Original Article

Impact of the Individual Counseling Program for Polycystic Ovary Syndrome Management among University Students: A Prospective Randomized Controlled Trial

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INTRODUCTION

Background: Polycystic ovary syndrome (PCOS) is common in women of reproductive age. Aim: This study aimed to investigate the impact of individual counseling program which had been designed from the transtheoretical model (TM) for students diagnosed with PCOS. Patients and Methods: The study is a prospective randomized controlled trial. The research was carried out in four stages as screening, diagnosis, randomization, selection, and counseling. The data for the analysis were drawn from a sample of 854 students at first and a total of 67 students were administered the scales. The control (n = 33) and experimental groups (n = 34) were formed based on the simple randomization technique. The sample characteristics were voluntary participation, absence of sexual activity for a minimum of 6 months, belonging to the age group of 19-24, an absence of chronic diseases or any physical disability, and a lack of mental disorders. Participants using medication and obtaining scores of above/below 18.5 and below/above 30 on the body mass index (BMI) were not included in the study. Results: The prevalence of PCOS among university students was found to be 8.8%. The findings indicated that the majority of the students have been experiencing various physical symptoms such as being overweight, menstrual irregularity, hirsutism, alopecia, acne, and psychological symptoms such as uneasiness, irritability, anger, anxiety, and fatigue. Based on the pretest and posttest scores, it was observed that the anthropometric values and psychological indicators such as the feeling of uneasiness, irritability, anger, anxiety, and fatigue were significantly decreased in the group of PCOS that took the counseling program. Conclusions: Individual counseling improved the anthropometric measurements and the clinical findings related to PCOS.

Keywords: *Individual counseling, polycystic ovary syndrome, transtheoretical model, university students*

Determining the incidence of polycystic ovary syndrome (PCOS) in young adult women and taking the necessary precautions are very important for reproductive health. PCOS is a complex and multifactorial syndrome that is primarily characterized by the presence of menstrual irregularity, chronic anovulation and hyperandrogenism.^[1,2] The prevalence of PCOS is quite high, occurring in 5% to 30% of women who experience their reproductive periods.^[3-5] These symptoms of PCOS can negatively impair women's

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health, leading to a range of physical problems such as type 2 diabetes mellitus (DM), hypertension (HT), cardiovascular diseases and infertility^[6,7] as well as psychological problems including declining quality of life, depression, and anxiety.^[8,9]

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The treatment and management of PCOS requires multidisciplinary teamwork. The treatment can be divided into three parts: medication, surgery, and supportive treatment methods, which promote behavioral changes. The key strategy in PCOS management involves changes in the general lifestyle of the patient, and preventing them from developing further long-term health problems.^[10] Thus, some theoretically based models such as transtheoretical model (TM) have been developed to facilitate behavioral change in individuals and help them maintain these changes by making them a part of their daily lives.^[11,12] Multidimensional lifestyle change programs encompassing behavioral counseling are encouraged to elucidate sustainable and successful coping strategies and to address both the physical and mental health outcomes of women with PCOS across the lifespan beyond temporary weight loss.^[13]

The main objective of the present study is to investigate the impact of the individual counseling program, which has been designed using the TM as a base and which suggests a healthy diet and physical activity for the management of the syndrome to university students diagnosed with PCOS. Individual counseling, which includes advice about healthy diet and physical activity, is provided to these students and behavioral change is promoted for efficient management of PCOS.

PATIENTS AND METHODS

Study design

The present study involved a prospective, randomized, and controlled experimental design that involved a series of steps including screening, diagnosis, randomized selection procedures, as well as counseling and follow-up stages. This study was conducted at the Faculty of Medicine, Veterinary and School of Health at Afyon Kocatepe University between September 2015 and November 2016.

Participants

The population of the study consisted of 1,189 female students of health-related fields at XXXX University in the 2014–2015 academic year. Considering the duration of the study and the counseling program, 55 students, in the process of graduating, were excluded from the study. A total of 854 students out of 1,134 students were reached through various brochures and announcements. At this stage, 293 out of 854 students were found to be at risk for PCOS using the "PCOS Risk Detection Form." A total of 75 out of 293 students, determined to be at risk for PCOS, were excluded from the study during the telephonic interviews (19 did not have any menstrual irregularity and/or hirsutism problems according to their statements in the questionnaire, 33 could not be reached at the mobile phone number they provided, and 23 did not want to participate in the study). The remaining 218 students with positive PCOS risk were referred to the clinic for diagnosis. This group was screened by the gynecologist (medical doctor, MD) at the Obstetrics and Gynecology Clinic at the XXXX Faculty of Medicine and a total of 76 students (8.9%) were diagnosed with PCOS based on the Rotterdam criteria (oligo or anovulation, clinical and/or biochemical signs of hyperandrogenism, and polycystic over-imaging in ultrasonography [USG]).^[14] Six of the 76 students diagnosed with PCOS were excluded from the study. (those who do not meet the participant criteria [n = 4], those who do not want to participate [n = 2]).

The sample characteristics were voluntary participation, absence of sexual activity for a minimum of 6 months, belonging to the age group of 19-24, an absence of chronic diseases or any physical disability, and a lack of mental disorders. Participants using medication and obtaining scores of below 18.5 and above 30 on the body mass index (BMI were not included in the study. Blinding could not be done in the study because individual counseling was provided. Research conditions were not suitable for blinding. Numbers from one to 70, which is the total number of students included in the study, were written on a piece of paper. After the names of the students were written on a piece of paper, simultaneously, the names and numbers in the bags for the control and intervention groups were picked and the student names and the numbers picked were matched. Students drawn in the same groups from the same class were placed in different groups by performing another draw for them. Randomization was managed by ensuring homogeneity between the BMI, age, and menstrual irregularity status of the students in the intervention and control groups. Students with normal BMI and preobese status were included in the study, and students' BMIs were ensured to be homogeneous for both groups. After the selection of the first normal BMI or preobese participant for each group, the draw was made for the other group until a participant with the same category was selected. Two students from the control and one student from the intervention group discontinued the follow-up and were excluded from the analysis. The control group (n = 33) and the experimental group (n = 34) were formed using simple methods of randomization. To find the effect size of the sample; a power analysis was conducted using the G power 3.1 software. The number of samples required for the study was found to be n = 30 as a result of the power analysis with 1st type margin of error (α) = 0.05, effect size (f) = 0.66, and power = $(1-\beta) = 0.80$. To complete the study with 80% power, it was planned to include at

least 30 participants for each of the groups. In the study, sufficient number of people were reached for the control group (n = 33) and intervention group (n = 34).^[15]

The progress of both groups was tracked monthly and six follow-up interviews were conducted. An individual counseling program that was based on TM and included motivational interview techniques was given to the experimental group, which involved general information about the importance of weight control, healthy diet, and exercise. A dietician, who prepared a diet rich in fiber and low in the glycemic index, recommended an intake of 1,600 calories/day to the overweight students in the experimental group while the rest of the students were recommended an intake of 1,500 calories per day. The experimental group was given a Benefits of Healthy Diet and Physical Activity in PCOS Training Booklet during their first counseling session. The progress of the participants in the control group was tracked routinely (Monthly health check, anthropometric measurements, general health recommendations related to nutrition and exercise) without any specific implementation. At the end of the study, the control group was also given the same booklet. The flow chart for the study is given in Figure 1.

Measurement

Several instruments were administered during the course of the study. These include the PCOS Risk Assessment Form, Descriptive Form for Individuals with PCOS, the Stages of Behavioral Change Form, the Menstrual Cycle Calendar, Type and Amount of Daily Food Consumption Form, International Physical Activity Questionnaire (IPAQ), and Ferriman-Gallwey (mFG). Among these scales, the PCOS Risk Assessment Form, Descriptive Form for Individuals with PCOS, The Stages of Behavioral Change Form, and the Menstrual Cycle Calendar were constructed by the researcher through consultation with five lecturers from the Departments of Obstetrics, Gynecology, and Nursing working in three different universities to ensure the face validity of the forms. The items were revised based on the feedback of the experts.

PCOS risk assessment form

This form consists of 10 questions related to the diagnosis of clinical PCOS symptoms. This form was given to the students during the screening procedure.

Descriptive form for individuals with PCOS

This form consists of 24 questions addressing sociodemographic and anthropometric characteristics of the students, the perception of PCOS, and lifestyle changes brought forth by PCOS. Anthropometric measurements (height, weight, BMI, waist, and hip circumference) of the students were evaluated after 1^{st} , 3^{rd} , and the 5^{th} month follow-ups.

The stages of behavioral change form

This form included two questions, pertaining to whether the students perform physical activity and have a healthy and nutritious diet. There are five options for each question regarding stages of changes with the scoring as (Prethinking Stage [PT] = 1 point, Thinking Stage [T] = 2 points, Preparation Stage [PS] = 3 points, Action Stage [A] = 4points, Maintenance Stage [M] = 5 points. Higher scores indicate a greater scope of behavioral changes.^[11]

Menstrual cycle calendar

The menstrual cycle calendar for the participants was constructed by the researcher to record the periodical cycles of the participants during the 6 months of the course of the study.

Type and amount of daily food consumption form

This form included 10 questions regarding information about nutritional habits (e.g., wheat, meat, vegetable, and fruit types) and the proportion and frequency of the food that the participants consumed in 24 h. The scoring is based on the daily calorie intake of the participants. This form was prepared by the researcher with inputs provided by three dietitians.

International physical activity questionnaire short form (IPAQ-SF)

This form was developed as an instrument for cross-national monitoring of physical activity and inactivity.^[16] It consists of seven questions about the physical activities, which last a minimum of 10 min, carried out in the past 7 days. The total score is calculated according to the frequency and length of the exercises with four dimensions. The form's Turkish adaptation was administered.^[17]

mFG score

The mFG score is commonly used for the detection of hirsutism. The distribution of hair on nine different parts of the body is scored between 0 and 4. The mFGscore ≥ 8 is described as hirsutism.^[18]

Ethical considerations

The ethical permission was granted by the Scientific Ethics Committee of Faculty of Nursing at XXX University (Issue: 205-84 Date: 15.07.2015). Written and oral consent was taken from the participants. The trial was registered enrollment at ClinicalTrials.gov (ID: NCT04471012).

Data analysis

The statistical analyses were implemented using the Statistical Package for the Social Sciences (SPSS) 20.0 software. The results were evaluated within 95%

confidence interval with a significance level of P < 0.05. As this study was part of a bigger project, several parametric and nonparametric analyses were calculated. These included descriptive statistics, Pearson correlation analysis, Chi-square test, McNemar test, McNemar Bowker test, Friedman test, Wilcoxon Signed-Rank test, Mann–Whitney U test, and Analysis of Variance in Repeated Measurements techniques were used.

RESULTS

Descriptive findings suggested that although 32% of the students (n = 274) from a total of 854 participants were at

risk for PCOS, only 76 students (8.8%) had a diagnosis of PCOS. Out of these 76 students, nine students were further eliminated, and thus the present study was carried out on 67 students (X = 20.79, SD = 1.43) ranging from the ages of 19 to 24 years. Among these 67 students, 25.4% were pursuing nursing, 23.9% were studying nutrition, 20.8% were pursuing physiotherapy, 16.4% were studying management of health institutions, 9% belonged to the veterinary department, and 4.5% were medical students. It was determined that 35.8% of the students who participated in the study were 1st-grade students (n = 24).

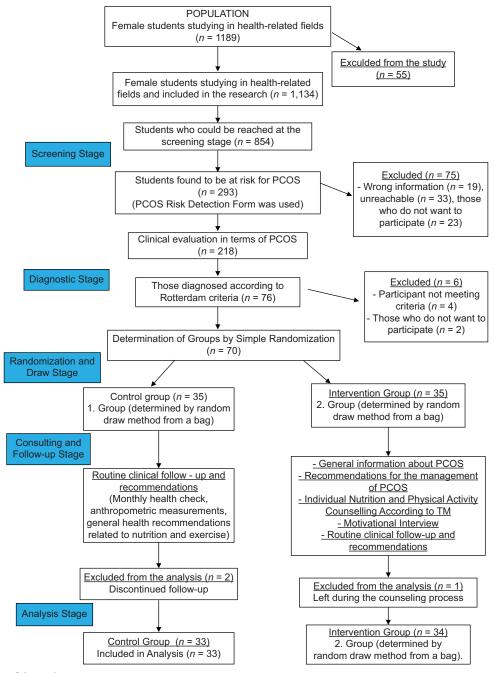


Figure 1: Flow chart of the study

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| Dilek | ot | $al \cdot$ | Counse | ling | for | polycyst | tic | ovary | syndrom | ۱e |
|-------|----|--------------|--------|------|-----|----------|-----|-------|---------|----|
| DHEK, | eı | <i>aı.</i> . | Counse | mg | 101 | porycys | ιic | ovary | synuron | 10 |

| experimental group PCOS | | | | | | | | | | | | |
|-------------------------|---------------|-----------|---------------|-----------|-----------------|-----------|----------------|-------|--------|-------------|--|--|
| Physical | Pretest | | Midtest | | Posttest | | Test | | | | | |
| Features | X±SD | Min-max | X±SD | Min-max | X±SD | Min-max | X ² | Р | Ζ | Р | | |
| Weight (kg) | 67.3±9.2 | 48-85 | 65.9±8.8 | 47-83 | 63.9±8.4 | 46-80 | 53.602 | 0.000 | -4.711 | 0.0001 | | |
| | | | | | | | | | -5.020 | 0.000^{2} | | |
| | | | | | | | | | -5.008 | 0.000^{3} | | |
| BMI | 25.5±3.3 | 19.0-29.8 | 24.9±3.1 | 18.7-29.4 | 24.1±2.9 | 18.4-28.3 | 53.601 | 0.000 | -4.662 | 0.000^{1} | | |
| | | | | | | | | | -4.988 | 0.000^{2} | | |
| | | | | | | | | | -4.918 | 0.000^{3} | | |
| Waist size | 82.4±11.0 | 64-103 | 81.6±10.5 | 64-101 | $80.2{\pm}10.1$ | 64-99 | 50.523 | 0.000 | -3.866 | 0.000^{1} | | |
| | | | | | | | | | -4.787 | 0.000^{2} | | |
| | | | | | | | | | -4.712 | 0.000^{3} | | |
| (mFG) | $9.0{\pm}7.1$ | 0-26 | 8.9 ± 7.0 | 0-26 | 7.3±5.5 | 0-19 | 19.776 | 0.000 | -2.000 | 0.040^{1} | | |
| | | | | | | | | | -3.601 | 0.000^{2} | | |
| | | | | | | | | | -3.526 | 0.000^{3} | | |
| | X±SD | Min-max | X±SD | Min-max | X±SD | Min-max | F | Р | MD | Р | | |
| Hip size | 103.7±6.8 | 91-121 | 103.2±6.6 | 91-120 | 101.7±6.5 | 90-118 | 62.644 | 0.000 | 0.559* | 0.0001 | | |
| - | | | | | | | | | 2.088* | 0.000^{2} | | |
| | | | | | | | | | 1.529* | 0.000^{3} | | |

Table 1. Comparison of physical (anthronometric) characteristics of protect midtest and posttest of students with

X² (Friedman Test), Z (Wilcoxon Signed-Rank test), F (Analysis of Variance in Repeated Measurements), MD (Mean Difference), ¹Prtest-Mid test, ² Pretest- Posttest, ³ Midtest- Posttest, *P* (Significance level *P*<0.05)

| Menstrual Cycle | Experimer | ıtal Group | Control | Test | | |
|--------------------|------------|------------|------------|---------|-----|-------|
| | X±SD | Min-max | X±SD | Min-max | U | Р |
| 1 month (pretest) | 59.58±38.0 | 10-180 | 67.93±46.6 | 10-180 | 496 | 0.412 |
| 2 month | 27.02±3.3 | 15-35 | 27.39±2.1 | 21-31 | 525 | 0.654 |
| 3 month (midtest) | 27.76±2.7 | 21-35 | 27.60±2.1 | 21-32 | 559 | 0.981 |
| 4 month | 27.70±1.6 | 25-31 | 28.57±3.2 | 22-38 | 510 | 0.506 |
| 5 month | 31.76±5.7 | 25-55 | 34.06±4.4 | 26-42 | 318 | 0.022 |
| 6 month (posttest) | 32.35±6.3 | 25-50 | 36.96±6.4 | 25-45 | 332 | 0.000 |

U (Mann-Whitney U Test), P (Significance level P<0.05)

Table 3: Comparison of physical activity and nourishment statuses of experimental and control group students with DCOG

| Behavioral Change | Pretest | | | | Midtest | | Posttest | | |
|-------------------|---------|-----|------|--------|---------|-------|----------|-----|-------|
| | Median | U | Р | Median | U | Р | Median | U | Р |
| Physical Activity | | | | | | | | | |
| Experimental | 2 | 515 | 0.54 | 4 | 291 | 0.000 | 4.5 | 157 | 0.000 |
| Control | 2 | | | 3 | | | 3 | | |
| Nourishment | | | | | | | | | |
| Experimental | 2 | 530 | 0.67 | 4 | 199 | 0.000 | 5 | 126 | 0.000 |
| Control | 2 | | | 3 | | | 3 | | |

U (Mann-Whitney U Test), P (Significance level P<0.05). 1. Prethinking Stage (PT), 2. Thinking Stage (T), 3. Preparation Stage (PS), 4. Action Stage (A), 5. Maintenance Stage (M)

When the anthropometric characteristics of the students were evaluated in the pretest, the mean weight of the patients was 65.8 ± 9.9 , the mean BMI was 24.8 ± 3.4 , the mean waist circumference was 81.0 ± 10.3 , the mean hip circumference was 102.2 ± 7.2 , and the (mFG score was 8.5 ± 7.0 . In the present study, 50.7% of the students were found to be obese and 49.3% had normal weight. No significant difference was found between the groups on the anthropometric follow-up (P > 0.05). However, a significant difference (P = 0.000, P < 0.001) was found in the experimental group between the pretest-midtest, pretest- posttest, and midtest-posttest values, and a decrease was observed in all anthropometric measurements [Table 1].

Significant differences were observed in the experimental group between the pretest and posttest scores in both clinical findings and perceptions of the disease. It was found that menstrual irregularity significantly decreased from 94.1% to 26.5% (P = 0.000, P < 0.001), additional weight that led to patients being overweight significantly decreased from 73.5% to 52.9% (P = 0.016, P < 0.05), and feelings of unease and anger significantly decreased from 70.6% to 38.2% (P = 0.012, P < 0.05). The scores of perceptions of a psychological change (P = 0.000, P < 0.001), feelings of anxiety (P = 0.045, P < 0.05), and fatigue (P = 0.000, P < 0.001) also reduced by the end of study. Participants feelings of control increased from 47.1% to 94.2% (P = 0.000, P < 0.001). On the contrary, there was no significant difference in the control group on any of these measures (P > 0.05). When the mean of the menstrual cycle of the experimental and control group was compared, the only significant difference was found in the posttest assessment, which indicated that the cycle of participants in the experimental group (32.35 ± 6.3) became more regular than that of the control group (36.96 ± 6.4) (P = 0.000, P < 0.001) [Table 2].

Significant behavioral changes were observed in the participants' physical activity and nutrition after the third assessment [Table 3]. There were significant differences between the groups' nutritional habits and physical activities (P = 0.000, P < 0.001), which were revealed during the middle and posttest assessments. The consumption of fruits and vegetables significantly increased and the daily calorie intake, including the consumption of bread, wheat, pulse, fat, and sweets significantly decreased in the experimental group, especially when compared with the control group (P = 0.000, P < 0.001). The daily period of sitting still and physical activities including walking were significantly different in the experimental group as compared with the control group (P = 0.000,*P* < 0.001) [Table 3].

DISCUSSION

The findings of the present study concluded that weight, BMI, waist circumference, hip circumference, and mFG values of all patients decreased significantly after their participation in counseling programs. Several researches support this evidence. Haqq *et al.*^[19] (2015) examined various randomized controlled PCOS studies conducted between 1966 and 2013. They found that women with PCOS who succeed in changing their lifestyles showed significant differences in their anthropometric measurements in comparison with women who did not make any such changes. In another study, McBreairty *et al.*^[20] (2014) observed that all the anthropometric measurements decreased in the follow-up measurement of the participants. These changes occur because even a small amount of weight loss (approximately 2%–5% of the total body weight) in overweight patients or patients at risk for obesity triggers reproductive functions and hormonal profile. Lifestyle interventions such as making a change in eating habits are claimed to be the most appropriate method for improving the anthropometric measurements of women with PCOS.^[19,21]

The students who received the counseling program displayed positive changes in the clinical and metabolic parameters such as weight loss, ovulation, menstruation, and psychological aspects such as self-confidence as well as the perception of PCOS. Clinical findings revealed that although there was no significant difference in the menstrual cycle between participants of the experimental and control group at the beginning of the study, women in the experimental group (32.35 ± 6.3) started to have more regular cycles than the women in the control group (36.96 ± 6.4) . A similar finding was revealed in a study that placed women with PCOS on a 16-week diet and exercise program. It was found that the average period of time between menstruation cycles significantly decreased (P = 0.04, P < 0.05).^[9] In other words, decrement in menstrual intervals pushed the menstrual cycle to start again. Changes in lifestyle lead to the recovery of the menstruation cycle and an increase in ovulation.^[21-23] Similarly, studies analyzing the impact of exercise on PCOS revealed that ovulation increases regardless of the length and type of the exercise, insulin resistance drops by 9%-30% and students start to lose around 4.5%-10% of their weight.^[19,22] The students who took counseling sessions on PCOS management exhibit significant decrement in the time they spend sitting every day and demonstrate an increase in intermediate physical activity scores, walking physical activity scores, and total physical activity scores. Thus, maintaining a diet along with exercise is an important step in managing PCOS.^[19] Some studies suggest weight loss as the first treatment option in PCOS management.[24-26]

The diet programs provided to groups with PCOS in the literature suggest that the calorie intake should include 40%–60% carbohydrates, 20%–30% fat and 15%–30% protein; in addition, pulp and foods with low glycemic index must be consumed.^[21,23,27] In the present study, a diet made up of 56% carbohydrates, 25% fat, and 19% protein that was provided by the dietitian was compatible with the advisement provided in literature for PCOS. Individual counseling that included advice about healthy eating habits led to an increase in the vegetable and fruit consumption of the experimental group while bread, wheat, pulse, fat and sweet consumption, and daily calorie intake all decreased during posttest

measure. In the literature, anthropometric measurements, total testosterone, and fasting insulin levels, hirsutism findings or FGS scores, menstrual cycles, and ovulation of the women, that were applied to the lifestyle intervention, showed improvement, which showed a significant difference compared with the control group (P < 0.05).^[27-29] Healthcare professionals can manage behavior change in patients with PCOS by using individual counseling because symptoms and problems in PCOS differ individually.^[25,30] These results are consistent with this study findings. In the current study, it was observed that the anthropometric values, clinical findings, perceptions of the disease, and psychological indicators such as menstrual irregularity, overweight, feelings of unease and anger, feelings of anxiety, and fatigue significantly decreased in the group of PCOS that took counseling program. Since the symptoms and problems of PCOS vary, health professionals should ensure behavioral change in students with PCOS through the use of TM.

Strengths and limitations of the study

While determining the prevalence of PCOS in university students and applying an individual psychological counseling program designed from the TM to participants diagnosed with PCOS was the strength of the study, including participants only from three departments (Faculty of Medicine, Veterinary, and School of Health) was the limitation of the study.

CONCLUSION

The TM-based individual counseling for the management of PCOS, facilitated the eating and physical activity habits of the university students in our sample. Individual counseling improved the anthropometric measurements and the clinical findings related to PCOS. Thus, this study confirmed that lifestyle changes such as promotion of healthy lifestyle behaviors, dietary habits, weight loss, exercise, regular medication, and routine check-ups enhance the recovery process in young women with PCOS.

Hence, the students' clinical findings relating to the syndrome, their understanding of the syndrome, and their ability to deal with PCOS can be managed through individual counseling provided with TM.

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Conflicts of interest

There are no conflicts of interest.

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