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The effectiveness of lifestyle training program promoting adolescent health with polycystic ovarian syndrome: A study protocol for a randomized controlled study

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Abstract:

BACKGROUND: Lifestyle training is of a key important in adolescent age for better life in the future. Healthy lifestyle in adolescents can management of any disease such as diabetes and polycystic ovarian syndrome (PCOS). Schools can provide an important environment to identify and change the lifestyle of students. The aim of this protocol is designing and evaluating the effectiveness of school-based lifestyle training program improving the PCOS of adolescents.

MATERIALS AND METHODS: A cluster-randomized controlled trial will be conducted to examine the effectiveness of school-based lifestyle training program in 16 to 18 years old adolescent girls. The healthy lifestyle program will be designed by modification of behavioral habit, dietary intake, and physical activity and educated in eight sessions for adolescents and one session for parents in the intervention groups with sixty participants.

RESULTS: Changes in primary and secondary outcomes in PCOS and healthy adolescents before and after intervention in the intervention and control groups will be analyzed for evaluation effectiveness by one-way ANOVA or other nonparametric equivalents.

CONCLUSION: The current study will provide information on the effectiveness of school-based lifestyle training programs for adolescents. With increasing numbers of PCOS at risk for long-term and/or late effects of treatment and other chronic diseases, efforts for promoting the healthy lifestyle of this important group are urgently needed. This lifestyle program may provide valuable information relating to the development of other healthy lifestyle interventions for PCOS and result in appropriate behavior change and self-management strategies.

Keywords:

Adolescence, education, lifestyle, polycystic ovarian syndrome

Introduction

Polycystic ovarian syndrome (PCOS) is a long-term recognized, and complex, heterogeneous familial disorder.^[1] Some clinical symptoms of this multifactorial syndrome, including hyperandrogenism and chronic anovulation initially appears

in puberty^[2]. Insulin resistance seemed inherent in PCOS independent of obesity;^[3] regardless of weight, PCOS can present in each girl with family history.^[4] Researchers in an international consortium update in PCOS adolescents reported that lifestyle modification is a first step PCOS treatment in adolescents.^[5]

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Lifestyle modification based on weight loss and increased activity is useful, especially in obese and overweight girls with PCOS.^[6] Even 5%–10% weight loss in obese patients has been beneficial effects. The benefits of lifestyle education for PCOS patients include improved clinical, hormonal, metabolic parameters of PCOS, improved mood and quality of life, body composition, sleep, self-esteem, depression, anxiety, and tiredness in PCOS patients.^[7] Although healthy lifestyle has positive effects on PCOS girls with obesity and overweight, these effects in normal weight or underweight adolescents are not proven.^[8]

Several studies in some countries investigated lifestyle education for PCOS management in adolescent girls with different significant outcomes.^[9–11] Parent role in achieving a healthy lifestyle by their adolescent is very important, and for this participant, facilitator and barrier should be considered.^[12] Next to the parents, schools are the major center for providing the guideline that prepares adolescents for their healthy lifestyle.^[13–15] The lifestyle intervention in PCOS including dietary, physical activity, and behavioral habits strategies need at least 6–12 months to be effective.^[16]

A variety of balance dietary approaches could be recommended to reduce dietary energy intake and induce weight loss in obese and/or overweight women with PCOS.^[17] Moreover, an energy deficit of 30% or 500–750 kcal/day could be suggested for PCOS women.^[18] Since there has been no evidence for specific diet in PCOS patients, a healthy dietary intake with energy balance for PCOS adolescents is recommended.^[19] Usage by taking some herbal medicines in Iranian women can help improving the symptoms for short time.^[20]

According to the World Health Organization, an adequate daily physical activity from 60 to 90 min is recommended. In particular, all young people should be active for at least 60 min each day (including at least 3 days a week and 30 min of structured physical activity or around 3000 steps).^[16] The presence of lifestyle guideline for adolescents based on indigenous culture and native language in each country can be an important step in the effectiveness of this type of intervention,^[21] however, the information alone is not sufficient to create changes in health behaviors. Information and awareness are the first step of healthy lifestyle training but not the final step toward behavior change.^[22]

Applying behavioral strategies, such as life skills reinforcement (self-monitoring, problem-solving, and coping with stress) can be effective in the elimination of bad habits during adolescents.^[23] The individual must be motivated and prepared to make health behavior

change.^[24] Without motivation and preparation for change, health behavior changes cannot be maintained over time.^[25] Motivational interviewing may be a good strategy to support adolescents in making decisions that will help them appropriately to manage their weight.^[26]

Although some studies stated that lifestyle along with weight loss can be effective in improving PCOS problems in adolescents^[9,10,27] but in another articles the effectiveness of this treatment was not confirmed.^[28,29] The researchers decided to design and evaluate school-based lifestyle training program in Iranian adolescents for managing of PCOS.

Objectives

- Design of a school-based lifestyle training program in adolescents for PCOS management
- Education of school-based lifestyle training program in intervention groups
- Evaluation of the primary outcomes before and after school-based lifestyle training program
- Evaluation of the secondary outcomes before and after school-based lifestyle training program.

Materials and Methods

Study design and setting

The methodological approach for lifestyle training in adolescents is a cluster-randomized clinical trials study. The design, conduct, and reporting of this study will adhere to the Consolidated Standards of Reporting Trials guidelines.

This study will be carried out in three phases: (1) design of a school-based lifestyle training program, (2) education of this program, and (3) evaluation of this program by comparison of clinical assessment 6 and 12 months after intervention [Figure 1]. This study will be done on high school girls in Tehran, Iran.

Study participants and sampling

Single girls between the range of 16 and 18 years old

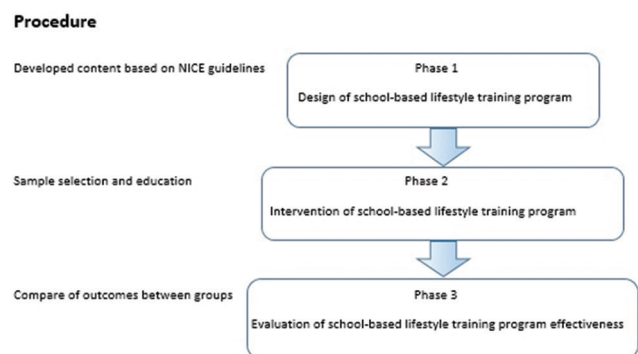


Figure 1: Study visual design

without sexual relation that at least 2 years has passed from their juvenile menarche and been healthy in terms of all diseases, including liver, kidney, thyroid, mental, heart, and skeletal diseases, are included in this study. They do not use any drug, smoke, and alcohol. They should not exercise professionally or attend sporting teams, or have a specific diet. PCOS adolescents based on the American Society for Reproductive Medicine criteria will be diagnosed and included in the study. Finally, healthy and PCOS adolescents, regardless of body mass index, will be included in the study.

Adolescents who for any reason will fail to attend a one-third of the classes held at the school or will be affected by a specific illness or need to take a particular drug after entering the plan are excluded from the study.

Participants will be recruited via school screening methods, including referrals by health professionals to Endocrine Sciences Laboratory Center at Shahid Beheshti University of Medical Sciences for assessment. Our strategies for achieving adequate participant enrollment to study are using student medical history that has been saved by school health educators.

Allocation will be done by stratified randomization by cluster method. In this study, the unit of randomization will be a school group in four geographical directions (west, east, south, and north) of Tehran, Iran. The researcher will use a random number table to allocate consenting school to intervention or control group, stratified by girls' high school code. Two schools will be selected in each direction (one school for the intervention and one school for the control). Finally, eight high schools will be enrolled in this study. Girls and their parents will be asked to read and sign an informed consent form before attending the project. After participants enrolled in the study, they will be referred for tests: blood tests and ultrasounds. They should also submit anthropometric indices, physical activity status, and dietary intake status information.

We will recruit 60 healthy adolescent girls and 60 PCOS adolescent girls, which will be divided into four groups: intervention groups (30 PCOS + 30 healthy) and control groups (30 PCOS + 30 healthy) [Figure 2]. One researcher (S.A) will generate the allocation sequence, another researcher (F.R.T) in endocrine research will enroll participants and will assign participants to interventions, and finally, S.A will hold a school-based lifestyle training program. In this study, the data analyzer will be blinded only after the assignment to interventions. All students in four groups are coded by ID number.

Adolescent girls in the intervention group will be school-based trained and control groups will receive only

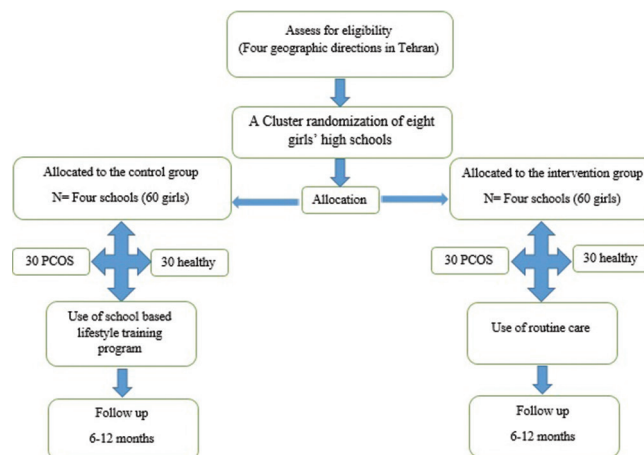


Figure 2: Consort diagram of study

routine care. The draft content of the healthy lifestyle program will be prepared in the first phase of the study. The content of lifestyle in intervention adolescents for PCOS management will be developed based on the National Institute for Health and Care Excellence guideline [Figure 3] and literature review. The program will be developed by a group of experts (reproductive health specialist, gynecologist, midwife, health psychologist, and nutritionist). The three main goals of the intervention are to increase physical activity, healthy diet, and change of behavior habit. The design of physical activity content was based on minimum facility and equipment availability at school or community. Each standard aerobic exercise is explained in terms of duration, repetition, and intensity. Traditional sports are also considered. The healthy diet regime is based on the consumption of essential nutrients, such as fluid, macronutrients, micronutrients, and adequate calories including five main food groups. The usage of supplements and herbal drugs will be considered. Change of behavior habit designed is based on life skill and motivational reinforcement in adolescents for daily energy balance.

Lifestyle training in high school will be conducted face to face, teaching in 45-min sessions of lecture and question-answer for eight training classes every week. The educator is obliged to teach the educational content based on the behavioral goals set for each session by the use of movie, PowerPoint, speech, and peer review of teaching.

A pamphlet for adolescents and their parents will be prepared and provided to them. Motivational interviewing strategy will be used for lifestyle training in school, thus asking open-ended questions, reflection statement, affirming response, and summaries. An educational session is also held for parents to participate in home to accompany the adolescent in maintaining a healthy lifestyle.

Topic	•Design of Adolescent Health Improvement Packages in the Treatment of Polycystic Ovary Ovarian Syndrome
Scoping	•Question: Can lifestyle changes (nutrition, exercise, and health behaviors) are effective in improving the health of healthy adolescents and adolescents with PCOS?
Search	•Searched in Up to date, Pubmed, Scopus, Google scholar, Cochrane Library, Web of science, books, guideline, Consortium conference, Consensus conference •keywords: "PCOS, poly cystic ovarian syndrome behavior, psychology, exercise, fitness, physical activity, adolescent, diet, lifestyle, nutrient, education, training, health "
Developed	•Collect educational content based on three dimensions of lifestyle •The committee discusses evidence reviews and expert testimony and develops draft recommendations •Finalized each session based on behavioral goals
Consultation	•In Delphi technique, qualitative and quantitative assessment will be done in several rounds with perfect stakeholder (reproductive health, obstetrics, nutrition, phycologic, endocrinologist) and they will comment on draft.
Revised	•The committee discusses and revises guideline in response to stakeholders' comments. The developer writes responses to stakeholders' comments.

Figure 3: Stage of developed content of school-based lifestyle training program based on NICE guideline

Participant evaluation of the educational program and sessions will be measured via a participant program evaluation form (to be completed by participants at the final educational session). The program evaluation form will consist of nine questions from the course evaluation module of the Health Education Impact Questionnaire.^[30] Participants in the intervention and control groups were required to take hormonal medications at any time during the study, they could be excluded from the study, and there was no interference with their treatment.

Data collection tool and technique

In this study for evaluation of program effectiveness, primary outcomes (anthropometric indices, clinical symptom, physical activity status, and dietary intake status) will be compared at baseline, 6, and 12 months after intervention and secondary outcomes (blood biomarkers and Sonography factors): will be compared at baseline and 12 months after intervention.

In anthropometric index measurement, weight, height, waist, and hip circumference will be submitted. Participants will be relaxed for 15 min before the measurements are taken. Body weight (to nearest 0.1 kg) and height (to nearest 0.01 m) will be measured while subjects had light clothing and stood barefoot, with eyes directed straight ahead.^[31] The waist circumference will be obtained by inelastic tape measure, with an accuracy of 0.1 cm, directly on the skin at the umbilicus level.^[32] Hip circumference will be measured at the point yielding the maximum circumference over the buttocks using a tape measure to measure to the nearest 1 cm at the widest part of the hips.^[33]

In clinical symptom measurement, menstrual cycle regularity, hirsutism status will be submitted. Participants who are 1–3 years postmenarche and their menstrual cycles are <21 days or more than 45 days will be considered an irregular menstrual cycle. Furthermore, more than 3 years postmenarche adolescents whose menstrual cycles are <21 or more than 35 days or have <8 cycles per year will be considered irregular.^[34] The Ferriman–Gallwey scale will be used for hirsutism status; a score of 1–4 is given for nine areas of the body. A total score <9 is considered normal, a score of 9–15 indicates mild hirsutism, and a score >15 indicates moderate or severe hirsutism.^[35]

Physical activity will be measured using the International Physical Activity Questionnaire (IPAQ). IPAQ has undergone extensive reliability and validity testing in 12 countries.^[36] This instrument has acceptable measurement properties for use in many settings and is specifically designed for population-based prevalence studies of physical activity. Dietary intake will be measured using a 24-h recall questionnaire.

Blood biomarkers (prolactin, testosterone, dehydroepiandrosterone sulfate, luteinizing hormone, follicle-stimulating hormone, sex hormone-binding globulin, thyroid-stimulating hormone, T4, triglyceride, low-density lipoprotein, high-density lipoprotein, anti-Mullerian hormone, and fasting blood sugar) will be measured in the Research Institute for Endocrine Sciences Laboratory Center at Shahid Beheshti University of Medical Sciences with blood sample before and after 12 months after intervention. Participants without oligomenorrhea will be referred to laboratory test in the follicular phase of menstrual cycle with 8 h fasting.

Sonography factors will be measured by one sonographer via transabdominal ultrasound, the usage of probes with 8 MHz, in Research Institute for Endocrine Sciences Laboratory Center at Shahid Beheshti University of Medical Sciences. Participants without oligomenorrhea will be referred to this center in the follicular phase of menstrual cycle. Sonography factors will include three dimensions and volume of each ovary and endometrial thickness.

It should be noted that all clinical tests have been performed at the Endocrine Research Institute of Shahid Beheshti University of Medical Sciences and no cost will be imposed on students.

The sample size was calculated in order to detect, with at least 90% power, and 95% certainty, and 0.05 level of statistical significance. Based on this formula, sample size was calculated to be 56 for intervention and 56 for control. Due to the follow-up duration time (12 months),

and considering the 20% attrition of sample, finally 60 samples will be assumed for each group. Data will be entered into IBM SPSS Statistics 25 (Chicago, IL, USA).

Ethical consideration

Ethical approval was obtained from the Ethics Committee of Shahid Beheshti University of Medical Sciences (reference number IR.SBMU.PHARMACY.REC.1397.100). Students and parents gave written active informed consent for participation of the student.

Results

Changes in primary and secondary outcomes in PCOS and healthy adolescents before and after intervention in the intervention and control groups will be analyzed for evaluation effectiveness by one-way ANOVA or other nonparametric equivalents.

Discussion

The current protocol describes a study that will investigate the design and effectiveness of school-based lifestyle training program targeting healthy lifestyle to deal with improving behavioral habit promoting dietary intake and physical activity in adolescents for PCOS management. The healthy lifestyle program meets a current gap in the provision of care to PCOS women during the adolescent phase of life. A healthy lifestyle is not only beneficial for obese or overweight adolescents but also protects normal or underweight adolescents against inherited diseases such as PCOS, diabetes, and cardiovascular disease in the future,^[37] and prevention is a cost-effective strategy for adolescents and its benefits are long-lasting.

It is of crucial importance that the school environment can provide students with competition and motivation interventions to help them for maintaining a healthy lifestyle. Lifestyle education at school makes school staff more sensitive to the health of adolescents and, as a result, oversees the school's food environment.^[38]

Training of lifestyle program focuses on important behavior strategy via motivational interviews that have the potential to address long-term and late effects. It is important that the educators have a good understanding of the interviewee's stage of readiness to make a change in behavior.^[24] Although the benefits of a healthy lifestyle intervention have been documented in many studies and suggested as a scientific fact for the treatment and prevention of PCOS,^[39] There are still many challenges regarding treatment of PCOS, especially in lean or normal weight adolescents. The best training time, the best training style, and the best training place which will be most effective on lifestyle change are challenging in other scientific studies.^[40,41]

If this study program works, it can become one of the lifestyle education guidelines for improving health in adolescent girls with PCOS.

Limitation and recommendation

Limitations of the study include the reliance on self-report data on adolescents in terms of physical activity and dietary behavior. A novel approach of the program is the emphasis on self-management constructs and training in socioeconomic variations in one metropolis and comparison of clinical assessment in health and PCOS women into four groups for control of several confounders. There is further potential for this program to be done school based. If this lifestyle program works, it can become one of the lifestyle education guidelines for improving health in Iranian adolescent girls with PCOS.

Conclusion

The current study will provide information on the effectiveness of school-based lifestyle training programs for adolescents. With increasing numbers of PCOS at risk for long-term and/or late effects of treatment and other chronic diseases, efforts for promoting the healthy lifestyle of this important group are urgently needed. This lifestyle program may provide valuable information relating to the development of other healthy lifestyle interventions for PCOS and result in appropriate behavior change and self-management strategies.

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Conflicts of interest

There are no conflicts of interest.

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