students was 17 and 60% of them were studying in the eleventh grade of high school.

The percentage of obese adolescents in PCOS intervention group (11%) versus non-PCOS group (9.6%) did not differ statistically. Also, in 6 and 12 months after the intervention, the number of obese girls in the PCOS intervention group changed to 5.7% and in the non-PCOS intervention group to 3.22%. The statistical results showed that the number of obese girls did not differ significantly between the two intervention groups after the completion of the study (p value>0.01).

Table 3 indicates a weight, BMI, WC, HC, WHR and FG score comparison of groups via GEE results (according to the PCOS and intervention) on average, every six months. Results of this study showed that on average, every six months, the average weight of the non-PCOS intervention group versus non-PCOS control group decreased by 2.60(-3.23,-1.98) kg ($p<0.001$), and the average weight of the PCOS intervention group compared to the PCOS control group decreased by 3.14(-3.73,-2.55) kg ($p<0.001$). Also, in this study, on average, every six months, the average waist circumference of adolescents in the non-PCOS intervention group compared to non-PCOS controls decreased by 4.95(-5.95,-3.93) cm($p<0.001$). and the waist circumference of the PCOS intervention group decreased by 4.68(-5.75,-3.61) cm ($p<0.001$). compared to the PCOS control group. According to the results of this study, the lifestyle promotion program, on average for every six months, could reduce the average hip circumference of adolescents in the non-PCOS intervention group compared to the non-PCOS control group by 3.34(-4.20,-2.50) cm($p<0.001$). Also, the average hip circumference of the adolescents in the PCOS intervention group versus

Table 2 Baseline characteristics of the study participants according to the PCOS[1] and intervention status

Characteristic	PCOS Intervention *n* = 35	PCOS Control *n* = 33	Non-PCOS Intervention *n* = 31	Non-PCOS Control *n* = 29
Puberty age (years) (mean (SD)	12.88) 1.07)	12.66)0.88)	12.67)0.79)	12.96)1.23)
SBP[2] (mm Hg) (mean (SD)	(34/10)42/94	(21/18)06/97	(38/11)06/97	(69/11) 8/97
DBP[3] (mm Hg) (mean (SD)	(6/9)34/61	(94/14)30/65	(25/13)38/63	(09/11)37/66
Weight (kg) (mean (SD)	62.26 (14.99)	58.99 (15.47)	62.31 (13.95)	56.14 (11.40)
BMI[4] (kg/m2) (mean (SD)	23.26 (0.89)	22.85 (0.99)	23.98 (0.85)	21.57 (0.73)
WC[5] (cm) (mean (SD)	79.98 (12.25)	73.33 (12.51)	80.83 (10.49)	71.44 (9.22)
HC[6] (cm) (mean (SD)	97.94 (11.11)	95.81 (11.77)	99.08 (10.73)	92.17 (9.09)
WHR [7](cm) (mean (SD)	0.81 (0.069)	0.76 (0.69)	0.81 (0.58)	0.77 (0. 65)
FG[8] score (mean (SD))	19.34 (6.13)	15.27 (6.12)	17.29 (7.8)	11.58 (4.59)
Regularity of menstrual cycle (N) %	3 (8%)	4 (12%)	25 (80%)	24 (82)
Acne mild, moderate (N) %	12 (34.3%)	2 (6.1%)	10 (32.3%)	8 (27.6%)
Hair loss mild, moderate (N) %	18 (51.5%)	15 (45.4%)	17 (54%)	9 (31%)
Physical activity (met/min/week) (mean (SD)	1956 (170.25)	2042 (208.09)	1949 (137.16)	1960.27 (167.09)
Energy (kcal/d) (mean (SD)	5463 (3161.81)	5874.74 (2231.73)	5157.691 (2430.57)	4356.16 (2075.25)
Fat (gr/d) (mean (SD)	204.77 (117.67)	180.20 (75.33)	176.56 (93.45)	164.81 (97.28)
Carbohydrate (gr/d) (mean (SD)	267.45 (177.61)	321.10 (186.46)	376.28 (254.16)	265.41 (166.63)
Protein (gr/d) (mean (SD)	174.34 (115.36)	147.60 (51.68)	160.09 (71.26)	125.02 (47.72)

[1] Polycystic ovarian syndrome

[2] Systolic blood pressure

[3] Diastolic blood pressure

[4] Body mass index

[5] Waist circumference

[6] Hip circumference

[7] Waist-Hip Ratio

[8] Ferriman-Gallway

the PCOS control group was reduced 3.49 (-4.29,-2.96) cm($p<0.001$). On average, every six months, the mean score of FG in the non-PCOS intervention group compared to the non-PCOS control group decreased significantly by 3.23(-4.21,-2.24) scores ($p<0.001$), and in the PCOS intervention group, it decreased significantly by 5(-5.93,-4.00) scores ($p<0.001$)compared to the PCOS control group. Anthropometrics changes in the PCOS groups were the same in the non PCOS groups. The BMI and WHR results can be found in Table 3.

In this study, the PCOS intervention group was 3.30 times more likely to have the regularity of the menstrual cycle every six months compared with the PCOS control group (ORAdj=3.30, 95% CI: 2.06,5.25, $P<0.001$). Additionally, the non-PCOS intervention group was 2.54 times more likely to have the regularity of the menstrual cycle every six months compared to the non-PCOS control group (ORAdj=2.45, 95% CI: 1.33, 4.52, $P=0.004$) (Table 4).

Also the odds ratio of acne in the non-PCOS intervention group compared to the non-PCOS control group was 0.44(0.28, 0.69), and the PCOS intervention group was 0.46(0.31, 0.70) compared to the PCOS control group ($p<0.001$). The OR for hair loss did not change in all groups after intervention ($p>0.05$).

Also, on average, every 6 months, the odds ratio of regularity of menstrual cycle in the non-PCOS intervention group compared to the non-PCOS control group was 3.30 and the PCOS intervention group was 2.45 compared to the PCOS control group ($p<0.001$).

Table 5 reveals that the mean score of physical activity of girls increased after 12 months of follow-up by 38.13 Met/ min/week (95% CI: 12.14, 110.42, $P=0.04$) in the PCOS intervention group compared with the PCOS control group and by 161.38 Met/ min/week (95% CI: 84.42, 238.35, $P<0.001$) in the non-PCOS intervention group compared with the non-PCOS control group.

Discussion

The present study findings indicate that the current study aims were achieved. Lifestyle promotion programs based on changes in behavioral habits such as physical activity can affect the anthropometric parameters and manifestation of PCOS in adolescents. Increase of moderate physical activity of students leaded to positive changes in anthropometrics parameters, hyperandrogenic signs (hirsutism and acne) and menstrual regularity. These positive changes were observed in PCOS and non-PCOS adolescents. Also, the positive changes made in the parameters

Table 3 Changes in the anthropometric parameters and FG[1] score according to the PCOS[2] and intervention status during follow ups (6–12 months)

Parameter mean change (95%CI)	PCOS Intervention *n* = 35	PCOS control *n* = 33	Non- PCOS Intervention *n* = 31	non-PCOS control *n* = 29	generalized estimating equation (GEE) Beta Coef (95%CI) P-value	
					PCOS Intervention VS. PCOS control	Non- PCOS Intervention VS. non-PCOS control
Weight (kg)						
6 month after vs. baseline	-1.28(-0.76,-1.80)	1.86(0.96,2.75)	-2.64(-3.51,-1.77)	1.82(1.21,2.42)	-3.14(-3.73, -2.55) < 0.001	-2.60(-3.23,-1.98) < 0.001
12 month after vs. baseline	-2.63(-1.81,-3.44)	1.76(0.68,2.85)	-3.28(-4.53,-2.02)	1.95(1.10,2.81)		
BMI[3] (Kg/m2)						
6 month after vs. baseline	-0.47(-0.08, 0.86)	0.43(0.20,0.66)	-1.17(-1.53,-0.08)	0.45(0.30,0.79)	-2.50(-3.04,-1.65) < 0.001	-1.07(-1.34,-0.81) < 0.001
12 month after vs. baseline	-1.11(-0.68, -1.53)	0.72(0.22,1.21)	-1.73(-2.18,-1.27)	0.42(0.11, 0.74)		
WC[4] (cm)						
6 month after vs. baseline	-3.20(-1.56,-4.83)	3.16(1.59,4.73)	-3.96(-5.22,-2.70)	3.10(1.80,4.39)	-4.68(-5.75,-3.61) < 0.001	-4.95(-5.95,-3.93) < 0.001
12 month after vs. baseline	-5.07 (-2.98,-7.16)	4.66(2.94,6.36)	-5.61(-7.40,-3.82)	3.93(2.36,5.49)		
HC[5] (cm)						
6 month after vs. baseline	-1.51(-0.49,-2.52)	2.45(1.49,3.41)	-1.98(-2.90,-1.06)	2.79(1.59,3.98)	-3.49(-4.29,-2.69) < 0.001	-3.34(-4.20,-2.50) < 0.001
12 month after vs. baseline	-3.51(-1.85,-5.17)	3.24(1.65,4.82)	-3.11(-4.18,-2.03)	3.82(2.31,5.33)		
WHR[6]						
6 month after vs. baseline	-0.01(-0.004,-0.03)	0.01(-0.00,0.02)	-0.02(-0.03,-0.00)	0.009(-0.00,0.02)	-0.02(-0.03,-0.01) < 0.001	-0.02(-0.03,-0.01) < 0.001
12 month after vs. baseline	-0.02(-0.006, -0.03)	0.02(0.00,0.04)	-0.03(-0.04,-0.01)	0.009(-0.00,0.02)		
FG score						
6 month after vs. baseline	-4.34(-3.09,-5.59)	1.09(-0.47,2.65)	-3.48(-4.81,-2.14)	1.03(-0.40,2.47)	-5.00(-5.93,-4.00) < 0.001	-3.23(-4.21,-2.24) < 0.001
12 month after vs. baseline	-6.74(-4.70,-8.78)	3.24(0.85, 5.63)	-5.19(-7.01,-3.37)	1.27(-0.30,2.86)		

1 Ferriman–Gallway

2 Polycystic ovarian syndrome

3Body mass index

4Waist circumference

5Hip circumference

6Waist–Hip Ratio

Table 4 Menstruation regularity, improvement of acne and hair loss after 6 and 12 months after intervention

Parameter	PCOS Intervention *n* = 35	PCOS control *n* = 33	Non- PCOS Intervention *n* = 31	non-PCOS control *n* = 29	generalized estimating equation (GEE) OR (95%CI) *P*-value	
					PCOS Intervention VS. PCOS control	Non- PCOS Intervention VS. non-PCOS control
Menstruation regularity N (%)						
6 month	17(48.6%)	3(9.1%)	28(90.3%)	23(79.3%)	3.30 (2.06, 5.25) < 0.001	2.45 (1.33,4.52) 0.004
12 month	22(62.9%)	5(15.2%)	29(93.5%)	21(72.4%)		
Improvement of acne mild moderate N(%)						
6 month	12(34.3%)	9(27.3%)	13(41.9%)	14(48.2%)	0.46 (0.31, 0.70) < 0.001	0.44(0.28,0.69) < 0.001
12 month	9(25.7)	18(54.5%)	11(35.5%)	14(48.2%)		
Improvement of hair loss mild moderate N (%)						
6 month	18(51.5%)	17(51.5%)	18(58.1%)	12(41.4%)	0.67(0.47, 0.95) 0.05	0.97(0.67,1.40) 0.8
12 month	22(62.9%)	19(57.6%)	19(61.3%)	17(58.6%)		

Table 5 Changes in physical activity and dietary intake according to the PCOS[1] and intervention status at the end of the follow up 12 months

Parameter Mean change (95% CI)	PCOS Intervention *n* = 35	PCOS control *n* = 33	Non- PCOS Intervention *n* = 31	Non-PCOS control *n* = 29	Univariate analysis of variance mean difference (95%CI) *P*-value	
					PCOS Intervention VS. PCOS control	Non- PCOS Intervention VS. non-PCOS control
Physical activity (Met/min/week)	39.31 (14.27,92.90)	-84.72 (-145.32,-24.12)	141.25 (82.07,200.44)	-31.31 (-88.65,26.03)	38.13(12.14,110.42) 0.04	161.38(84.42,238.35) < 0.001
Energy(kcal/d)	-391.98 (-618.3, 140.23)	530.45 (28.93,1031.96)	-667.19 (-1489.56,155.17)	217.42 (-1024.48,1459.62)	-638.29(-2097.95, 821.367) 0.386	-1240.72(-2694.08, 212.64) 0.093
Protein(gr/d)	-6.87 (-41.22,27.47)	2.11 (-14.8,10.61)	-8.06 (-35.68, 19.36)	1.70 (-24.66,28.07)	-18.44(-71.35,35.00) 0.077	-36.013(-45.20,117.23) 0.380
Fat(gr/d)	-33.57 (-73.83,6.68)	43.86 (-31.79,216.11)	-39.88 (-80.15, 0.380)	19.01 (-45.99,84.01)	-11.02(-83.96,61.90) 0.764	-29.69(-42.92,102.32) 0.418
Carbohydrate (gr/d)	-71.54 (-121.42,21.56)	26.30 (-22.08, 30.36)	-68.48 (-148.88,21.91)	24.57 (-87.33,136.47)	-27.50(-161.96,106.95) 0.684	-102.90(-238.06,32.265) 0.324

1Polycystic Ovarian Syndrome

investigated in this study were the same in the obese adolescents with PCOS and non-PCOS.

Implementation of lifestyle promotion in adolescents is associated with some challenges such as low self-esteem, unsatisfactory results, scarcity of resources, and inadequate education [44]. If such problems can be overcome through education and heightening the enthusiasm of adolescents to improve their lifestyle, we can hope to improve the parametric factors and eventually, clinical symptoms of this syndrome. In this field, many studies have been conducted on adolescents [17]. Lifestyle promotion leads to a weight loss of 3.6–8 kg during six months to one year in PCOS adolescents [45, 46]. In other studies, healthy lifestyle training can reduce the waist circumference of PCOS adolescents by 1.25–7 cm after three months to one year [46–49]. Lifestyle interventions, even based on cyber education and awareness, were able to reduce the waist size of healthy individuals by an average of 3 cm [50]. In this study, waist to hip circumference ratio (WHR) and BMI were reduced in the two intervention groups versus the two control groups, which were comparable with a meta-analysis result that found a 0.03 decrease in WHR after intervention in PCOS adolescents [51] and 0.45 decrease in BMI after lifestyle intervention [17]. Most lifestyle studies have been performed on obese patients and it has been concluded that weight loss of 5 to 10% in overweight people with polycystic ovary syndrome can improve their symptoms [46, 52, 53]. The results of lifestyle studies in healthy adolescents to prevent their obesity in adulthood in most countries has shown that this type of intervention leads to weight loss in obese adolescents and an increase in nutritional quality in normal weight adolescents [45, 54, 55].

Based on the findings of this study, hyperandrogenism in adolescents can be positively influenced by weight management and lifestyle promotion, resulting in a decrease of 5 scores in the FG score after intervention in girls with PCOS. The findings of several studies were comparable with our results that showed that hirsutism can be improved after adolescent lifestyle intervention [46, 52, 53] However, one study showed that changes in lifestyle status did not affect the hirsutism mean score after a three-month intervention [56]. According to the results of this study, lifestyle training demonstrated deterrent effects against acne in the two intervention groups and improved the odds ratio by 0.4." This result is the same as findings of another study in Egypt, which showed that after one year of intervention, acne decreased by eight scores in PCOS adolescents [46]. There is no study on the effect of exercise on the severity of acne, although a theory has been suggested that exercise has no effect on androgens, but professional and continuous exercise with a decrease in estrogen and progesterone levels leads to a significant increase in androgen binding capacity at the receptor level [57]. No similar study has examined the effect of lifestyle interventions on PCOS adolescent hair loss, and in our study result, lifestyle intervention was not seen to effect hair loss status. It seems that it takes longer than a year for hair loss in PCOS adolescents to be affected by lifestyle interventions. Nonetheless, nutritional interventions such as the use of sea supplements and minerals for six months could improve female hair

loss [58, 59]. Also, physical activity can also reduce female hair loss by improving scalp blood flow [60].

Cultural differences and emotional support of the family, along with economic issues, has an impact on whether adolescents consume healthy foods and do adequate physical activities [61]. Since socioeconomic status, social-cultural values have been reported to be very effective on the effectiveness of lifestyle interventions in adolescents [62, 63]. Accordingly in this study, the design of a comprehensive educational package that includes a localized lifestyle based on the culture and socioeconomic status of adolescents with the help of the opinions of nutritionists, physical education experts, and psychologists was one of the important factors that were found to influence the activity conditions of adolescents. Attention to social and communication skills in the lifestyle training pertaining to adolescents was an important factor [64] that was available in this package. Also, the teaching method, student-centered face-to-face classes, along with motivational interviewing techniques which can be associated with 25–30% success in lifestyle changes [65], were other influential factors that were considered for the implementation of this study.

According to the results of our study, lifestyle training could not significantly change the adolescents' nutrition status. There was no significant difference in terms of calories consumed, and total fat, total carbohydrate, and protein intakes. Comparable to our study result, lifestyle intervention such as nutritional interventions at six months and physical activity interventions at three months could increase the regularity of menstrual cycle of adolescents [52, 53], while in obese adults with PCO, no significant changes in the menstrual cycle occurred [66]. According to the results of a review study, with increasing age of women, the effectiveness of lifestyle changes on the menstrual cycle in women decreases [67]. Healthy eating habits also reduce visceral fat and regulate the menstrual cycle by reducing fat intake, balancing protein intake, and increasing fiber, fruits and vegetables [68]. Reducing carbohydrate intake and increasing protein intake are a type of diet that has been confirmed by meta-analysis study for improving PCOS symptoms [69]. In this study, calorie balance was recommended, and there was no emphasis on a specific diet. Lifestyle training for healthy adolescents also failed to make any significant difference in calorie and macronutrient and micronutrient levels after three months [70].

Based on the results of our study, lifestyle training can significantly change the physical activity of adolescents in the intervention groups compared to adolescents in the control groups after one year, so that the adolescents in the intervention groups maintained their average physical activity, while in the adolescents in the control group demonstrated reduced average physical activity. In a similar study in adolescents with PCOS, exercise in the form of yoga independent of their body mass index and without significant weight loss was able to improve their blood biomarkers [52]. Aerobic exercise, during 16 weeks, can improve both the level of insulin resistance in patients and their ultrasound results [71]. According to the results of meta-analysis and review studies, 120 min of moderate-intensity exercise per week can affect insulin resistance, body structure and improve the symptoms of polycystic ovary syndrome in obese women [72]. Most of the studies on the design of specialized sports programs have been carried out in adolescents, but in our study, adolescents were advised to increase their physical activity in any condition and at any time, and no specific specialized sports program was recommended and Implemented.

Nonetheless, the results of this study about abese adolescent in in both intervention groups showed that adolescents are interested in awareness and information about a healthy lifestyle and sound lifestyle interventions, even in healthy adolescents, indicating such a program could potentially be successful and constructive. And maybe adolescence is the best time to teach people a healthy lifestyle because they are motivated to be fit and healthy more than other ages [73].

Specialized nutrition and activity recommendations for adolescent with PCOS were important features of the educational package designed in this study that were recommended in some researches. Modifying protein, carbohydrate or fat quality or quantity [16], acupuncture and yoga [74], Aerobic Exercises [75], and supplement and herbal medicine [76] were recommended to PCOS adolescent in this study.

Although in our study, the degree of adherence to these points by the patients after the intervention was not investigated, but traditional medicine is one of the cases that are well accepted by the parents of teenagers and can be recommended by them.

Strengths and limitations

One of the strong points of this study is that only obese people were not examined, but students were included in the study regardless of their weight, which may be effective in preventing adolescent weight gain in adulthood. Of course, another the strengths of this study is the separate education of affected and healthy people in the intervention group and the existence of a healthy control group due to the overlap of puberty symptoms with syndrome symptoms.

It is recommended to investigate the long-term effects of lifestyle education in adolescents in future studies and determine the consequences of its impact in adulthood, especially in terms of weight and obesity. This study faced major limitations. The Covid-19 restrictions in schools

causing the virtual holding of half of the training session could have influence the effectiveness of the training on the improvement of the adolescents' lifestyle. Also, the lack of direct access to students at all times of the follow-ups lead to some measurement errors in anthropometric indices in the adolescents in the 6-month and 12-month follow-ups.

Practical implications

Patient education is acknowledged as a pivotal component and a benchmark of quality in healthcare delivery. Optimal timing for imparting lifestyle education is during childhood and adolescence, which serves as a preventative measure against the onset of diseases in later life. The rectification of erroneous dietary and physical activity patterns among adolescents, particularly within the educational milieu where peer influence is pronounced, warrants attention. The outcomes of this study have implications for the training of healthcare providers, underscoring the necessity of comprehensive care for individuals with polycystic ovary syndrome amidst the existing lacunae in healthcare services. Reproductive health experts and midwifery professionals, in conjunction with the extended medical team, bear significant responsibility in the prophylaxis and management of polycystic ovary syndrome, thereby ameliorating the health of those afflicted.

Conclusion

In conclusion, among adolescents with PCOS and non-PCOS, this study showed that lifestyle training led to positive changes in their activity status after one year, and these training sessions were also effective in improving anthropometrics criteria, menstrual regularity, and hyperandrogensim (i.e., hirsutism and acne).

Abbreviations

PCOS	Polycystic Ovarian Syndrome
BMI	Body Mass Index
LH	Luteinizing Hormone
SBP	Systolic Blood Pressure
DBP	Diastolic Blood Pressure
FG	Ferriman-Gallwey
DHEAS	Dehyroepiandrosterone Sulfate
FAI	Free Androgen Index
GEE	Generalized estimation equations

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

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Author contributions

(F.N), (D.GH), and (M.J) prepared the training program and study design, (S.A) generated the allocation sequence, another researcher (F.R.T) in endocrine research enrolled the participants and assigned them to the interventions, and S.A conducted the lifestyle training program. The data was analyzed by (H.A).

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Data availability

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

Declarations

Ethics approval and consent to participate

The study was approved by the Ethics and Research Committee of Shahid Beheshti University of Medical Sciences (reference number: IR.SBMU.PHNM.1397.100). We obtained written informed consent from parents of all eligible participants after the study content was clearly explained to the subjects by the trial assistant.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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