Nursing Section

# Effectiveness of Multimodular Interventions of Lifestyle Modification on Symptoms of Polycystic Ovarian Syndrome and Quality of Life among Women- A Pilot Study

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## **ABSTRACT**

Introduction: Polycystic Ovarian Syndrome (PCOS) is a common endocrine disorder encountered in female. Multimodular interventions of lifestyle modifications emphasise bearable weight loss through dietary, exercise, and behavioural modification. The timely recognition, understanding, and handling of clinical characteristics of this syndrome shall prevent long-term health issues.

**Aim:** To evaluate the efficacy of multimodular interventions on symptoms of PCOS and the quality of life of women with PCOS.

Materials and Methods: A pilot study was conducted at Father Muller College of Nursing, Mangaluru, Karnataka, India, between May 2019 to February 2020. The female diagnosed with PCOS were selected through a purposive sampling technique, from two tertiary settings (15 subjects for the intervention group and 15 for the control group). The multimodular interventions (diet, exercises, and behavioural modifications) were provided to the study group. Follow-up was done in the 2<sup>nd</sup>, 4<sup>th</sup> and 6<sup>th</sup> month. The control group subjects continued the regular medical treatment and followed-up at 6<sup>th</sup> month. The intervention and control group results were compared in the 6<sup>th</sup> month. The tools used for data collection were baseline variables, PCOS symptom assessment tool, and World Health Organisation Quality of Life questionnaire (WHOQOL-BREF) tool.

Results: The mean age of study participants was 24.26±3.84 years in the intervention, and 24.20±3.54 years in the control group. A significant improvement in the waist-hip ratio, hirsutism acne (p-value <0.001) and quality of life in women with PCOS was observed in the post-test 2 (2nd month), post-test 3 (4th month), and post-test 4 (6th month) in the intervention group (p-value <0.001). A minimal change was noticed in the Body Mass Index (BMI) and Fasting Blood Sugar (FBS) scores. The Mann-Whitney test (z values) revealed a significant difference in the symptoms of PCOS of waist-hip ratio (z value=3.328, p-value <0.001) and hirsutism (z-value 2.296, p-value <0.022) between intervention and control group after the 6 months. The pretest mean and standard deviation of physical health domain was 21.00±2.59, psychological health domain 18.13±3.04, social relationship 9.27±1.67, and environmental domain 23.00±3.66. The post-test mean and standard deviation was 24.00±3.05, 22.67±4.03, 12.20±1.74, 28.07±6.71 (p-value <0.001) in physical, psychological, social, and environmental domain, respectively. A statistically significant increase in quality of life observed in the intervention group (p-value <0.001) whereas in the control group there was no change.

**Conclusion:** The multimodular interventions were found to be effective in reducing the clinical symptoms of PCOS like hirsutism acne and the quality of life steeply improved after 6 months of these interventions in PCOS women.

Keywords: Anthropometric measurements, Diet, Exercises, Obesity, Psychological health

# **INTRODUCTION**

As per the Rotterdam criteria, if one ovary of a woman reveals multiple cysts and is associated with ovulatory dysfunction and excessive secretion of androgens with or without complaints of oligomeneorrhoea it is said to be a polycystic ovary [1]. Polycystic Ovary Syndrome (PCOS) is an endocrine disorder characterised by changes in hormonal levels. The common symptoms are menstrual irregularities, anovulation, obesity, acne, hair growth in unwanted areas, alopecia, and a male pattern of baldness [2]. Infertility, Type 2 diabetes, gestational diabetes, hypertension, and gynaecological cancers are found to be long-term complications of PCOS [3].

Worldwide, the prevalence of the syndrome ranges from 2.2%-26%, depending on the choice of diagnostic criteria and population being studied [4]. In India limited prevalence studies on PCOS have been conducted. Based on these data, it can be said that the occurrence of PCOS ranges from 3.7%-22.5% [5]. A large scale survey conducted in 2020 reported 16.81% incidence of PCOS among women aged 20-29 years [6]. Another cross-sectional survey identified approximately 28.5% of females diagnosed as PCOS and 40.5% of females have two or more features of PCOS. An urban community-based study in Mumbai found 22.5% of PCOS [7]. One

of the studies in south India observed 18% of young adolescent girls are with PCOS [5].

Familial history, stress, unhealthy diet, less or and lack of physical activity and lack of sleep are contributing factors to PCOS [8]. Sedentary lifestyle, access to junk food, addiction to social media and the use of complex gadgets for simple daily tasks is highly prevalent among the higher socio-economic population and is also a contributor to the rise of PCOS [9].

Many researchers have pointed out the poor quality of life in women with PCOS. Psychological morbidities like mood swings, anxiety, depression, poor body image, self-esteem, and eating disorders, are frequently observed in PCOS women. These symptoms hamper the work environment, personal and professional life which in turn leads to distress in health-related quality of life [10].

The management of PCOS addresses the associated manifestations and co-morbidities of the syndrome. Weight loss is the first recommended line of management. Healthy diet, regular physical activity, aimed to control excess weight gain, menstrual irregularities, and control of acne and hirsutism [5]. The counselling strategies on lifestyle modification encourage women positively to adapt and continue the healthy practice [8]. However, in some severe

conditions, insulin-sensitising agents and androgen blockers, along with the modified lifestyle are beneficial [9].

In the present study, the Multimodular Intervention (MMI) of lifestyle modification was used. It refers to a comprehensive approach which includes nutritional therapy, physical activity and behavioural modifications. The lifestyle is categorised as moderate (high or moderate levels of physical activity and low prohealthy diet); sedentary (low or no physical activity and low prohealthy diet); healthy (high or moderate levels of physical activity and prohealthy diet) [11].

The American College of Sports Medicine reported that 200-300 minutes of moderate exercise per week facilitates long-term maintenance of weight loss. However, the short sessions of exercises (15-30 minutes), 5 days per week have shown greater effectiveness compared with the traditional structured approach [12]. A systematic review highlights that a 3-4 month structured aerobic training programme reduces total testosterone and free androgen index and fasting insulin levels [13]. Thomson RL et al., reported that 20 weeks of aerobic-resistance exercises and an energy-restricted diet significantly improved the glucose fasting insulin, testosterone, free androgen and reproductive functions of PCOS women [10]. In view of these considerations, the pilot study was conducted to evaluate the efficacy of MMI on symptoms of PCOS, and the quality of life of women with PCOS.

## **MATERIALS AND METHODS**

A pilot study was conducted at Father Muller College of Nursing, Mangaluru, Karnataka, India, between March 2019 to December 2019. The study included 30 female diagnosed with PCOS. Ethical clearance was obtained (letter number FMMCTEC/CCM/430/2018), followed by prior permission from the hospital authorities.

**Sample size calculation:** The sample size was calculated based on the sample size determination table (95% confidence intervals,  $\pm 2.5\%$  margin of error) [14]. Total 15 subjects for the intervention group and another 15 subjects for the control group were recruited, from the Obstetrics Outpatient Department (OPD) of the two tertiary care settings, which belongs to Father Muller Medical College and Hospital.

**Inclusion criteria:** The study included women between age group of 18-30 years who have been diagnosed with PCOS by an Obstetrician.

**Exclusion criteria:** The antenatal women, postpartum women with symptoms of PCOS up to one year, surgical conditions which contraindicate exercises (fractures, cardiac diseases, musculoskeletal disorders), women with medical conditions such as (thyroid impairments, cushing syndrome, and metabolic disorders) and those who were already with similar treatment and already engaged in exercise schedule were excluded from the study.

## **Parameters**

Informed written consent was obtained from the study participants after explaining the client information sheet. A pretest was conducted; baseline proforma was used to collect the baseline characteristics of females, followed by a PCOS assessment tool was administered. This tool consists of the following information:

- Information on menstrual irregularities [15] such as amenorrhoea (absence of menstruation more than 3 months), polymenorrhoea (monthly bleeding less than 21 days), oligomeneorrhoea (bleeding occurring more than 35 days apart), regular (bleeding at 28-35 days interval).
- Body Mass Index (BMI) {World Health Organisation (WHO) Asian criteria [12]} was calculated for which weight was measured by using a digital weighing scale to the nearest 0.1 kg, which was calibrated by the Biomedical Department; while height was measured using a standard stadiometer to the nearest 0.5 cm.

- Waist-hip ratio was calculated based on WHO criteria [16].
- Acne was assessed using the Acne Global Grading Scale [17].
- Fasting Blood Glucose (FBG) was interpreted based on the American Diabetes Association- normal (<100 mg/dL), prediabetes (100 to 125 mg/dL), and diabetes (126 mg/dL or higher). The venous blood was collected in the laboratory after an overnight 8 hours of fasting [18].
- Hirsutism was assessed by using the modified Ferriman and Gallwey Scale where a score of 8 or more indicates hyperandrogenism [19].

World Health Organisation Quality of Life questionnaire (WHOQOL-BREF): The quality of life was measured by using WHOQOL- Bref tool. The tool consists of a total of 26 items. Out of it, 24 items are distributed on the four domains such as physical health, psychological health, social relationships, and environment. And one question is about the overall perceived quality of life, another one about the overall perceived satisfaction with health. Item number 21 was reworded as menstrual health from sexual life because the study involves women who have not experienced sexual life [20]. The reliability of the Kannada version was 0.56-0.95) [21], internal consistency was measured by using Cronbach's alpha (0.94).

#### **Procedure**

For the women in the interventional group, subjects were counselled for an insulin resistance diet which is composed of healthy fat, high protein, and fewer carbohydrates. The diet menu was prepared with the help of a dietician based on the BMI. Brisk walk for 30 minutes first one month followed by jogging from the month onwards for the same duration was advised. Core muscle exercises, half pushups, and four types of burpees (beginners, basic, squat thrust, and mountain climber) were demonstrated by the investigator. Subjects practiced for the first month, each exercise repeating for 10 counts; second month onwards same exercises (two sets) were continued with 5 minutes of warm-up and cool down for five days a week, with a total of 20 minutes per day. A video on exercises and the instructional booklet with detailed information on diet and prescribed exercises and a logbook was given to the subjects to document the diet and exercise on daily basis. A compliance chart was maintained by the investigator. The participants who were absent for 2<sup>nd</sup> posttest were excluded from the study. Reminders on What's App were sent to the clients as motivation. Follow-up was done every month and post-test was conducted after the 2<sup>nd</sup>,4<sup>th</sup>, and 6<sup>th</sup> months from the pretest.

Regular hospital medical treatment was continued for both intervention and control group. For the control group pretest and after the  $6^{\text{th}}$  month post-test was done. A comparison of the measurements was done.

## STATISTICAL ANALYSIS

Data were tabulated, analysed, and interpreted using descriptive and inferential statistics like frequency, percentage. Mann-Whitney test, Analysis of Variance (ANOVA), post-hoc test, and paired Eta square. IBM Statistical Package for the Social Sciences (SPSS) version 23.0 was used.

## **RESULTS**

Distribution of baseline characteristics and homogeneity of the subjects are presented in [Table/Fig-1]. Total 53% of women were aged between 21-25 years in both groups and the mean age was 24.26±3.84 years, 24.20±3.54 years in the intervention and control group, respectively. Out of 15 women in the interventional group, more than 70% of them were qualified above 12<sup>th</sup> standard in both the groups, above 65% of subjects practiced moderate type of lifestyle, and above 70 % of them did not have a family history of PCOS in the intervention and control group.

Variables	Intervention group (15)	Control group (15)	p-value (Fishers exact test)	
Mean age (years)	24.26±3.84	24.20±3.54		
18-20	2 (13.3%)	2 (13.3%)		
21-25	8 (53%)	8 (53%)	1.0	
26-30	5 (33.3%)	5 (33.3%)		
Qualification				
1st to 7th standard	0	1 (6.7%)		
8 <sup>th</sup> to 10 <sup>th</sup> standard	1 (6.7%)	1 (6.7%)	1.0	
11th to 12th standard	2 (13.3%)	2 (13.3%)	1.0	
Above 12th standard	12 (80%)	11 (73.3%)		
Lifestyle				
Sedentary	2 (13.3%)	4 (26.7%)		
Moderate	11 (73.3%)	10 (66.7%)	0.717	
Healthy	2 (13.3%)	1 (6.7%)		
Residence				
Urban	10 (66.7%)	9 (60%)	0.7005	
Rural	5 (33.3%)	6 (40%)	0.7095	
Menarche (years)				
10-12	3 (20%)	7 (46.7%)	0.1077	
13-15	12 (80%)	8 (53.3%)	0.1277	
Family history of PCOS				
Yes	2 (13.3%)	4 (26.7%)	0.051	
No	13 (86.7%)	11 (73.3%)	0.651	
[Table/Fig-1]: Distribution of baseline characteristics and homogeneity of the subjects.				

Assessment of symptoms of PCOS in various time points are presented in [Table/Fig-2], shows the steady improvement in menstruation pattern, Body Mass Index, (BMI) waist-hip ratio, acne, and FBS scores in the intervention group after 6 months comparing to control group.

The [Table/Fig-3] shows the quality of life of women in each domain is considerably increased (p-value <0.001).

		Intervention group		Control	
Symptom	Pretest N (%)	6 <sup>th</sup> month N (%)	Pretest N (%)	6 <sup>th</sup> month N (%)	
Menstrual pattern					
Regular	3 (20%)	12 (80%)	5 (33.3%)	5 (33.3%)	
Amenorrhea	6 (40%)	2 (13.3%)	7 (46.7%)	4 (26.7%)	
Polymenorrhea	4 (26.7%)	0 (0%)	0 (0%)	1 (6.7%)	
Oligomeneorrhoea	2 (13.3%)	1 (6.7%)	3 (20%)	5 (33.3)	
Body mass index					
Underweight	5 (33.3%)	1 (6.7%)	3 (20%)	3 (20%)	
Normal	1 (6.7 %)	10 (66.7%	3 (20%)	3 (20%)	
Overweight	3 (20%)	2 (13.3%)	2 (13.3%)	3 (20%)	
Obese	6 (40%)	2(13.3%)	7 (46.7%)	6 (40%)	
Waist-hip ratio					
0.85	3 (20%)	11 (73.3%)	7 (46.7%)	6 (40%)	
>0.85	12 (80%)	4 (26.7%)	8 (53.3%)	9 (60%)	
Hirsutism					
<8	3 ( 20%)	3 (20%)	5 (33.3%)	5 (33.3%)	
≥8	12 (80%)	12 (80%)	10 (66.7%)	10 (66.7%)	
Acne					
Mild	14 (93.3%)	15 (100%)	15 (100%)	15 (100%)	
Moderate	1 (6.7%)	0	0	0	
Fasting blood sugar					
Normal	10 (66.7%)	14 (93.3%)	10 (66.7%)	12 (80%)	
Prediabetes	5 (33.3%)	1 (6.7%)	5 (33.3%)	3 (20%)	
[Table/Fig-2]: Assessment of symptoms of PCOS at various time points.					

	Intervention group					
Domains	Before intervention	2 months Mean±SD	4 months Mean±SD	6 months Mean±SD	p1 value	p2 value
Physical health	21.00± 2.59	22.73± 2.81	23.67± 2.79	24.00± 3.05	0.001	0.013
Psychological health	18.13± 3.04	19.13± 2.77	21.60± 3.98	22.67± 4.03	0.001	0.004
Social relationships	9.27± 1.67	10.00± 1.81	12.13± 1.64	12.20± 1.74	0.001	0.001
Environmental health	23.00± 3.66	25.20± 4.93	27.27± 5.90	28.07± 6.71	0.001	0.019

[Table/Fig-3]: Domain-wise comparison of quality of life within the intervention group at various time points.

The [Table/Fig-4] shows that the subjects' perception on QOL and satisfaction with health is improved after the interventions (p-value <0.001).

	Intervention group					
Variables	Before intervention	2 months Mean±SD	4 months Mean±SD	6 months Mean±SD	p1 value	p2 value
Perception of QOL	11.33±8.10	11.40± 7.61	13.07± 8.68	13.93± 9.46	0.001	0.005
Satisfaction with health	5.80±3.45	6.40±3.48	8.40±4.07	8.47±4.00	0.001	0.001

[Table/Fig-4]: Comparison of the overall perception of the quality of life and satisfaction with health within the intervention group at various time points. p1-intragroup (ANOVA), p2-intergroup (Bonferroni test)

The [Table/Fig-5] shows the improvement waist hip ratio (p-value <0.003), hirsutism (p-value <0.001), and acne (p-value <0.008) within the group at various time points. A significant difference is noticed between pretest and post-test 3 values of hirsutism (p-value <0.036).

	Intervention group					
Symptoms	Before intervention	2 months Mean±SD	4 months Mean±SD	6 months Mean±SD	p1 value	p2 value
Body mass index	23.39± 6.16	23.03± 5.34	22.54± 4.80	22.30± 4.64	0.109	0.893
Waist-hip ratio	0.90±0.07	0.89±0.07	0.87±0.03	0.87±0.03	0.003	0.159
Hirsutism	13.93± 8.71	14.00± 8.47	12.53± 8.03	12.27± 7.68	0.001	0.036
Acne	12.00± 6.23	11.67± 5.19	10.27± 4.92	9.67±4.39	0.008	0.030
Fasting blood sugar	95.00± 8.61	91.41± 6.50	92.67± 6.29	85.93± 21.22	0.121	0.556

**[Table/Fig-5]:** Comparison of scores of symptoms of PCOS within the group at various time points. p1-intragroup (ANOVA), p2-intergroup (Bonferroni test)

[Table/Fig-6] depicts the significant difference in the waist-hip ratio p-value=0.001 and hirsutism p-value=0.022 after the intervention compared to the control group.

[Table/Fig-7] shows a highly significant difference in all domains of quality of life in the intervention group, while there was no improvement in the control group after 6 months.

[Table/Fig-8] shows a highly significant difference in the perception towards the quality of life and satisfaction with health in the intervention group, whereas the scores of the control group remained stable after six months.

Karl Pearson's correlation showed a moderately strong positive relationship between BMI and satisfaction with health (r=0. 568, p-value <0.027) and waist-hip ratio (r=0.521, p-value <0.046) in the intervention group.

The statistical test MANOVA showed the association of BMI with menarche (p-value <0.033) and qualification (p-value <0.014) in the intervention group, whereas, in the control group the association

Parameters	Group	Paired difference Mean±SD	Mann Whitney test Z value	p- value	
Body mass	Interventional	1.09±2.76	1.011	0.070	
index	Control	-0.53±1.75	1.811	0.070	
Waist-hip	Interventional	0.04±0.06	0.000	0.004	
ratio	Control	-0.01±0.02	3.328	0.001	
Fasting	Interventional	9.07±19.46	1 400	0.151	
blood sugar	Control	0.93±10.21	1.438		
I the state of	Interventional	1.67±2.61	0.000	0.000	
Hirsutism	Control	0.00±1.13	2.296	0.022	
Acne	Interventional	2.33±3.50	1.710		
	Control	0.47±3.20	1.712	0.087	

[Table/Fig-6]: Comparison of post-test scores of PCOS symptoms. (post-test is 6th month)

Parameters	Group	Paired difference Mean±SD	Mann Whitney test Z value	p- value	
Dby sign booth	Intervention	-3.00±3.12	2.645	0.008	
Physical health	Control	0.60±2.32	2.045	0.008	
Psychological	Intervention	-4.53±3.98	3.627	0.000	
health	Control	1.07±2.55	3.027	0.000	
Social	Intervention	-2.93±2.12	2.982	0.003	
relationships	Control	1.00±6.22	2.962	0.003	
Environmental	Intervention	-5.07±5.52	0.500	0.010	
health	Control	0.60±3.44	2.566	0.010	

[Table/Fig-7]: Comparison of post-test scores of quality of life (domain wise) N=15+15. (post-test is 6<sup>th</sup> month)

Parameters	Group	Paired difference Mean±SD	Mann Whitney test Z value	p- value
Ovality of life	Intervention	-2.60±3.29	3.247	0.001
Quality of life	Control	-0.13±0.52	3.247	0.001
0-4-6-4	Intervention	-2.67±1.68	0.050	0.004
Satisfaction	Control	-0.07±0.70	3.953	0.001

**[Table/Fig-8]:** Comparison of post-test scores of perceptions of the quality of life and satisfaction with health N=15+15. (post-test is 6<sup>th</sup> month)

was observed with a family history of PCOS (p-value <0.038) and BMI ( $\eta^2$ =0.541).

# **DISCUSSION**

Lifestyle reform is forefront in the management of PCOS symptoms. Healthy diet and physical exercise regimes are an excellent rehabilitation in mitigating PCOS signs and related metabolic illnesses. Additionally, these regimes had highlighted positive results in improving holistic health of women with this the disorder.

This study was focussed to reduce the symptoms and improve the quality of life of women with PCOS after administering the MMIs of lifestyle modification. Overall, this study revealed a statistically and clinically significant improvement in reducing PCOS symptomology and quality of life.

The efficacy of MMI was more evident in reducing waist-hip ratio  $\{df(3,42)=5.304, hirsutism df(3,42)=6.853, and acne df(3,42)=4.497, p-value<0.001\}, within the intervention group over 6 months. Moreover, 80% of women had menstrual irregularity, 33.3% were prediabetes and only 6.7% of them were with normal BMI before intervention. After 6 months of interventions 80% attained regular menstruation, 13.3% of subjects remained as prediabetes and 66.7% achieved normal BMI compared with control group. These findings were congruent with the trial outcomes conducted by Arentz S et al., [22]. They found improvement in the menstrual cycle, BMI and fasting insulin (p-value <0.001). Another study by Jiskoot G et al., supports the finding of the current study [23].$ 

In the present study, the  $\eta^2$  values (0.373 -0.641) in each domain of quality of life showed improved after the 6 months of MMI administration in the intervention group. The p-values (p-value <0.001), denote highly significant influence of MMI on enhancing quality of life comparing to control group. Several research studies have reported that the lifestyle modification will improve the quality of life of women with PCOS [21]. Ramya R et al., conducted a hospital-based intervention for 6 months on women suffering from PCOS, used WHOQOL-Bref tool and found increased quality of life in each domain in the post-test [24]. Evidences show that the lifestyle modification is the prime need of women with PCOS to improve the physical, clinical, and metabolic parameters and heighten the quality of life [25].

#### Limitation(s)

Even though exercise had a good effect on the PCOS symptoms and quality of life there was some drawback in the study. The study outcomes were limited to physical, clinical parameters and quality of life of women. Further studies can be done on various pattern of exercises which in moderate intensity will help to control the physical signs, clinical and metabolic parameters of women with PCOS.

## CONCLUSION(S)

The PCOS is one of the reproductive health problems faced by the females. The quality of life is significantly lower in females with PCOS in comparison to healthy women. The lifestyle modification remains as utmost priority in women to sustain good reproductive health. The current study has demonstrated its efficacy on a small sample. Nevertheless, this information can be used for better patient outcomes by clinicians, nurses and paramedical personnel when they encounter the PCOS female.

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