Original Article

Effect of Using 5A's Model for Self-management Counseling on Quality of Life and Self-Efficacy in Women with Polycystic Ovary Syndrome: A Randomized Clinical Trial

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Abstract

Background: Polycystic ovary syndrome (PCOS) has adverse effects on mental health and quality of life. International guidelines recommended the provision of cognitive behavioral models to support self-management for these women. The patient-centered 5A's model might meet this need. Thus, this study aimed to evaluate the effect of using the 5A's model for self-management counseling on quality of life and self-efficacy in women with PCOS. **Materials and Methods:** This study is a randomized clinical trial, and the research population included women with PCOS referred to Baghaeipour Clinic in Yazd, Iran, between April 2023 and October 2023. Sixty-four women were randomized to the intervention (the self-management program based on the 5A's model) and active control groups (educational booklet). PCOS Quality of Life and General Self-Efficacy Scale were completed by participants. Data were analyzed using SPSS 19, independent *t*-test, and repeated measures ($p < 0.05$). **Results:** The mean difference between quality of life ($F_{2,60} = 75.25$, $p < 0.001$) and self-efficacy ($F_{2,60} = 29.09$, $p < 0.001$) scores before, after, and follow-up in the intervention group was significant. The mean difference between quality of life ($F_{2,62} = 24.64$, $p < 0.001$) and self-efficacy ($F_{2,62} = 20.39$, $p < 0.001$) scores before, after, and follow-up in the active control group was significant. However, the increase in the quality of life and self-efficacy score in the intervention group was higher than in the control group. **Conclusions:** The 5A's model and educational booklets to improve self-management increased quality of life and self-efficacy of women with PCOS, which can be used in clinical settings for healthcare providers.

Keywords: *Polycystic ovary syndrome, program, quality of life, self-efficacy, self-management*

Introduction

Polycystic ovary syndrome (PCOS) is a common chronic endocrine and cardiometabolic condition that affects approximately 5.6%–21.0% of women of reproductive age.[1-4] This disease is a significant global health burden that needs urgent attention.[2,5] PCOS can affect women throughout their lives, from adolescence to menopause.[6,7] It is also associated with adverse clinical complications, including metabolic (cardiovascular risk, insulin resistance, diabetes mellitus),[8,9] reproductive (menstrual irregularity, infertility, pregnancy complications),[10,11] and psychological disability (anxiety, depression, disordered eating, low self-esteem).[12,13] These reasons and the complex nature of the disease can lead to a decrease in the quality of life of these women.[14,15] In the 21st century, quality of life is considered an important factor for evaluating the outcome of health care, especially in chronic diseases such as PCOS.[16] However, the chronic nature of PCOS and its manifestations, such as acne, hirsutism, infertility, negative perception of body image, menstrual disorders, and social problems, will reduce patients' self-efficacy.[17,18] Self-efficacy is an individual's belief in their ability to plan and execute a specific course of action. Furthermore, improving the level of self-efficacy can effectively improve the quality of life of patients.[19]

Treatment for PCOS includes surgical options, pharmacological options, and lifestyle management, such as self-management strategies (diet and physical activity).[20,21] Self-management emphasizes the individual's responsibility in

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performing daily health behaviors and helps them promote their condition by improving self-efficacy.[22] Despite the fact that self-management is recommended to women with PCOS, studies show that women still have challenges in implementing self-management strategies. Women with PCOS face a wide range of barriers to following the recommendations of health professionals regarding lifestyle modification and self-management behaviors. These women's motivation to adhere to recommended lifestyle changes may be affected by the complex nature of PCOS, and it is recommended that the ideal models of care for these women include evidence-based and patient-centered models.[23] To date, fewer studies have identified the types of self-management strategies and models employed to optimize behavioral change in women with PCOS.[2,23] However, an integrated model is needed to provide self-management counseling services for women with PCOS.[24,25]

Among the self-management strategies and models, the 5A's model is known as a patient-centered, counseling, and behavior change model that focuses on the individual's cognition of the situation.[26] In addition, the 5A's model is an evidence-based approach with five steps, including Assess, Advise, Agree, Assist, and Arrange, which emphasize behavior modification and health achievement.[24] However, a limited number of previous studies have assessed the effect of self-management counseling using the 5A's model on women with PCOS. One study showed that using the 5A's model for lifestyle counseling reduced psychological symptoms in women with PCOS.[2] The results of some studies showed that the 5A's model was not effective in improving quality of life and physical activity as one of the self-management behaviors.[27-29] Besides, the main reason for performing this model in women with PCOS is that the ability of PCOS women to adhere to the recommended behavioral changes for lifestyle modification and self-management may be influenced by the complex and multifaceted nature of PCOS and its complications and symptoms, including fatigue, anxiety, depression, eating disorders, stress, and sleep disorders. Therefore, these women need appropriate behavior change models.[23] Accordingly, the present study was conducted to evaluate the effect of using the 5A's model for self-management counseling on the quality of life and self-efficacy of women with PCOS. Thus, this study aimed to evaluate the effect of using the 5A's model for self-management counseling on quality of life and self-efficacy in women with PCOS.

Materials and Methods

This parallel randomized clinical trial (IRCT20230307057652N1) used a pretest–posttest design with an active control group. The study was conducted on 63 women with PCOS based on Rotterdam criteria from April to October 2023 in Yazd, Iran. The sample size was estimated as 64 women based on Zhang *et al*.,[30] considering the significance level of 5%, a test power of 80%, 95% confidence level, and a subject attrition rate of 15%.

Simple random sampling was performed among women referred to Baghaeipour Obstetrics and Gynecology Clinic, affiliated with Shahid Sadoughi University of Medical Sciences, Yazd, Iran. Subsequently, the samples were randomly assigned into intervention (32 women) and control (32 women) groups through the online software (www.Random.org/sequences). To comply with concealment, random allocation was implemented by the fourth researcher.

The inclusion criteria included women with PCOS according to the Rotterdam criteria and the approval of the center's gynecologist or based on the patient's medical record, passage of at least 1 year since the diagnosis of the disease, age 15–49 years, Iranian nationality, being literate, having a smartphone, and the possibility of participating in training sessions. Exclusion criteria included severe psychological disorders, use of tobacco, alcohol abuse, stressful events, such as migration, divorce, or death of parents, during the past 6 months, undergoing treatment of assisted reproductive methods, restrictions on physical activity, and affliction with diseases, such as phenylketonuria, that require following a special diet. Data collection instruments included a demographic questionnaire, the Polycystic Ovary Syndrome Quality of Life Questionnaire (PCOSQOL), and the General Self-Efficacy Scale (GSE).

PCOSQOL, developed by Cornin *et al.* (1998), remains the most popular tool for assessing the impact of PCOS on the Quality of Life of affected women.[31] It includes 26 items and measures PCOS quality of life separately in emotional areas, hirsutism, weight, infertility, and menstrual disorders. The items are scored using a 7-point Likert scale. The overall quality of life score and its subcategories are reported based on a 0–100 scale. The reliability of the PCOSQOL was evaluated with the test–retest method, and it was confirmed with excellent internal consistency (α: 0.96).[32] This questionnaire has been psychometrically evaluated in Iran. The internal consistency of this questionnaire in all areas except "menstrual disorders" was 0.52 and had a Cronbach's α coefficient of >0.7.[31]

Sherer's general self-efficacy questionnaire entails 17 items with a maximum score of 85 and a minimum score of 17. A range of scores between 17 and 34 indicates weak, 35–51 moderate, and 52–85 high self-efficacy.[33] The Cronbach's α for this questionnaire was reported to be 0.86.[34] Moreover, the reliability of this test was confirmed with a Cronbach's alpha of 0.81.[35] The research units of both groups completed the study questionnaires online and through Google Forms before and after the intervention.

The first researcher wrote down the phone numbers of the eligible participants based on their medical records in the Baghaeipour Obstetrics and Gynecology clinic, affiliated with Shahid Sadoughi University of Medical Sciences, Yazd, Iran. Then, a telephone call was made to these women from the Baghaeipour Obstetrics and Gynecology clinic, and it was explained to them that in the study, there were two groups. For one group, self-management educational counseling sessions would be held virtually based on the 5A's model, and for the other group, educational booklets about PCOS and the importance of self-management would be provided. After subjects were randomly assigned to intervention and active control groups, the link to the study questionnaires and the informed consent form were sent to them via the Eitaa messenger service. Afterward, the intervention group received the self-management program based on the 5A's model (Assess, Advise, Agree, Assist, Arrange) [Table 1]. In addition, the active control group received an educational booklet about PCOS and its complications and the importance of self-management through the Eitaa messenger service.

Table 1: Content of the 5A's Model for self-management counseling

Step	Sessions	Content of sessions
Step 1	Assess	In this step, patients were assessed by telephone interviews regarding risk factors, history of diseases, PCOS* complications, stress status, nutrition, and type of activity.
Step 2	Advise	In this step, the previous analysis results were considered to inform women with PCOS of the diagnosed health risks and emphasize the benefits of behavioral change.
Step 3	Agree	Considering the identified problems, appropriate and agreed behavioral goals were set according to the conditions, interests, and priorities of each person to carry out stress management, weight loss, appropriate physical activity, and nutritional modification.
Step 4	Assist	The patients were instructed about stress management, nutrition, weight loss, and physical activity. Moreover, based on the behavioral goals agreed with the affected women, a checklist related to physical activity or a form for completing the food regimen, or a daily checklist for practicing the relaxation technique, or all three were presented. To ensure the implementation of the program, the patients were requested to record their performance status regarding each of the goals in the self-report checklist on a daily basis until the end of the intervention period in the 12th week.
Step 5	Arrange	In this stage, the status of the patient's progress and success was monitored through SMS**. In so doing, a daily SMS was sent during the first 2 weeks. After 2 weeks, SMS was sent twice a week, and then once a week. The follow-up was continued for a month to remind the implementation of the practical program.

*Polycystic Ovary Syndrome. **Short Message Service

At the completion of intervention in the 12th week and follow-up at the end of intervention in the 16th week, the study questionnaires were completed again by the research units in both groups.

All statistical analyses were performed using SPSS software version 19 (IBM Corporation, New York, USA). The data were analyzed using an independent *t*-test, Chi-square, Fisher's exact test, and repeated measures ($p < 0.05$).

Ethical considerations

The permission was obtained from the Committee of Ethics in Shahid Sadoughi University of Medical Sciences in Yazd, Iran (IR.SSU.REC.1401.111). Informed consent was also obtained from the participants.

Results

Out of 237 eligible women invited to the study, 64 accepted the invitation. One participant in the intervention group was excluded from the study due to her refusal to participate in the research, and finally, 31 women in the intervention group and 32 individuals in the control group remained [Figure 1]. Based on the results, there were no significant differences between the two groups in terms of quantitative [Table 2] and qualitative [Table 3] basic characteristics ($p > 0.05$).

The mean score of quality of life showed no statistically significant difference between the two groups before the intervention ($t_{61} = -1.87$, $p = 0.066$). The mean score of quality of life was not significantly different between the two groups after the intervention ($t_{61} = -0.41$, $p = 0.683$) and follow-up time ($t_{61} = 0.43$, $p = 0.668$). However, the mean differences of quality of life scores before the intervention, and after it, and during follow-up in the intervention group ($F_{2,60} = 75.25$, $p < 0.001$) and before the intervention after it, and during follow-up in the active control group ($F_{2,62} = 24.64$, $p < 0.001$) were significant. However, the increase in the quality of life score in the intervention group was higher than in the active control group [Table 4].

The mean score of self-efficacy showed no statistically significant difference between the two groups before the intervention ($t_{61} = -1.40$, $p = 0.168$). The mean score of self-efficacy was not significantly different between the two groups after the intervention ($t_{61} = -0.58$, $p = 0.562$) and follow-up time ($t_{61} = 0.3$, $p = 0.766$). However, the mean difference of self-efficacy scores before the intervention and after it and during follow-up in the intervention group ($F_{2,60} = 29.09$, $p < 0.001$) and before the intervention and after it and during follow-up in the active control group ($F_{2,62} = 20.39$, $p < 0.001$) was significant. However, the increase in the self-efficacy score in the intervention group was higher than in the active control group [Table 5].

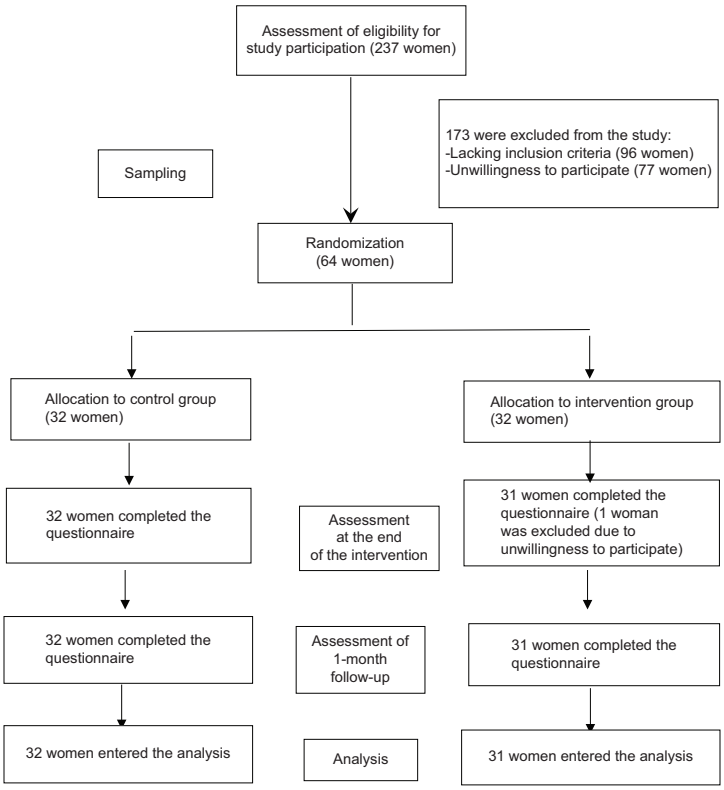

Figure 1: The consort diagram

Table 2: Comparison of basic quantitative characteristics of women with Polycystic ovary syndrome (PCOS) in two groups

Group Variable	Intervention (*n*=31) Mean (SD)	Control (*n*=32) Mean (SD)	*p*
Age (years)	29.77 (6.22)	28.87 (6.19)	0.567*
Weight (kg)	71.35 (9.23)	66.43 (11.22)	0.063*
Height (cm)	161.80 (7.95)	160.28 (6.63)	0.411*
BMI**(weight/square of height)	27.34 (3.99)	25.82 (3.95)	0.134*
Disease duration (years)	7.67 (3.76)	7.43 (4.26)	0.814*

*Independent Sample *t*-test. **Body Mass Index (BMI)

Discussion

This study aimed to evaluate the effect of using the 5A's model for self-management counseling on quality of life and self-efficacy in women with PCOS. The results indicated the effectiveness of self-management counseling based on the 5A's model in improving the quality of life and self-efficacy of these women in the intervention group. Moreover, the educational booklet in the active control group improved the quality of life and self-efficacy of these women. However, in the self-management counseling group based on the 5A's model, the increase in the quality of life and self-efficacy of women with PCOS was higher than in the active control group.

Self-management strategies in women with PCOS include self-regulatory models of behavior changes and social cognitive theory that may help improve self-efficacy and quality of life. However, these strategies are occasionally used by women with PCOS.[23] According to the results of a 2022 meta-analysis, CBT showed clear benefits in reducing anxiety and improving quality of life in patients with PCOS. Nevertheless, higher quality and larger randomized controlled trials are needed to clarify the role of CBT in PCOS.[36] The 5A's model is known as a self-management and counseling model to change behavior, which focuses on one's understanding of the situation and the patient-centered model.[24] In 5A's model, the counselor focuses on the client's knowledge of their conditions and behaviors.[37] In this model, the client actively participates in the design of their self-management plan and agrees with the counselor on behavioral goals.[38]

In a limited number of previous studies, the 5A's model in self-management counseling of PCOS women has been investigated.[24,39] In this regard, the results of a study showed that counseling with the 5A's approach improved the psychological condition of women with PCOS.[24] Another study aimed at investigating the effect of the 5A's model along with nursing management on self-efficacy and quality of life before surgery in patients with uterine fibroids showed that the self-efficacy score after the intervention in the experimental group was significantly higher than before the intervention and compared to the control group.[40] The results of the present study are consistent with those of the above studies. The reason for the consistency of the research results with those of the above studies is the use of the same consulting approach.

Table 3: Comparison of basic qualitative characteristics of women with Polycystic ovary syndrome (PCOS) in two groups

Group Variable	Intervention *n*=31 *n* (%)	Control *n*=32 *n* (%)	*p*
Marital status			
Married	26 (83.90)	23 (71.90)	0.365*
Single	5 (16.10)	9 (28.10)	
Education level			
Primary school	7 (22.60)	8 (25.00)	0.725*
High school diploma	8 (25.80)	11 (34.40)	
Academic degree	16 (51.60)	13 (40.60)	
Occupation			
Housewife	16 (51.60)	16 (50.00)	0.606*
Employed	11 (35.50)	9 (28.10)	
Unemployed	4 (12.90)	9 (21.90)	
Menstrual cycle			
Regular	10 (32.30)	13 (40.60)	0.490*
Irregular	21 (67.70)	19 (59.40)	
History of pregnancy			
Yes	15 (48.40)	14 (43.80)	0.712*
No	16 (51.60)	18 (56.20)	
Having children			
Yes	16 (51.60)	16 (50.00)	0.898*
No	15 (48.40)	16 (50.00)	
Type of infertility			
Primary	13 (41.90)	11 (34.40)	0.537*
Secondary	18 (58.10)	21 (65.60)	
Infertility			
Yes	13 (41.90)	12 (37.50)	0.719*
No	18 (58.10)	20 (62.50)	
Hirsutism			
Yes	29 (93.50)	24 (75.00)	0.054*
No	2 (6.50)	8 (25.00)	
Acne			
Yes	19 (61.30)	13 (40.60)	0.101*
No	12 (38.70)	19 (59.40)	
Hair fall (Alopecia)			
Yes	26 (83.90)	25 (78.10)	0.561*
No	5 (16.10)	7 (21.90)	

*Chi-Square test

However, the results of other studies that examined the effect of counseling with the 5A approach on individuals' physical activity showed that this approach was not effective in improving quality of life and physical activity as a self-management behavior.[27-29] Moreover, the results of another study that investigated the effect of counseling on behavior change based on the 5A's model for smoking cessation showed that this approach did not lead to smoking cessation.[41] The results of the present study are not consistent with these studies, and the reason for this could be the different research community since the nature of PCOS is complex and different, and these women need patient-centered counseling approaches.

According to studies, managing depression and anxiety is essential to improving the quality of life of women with PCOS.[42] 5A's model provides an opportunity to correct one's misconceptions. Therefore, using these opportunities can improve the mental health of participants with PCOS and, therefore, lead to an increase in the quality of life of these women.[24] By using this model, a person gains the necessary knowledge about the disease and the effect of behavior change programs and planning for self-management.[39]

On the other hand, according to studies, women with PCOS need education about disease management.[43] Therefore, in the present study, providing an educational booklet in the active control group regarding the importance of self-management to these women improved the quality of life and self-efficacy, which could be due to the women with PCOS's need for education. Given the lifelong, extensive, and multifaceted effects of PCOS, it is important to provide adequate education, information, and coping skills to achieve sustainable long-term management.[44] Previous studies have shown that many individuals with PCOS report a lack of educational support and insufficient information.[45,46] Therefore, improving the quality of life and self-efficacy in both study groups shows the clear need for education and counseling in women with PCOS.

One of the strengths of this study was the use of a patient-centered and evidence-based counseling approach and setting goals for each individual with their participation. One of the limitations of this study was the impossibility of using the second intervention group due to the financial limitations of the current research project, and, therefore, we used the active control group in the design of the research. Therefore, this point should be taken into account when interpreting the results. It is suggested that more research be conducted regarding the use of the second intervention group with the nature of a counseling approach.

Conclusion

This study presented a client model for self-management counseling in women with PCOS, which can also improve their quality of life and self-efficacy. The results showed that using the 5A's model and providing educational booklets to promote self-management can lead to positive outcomes in relation to the quality of life and self-efficacy of women with PCOS. Thus, the results indicate the clear need for education and counseling among PCOS women. Therefore, it is necessary for the health team to attach increasing importance to counseling and education in self-management in providing health care to these women.

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Table 4: Comparison of the mean scores of quality of life between the two groups

Quality of life	Mean (SD)			F (df_1, df_2)	p
	Before	After intervention (12th week)	Following-up (16th week)		
Intervention	84.81 (27.75)	99.61 (26.44)	106.74 (25.24)	75.25 (2, 60)	<0.001**
Control	96.47 (21.30)	102.19 (23.31)	104.13 (22.88)	24.64 (2, 62)	<0.001**
Statistical test *t* (df)	-1.87 (61)	-0.41 (61)	0.43 (61)		
p	0.066*	0.683*	0.668*		

*Independent Sample *t*-test. **Repeated measures test

Table 5: Comparison of the mean scores of self-efficacy between the two groups

Self-efficacy	Mean (SD)			F (df_1, df_2)	p
	Before	After intervention (12th week)	Following-up (16th week)		
Intervention	56.45 (10.27)	60.68 (8.48)	63.26 (7.19)	29.09 (2, 60)	<0.001**
Control	59.72 (8.22)	61.91 (8.26)	62.69 (7.90)	20.39 (2, 62)	<0.001**
Statistical test *t* (df)	-1.40 (61)	-0.58 (61)	0.3 (61)		
p	0.168*	0.562*	0.766*		

*Independent Sample *t*-test. **Repeated Measure test

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Conflicts of interest

Nothing to declare.

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