Effect of Lifestyle Modifications on Polycystic Ovarian Syndrome Symptoms

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Abstract: Polycystic ovary syndrome (PCOS) is a complex heterogeneous endocrine disorder associated with reproductive morbidity, including menstrual dysfunction and infertility. A comparative prospective intervention study aimed at assessing the effect of lifestyle modification on polycystic ovary syndrome and assessing the effect of exercise and nutritional counseling (EN) compared to nutritional counseling (N) only on PCOS symptoms. The study was conducted in outpatient gynecological/infertility clinic at Ain Shams Maternity University hospital, from 1st March 2011 to 1st May 2012. Purposive sample of 72 cases were enrolled at the beginning. The attraction rate was 11.1%, and 64 cases completed the study. Tools used for data collection consisted of Arabic Structured Interviewing questionnaire, Psychological quality of life assessment tool, Two Arabic Weekly log to record regularity of diet & exercise, Woman's follow up card to record measures changes pre/post intervention and. the intervention consisted of counseling session and distribution of Arabic leaflet to the participants. Post test assessment was conducted after 6 months. Results revealed that there is a significant improvements in menstrual frequency, problems and weight loss. Also significant decreases in waist and hip girth. A trend towards an improved hormonal profile, fasting insulin level & free testosterone occurred. There is a significant reduction in hirsutism total score. However, there were no significant differences the improvement between the (N & EN) groups . In conclusion the present study drew attention that lifestyle modification with weight loss leads to improved hormonal profile, which restores ovulation the best initial management for overweight & obese women seeking to improve their reproductive function. The study recommended didactic center for PCOS cases inside infertility/gynecological clinics to ensure lifestyle modification, Future research should focus on the optimal dietary strategies and exercise regimens for PCOS treatment and the relative efficacy and appropriate use of lifestyle management versus anti-obesity pharmacologic agents and surgery, further research on larger sample size.

1. Introduction

Polycystic ovarian syndrome (PCOS) is a complex hormonal disturbance with numerous implications for general health and well-being. It is the most common endocrine gland disorder in women of reproductive age and has a prevalence of 5-10 per cent in this group. However, many women remain undiagnosed or are misdiagnosed as having other conditions such as premenstrual syndrome. PCOS is a health problem that can affect a woman's menstrual cycle, ability to have children, hormones, heart, blood vessels, and appearance. Doctors say that 1 out of 10 women suffer from PCOS in today's world and the exact reason for the disease is still unknown. The syndrome usually presents at puberty, with irregular or absent periods. As the term polycystic ovary syndrome suggests, the syndrome often is accompanied by enlarged ovaries containing multiple small painless "cysts" or tiny follicles about 1/4 to 1/2 inch in diameter. A "polycystic" ovary generally is defined as having more than 12 small cysts, or being of increased size, sometimes called Stein-Leventhal syndrome; Polyfollicular ovarian disease. *(Perb., 2004)*

No one is quite sure what causes of PCOS, and it is likely to be the result of a number of both genetic (inherited) as well as environmental factors. Women with PCOS often have a mother or sister with the condition, and researchers are examining the role that genetics or gene mutations might play in its development. (*Taylor, & Dunai., 2000*)

In women with PCOS, however, high levels of hormones called androgens halt the normal hormonal process and the egg's development. These halted or arrested follicles--whose appearance (via an ultrasound) is sometimes likened to a string of pearls--form the "cysts" observed in PCOS. The symptoms of PCOS may begin in adolescence with menstrual irregularities, or a woman may not know she has PCOS until later in life when symptoms and/or infertility occur *(Michael., 2004)*

The principal signs and symptoms of PCOS are related to menstrual disturbances and elevated levels of male hormones (androgens). Menstrual disturbances can include delay of normal menstruation (primary amenorrhea), the presence of fewer than normal menstrual periods (oligomenorrhea), or the absence of

menstruation for more than three months (secondary amenorrhea). Menstrual cycles may not be associated with ovulation (anovulatory cycles) and may result in heavy bleeding. Symptoms related to elevated androgen levels include acne, excess hair growth on the body (hirsutism), and male-pattern hair loss. Other signs and symptoms of PCOS include: obesity and weight gain, elevated insulin levels and insulin resistance, oily skin, infertility, skin discolorations, high cholesterol levels, elevated blood pressure, and multiple, small cysts in the ovaries. *(Lord et al., 2003)*

Any of the above symptoms and signs may be absent in PCOS, with the exception of irregular or no menstrual periods. All women with PCOS will have irregular or no menstrual periods. Women who have PCOS do not regularly ovulate; that is, they do not release an egg every month. This is why they do not have regular periods and typically have difficulty conceiving. There appears to be higher rates of miscarriage, gestational diabetes, pregnancy-induced high blood pressure and premature delivery in women with PCOS. *(Aaron & Sue, 2009-2010).*

The diagnosis is based on the patient's symptoms and physical appearance. If the diagnosis seems likely because the patient's history contains many of the symptoms described already, certain investigations are done to provide confirmatory evidence or to indicate another cause for the symptoms. These include: blood tests such as: female sex hormones (estrogen/progesterone at a certain point in the cycle if possible). Trans-vaginal ultrasound is a sensitive and specific tool for detecting PCO. Assessing the levels of active androgens includes measuring free testosterone and calculating the free androgen index. Measuring dehydroepiandrosterone (DHEA) and DHEA with sulfate ester may also be helpful**. *(Hunter & Sterrett, 2004)***

There is no cure for PCOS. Health care professionals usually address the most bothersome symptoms. Health care professionals rarely remove these benign cysts, usually opting to prescribe lifestyle modifications and medication to treat symptoms. Regular exercise, healthy foods & weight control are key treatments for PCOS. Intake of starches and grains increases the insulin content in the body thus leading to triggering of the hormone called androgen which causes PCOS, rich proteins and healthy fats which balance the fatty acids and vitamins percentage inside the body. Diet like meats, eggs, diary products, green leafy vegetables contain magnesium and vitamins in large quantity help to restore the lost minerals and vitamins in the body. Since Stress and depressions may also aggravate PCOS, it can be reduced by doing some exercises regularly, yoga and also meditation. Nurses should be aware of the various agencies that offer further advice and support. Counseling and follow-up

should also be made available to all women with PCOS *(Norman, 2004 & Lobo, 2007)*

Health care professionals including nurses need an in-depth understanding of the condition, its pathophysiology, diagnostic measures and symptom management. Women presenting with menstrual irregularities should be encouraged to monitor their symptoms as this will help in the diagnosis of possible PCOS. Once diagnosis has been confirmed, nurses need to ensure patients receive adequate written information, such as leaflets, to clarify issues discussed on initial diagnosis *(Radosh, 2009).* The first step in managing PCOS is to get regular exercise and eat heart-healthy foods. As a diet regimen is one of the main treatments for PCOS, a referral to a dietitian should be discussed once diagnosis has been confirmed. A suitable exercise regimen should also be discussed, and the importance of both diet and exercise should be explained to the patient. Psychological support is vital, particularly on initial diagnosis**.** *(Ann, 2005)*

Justification of the study:

As there is no cure for PCOS except surgery, the management of PCOS is directed towards improving the women's quality of life by means of symptomatic alleviation. Women with Polycystic ovary syndrome face serious physical & psychological problems, if not resolved well, through early intervention for life style modifications and the use of various counseling program on psychological adaptation on changes associated with polycystic ovary syndrome. This can also provide support for women dealing with negative self-image secondary to physical manifestation of PCOS & build their coping skills *(Hoeger, 2006).* Much research was done in this area of interest but no specific research was done to deal with the impact of lifestyle modifications including stress management on PCOS symptoms, there is no researches tackled this issue in Egypt the current study tries to explore this issue among Egyptian women.

Aim of the study:
Objectives of the study are;

Primary objective to assess the effect of lifestyle modifications on hormonal, menstrual, and reproductive function of women with PCOS.

Secondary objective to compare the effect of exercise and nutritional counseling (EN) versus to nutritional counseling (N) only.

Study Questions:

What is the effect of lifestyle modifications on PCOS symptoms?

Is exercise and nutritional counseling effective as nutritional counseling only on relieving PCOS symptoms?

2.Subject and Methods:
### Study Design, Site, and Sampling:

A comparative prospective intervention study was conducted in the Department of obstetrics and gynecology (outpatient gynecological/infertility clinic) at Ain Shams Maternity University hospital, from 1st March 2011 to 1st May 2012. Data were collected 1 day/ week starting from 10 am to 2 pm. The Preparation phase started from March 2011 to May 2011 (literature review & designing tools), followed by ten months implementation phase from June 2011 to March 2012 (data collection, intervention & follow up for intervention) and two months for data analysis and results discussion.

The sample size was calculated using Simple Interactive Statistical Analysis online. With a power of 80% and at Alpha equals 0.05, a of minimum 57 cases had to be included to catch a significant change in fasting insulin level after the intervention. Purposive sample technique was used to enroll 72 patients with PCOS. Patients were fulfilling the following criteria;

diagnosed with PCOS, at reproductive age (15-49), can read and write, a history of irregular menstrual cycles for more than 12 months, their body mass index (BMI) exceeds 25, nonsmokers, non-pregnant, taking no medications and had no endocrine disease or medical conditions.

The 72 cases were assignment randomly into 2 groups, 36 women went through exercise and nutritional (EN) counseling. The other group 36 women went through nutritional counseling (N) only. Both groups were followed to insure compliance to exercise and nutritional regimes throughout the study period 6 months.

8 cases (5 from EN group and 3 from N group) dropped out throughout the study; (6) cases become pregnant, there were three pregnancies in each arm of the study within 4 - 6 months of commencing. The total numbers of conceptions in the EN group (3) and the N group (3) cases. The rest (2) cases had complications of diet (anemia) in EN group. So the reminder number of cases (valid cases) is 64.
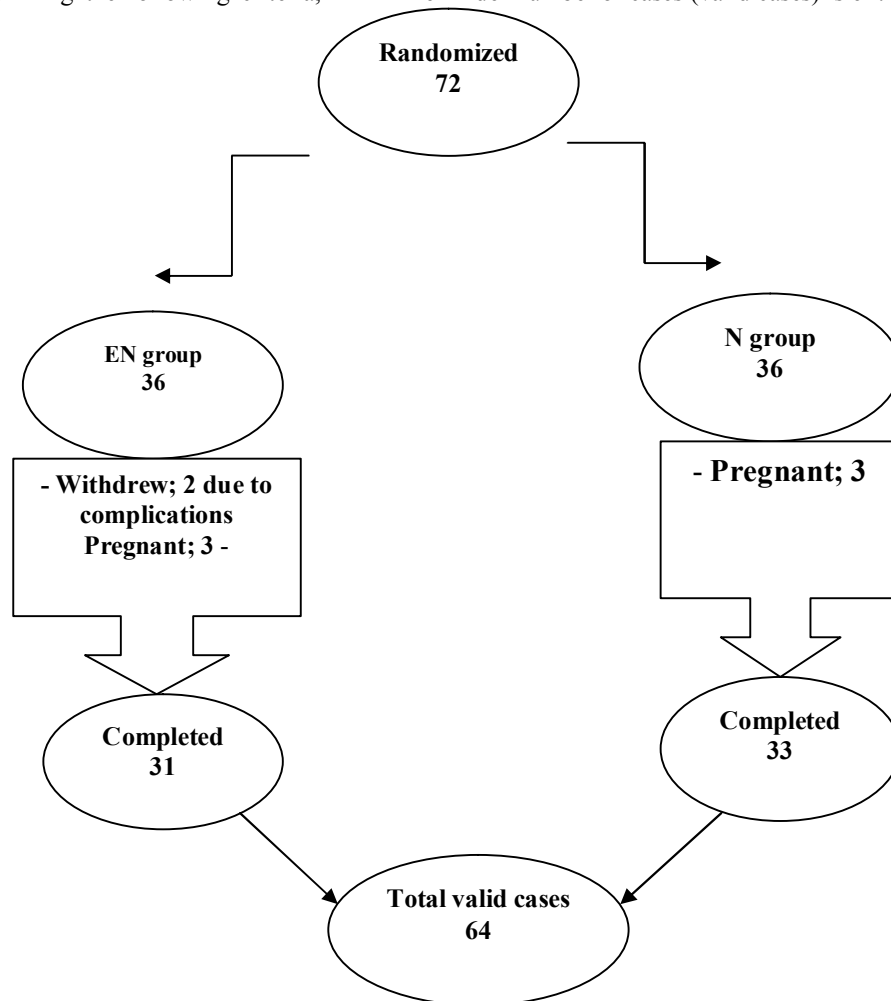
Tools of the study:

Four types of tools were used for data collection and conduction of the study. These consisted of structured interviewing questionnaire, Psychological quality of life assessment tool, weekly log and woman's follow up card, in addition to an Arabic leaflet. Before data collection, the tools were tested on 7 women those were excluded in the main study sample. the aim was to evaluate the simplicity and clarity of the tools. It also helped in the estimation of the time needed to fill in the forms. According to the results of this test, modifications were done. These tools were reviewed by jury of expertise in the field of obstetric and gynecological medicine and nursing, to test its contents and face accurately.

1. Arabic Structured Interviewing Questionnaire:

The questionnaire was designed by the research team after reviewing the related literature. The tool which included 29 questions, close-ended questions and was divided into three parts: **Part I:** It covered the general characteristics of the sample as personal identification, and demographic data. **Part II:** This part is concerned with women menstrual, reproductive/ gynecological history. **Part III:** This part is concerned with women lifestyle habits; number of meal/day, components of meal, consumption of caffeine, dealing with stressors…

2. Psychological quality of life assessment tool (cronin, et al., 1998;

Guyatt, *et al.,* **2004):** It issued to assess women's psychological Health related quality of life level before & after intervention. The scale used to evaluate the impact of problems associated with PCOS upon psychological correlates quality of life. It was translated to Arabic language and reviewed by jury. (It consists of 12 statements every woman had three responses for each statement to choose from, No problem, some problem, Sever problem , the scoring was done according to the following as women with Sever problem response were scored 1, women with some problem response were scored 2 and women with No problem response were scored 3.Then Total women calculated the score ranged from (12-36);women with total score from (1-12)were specified as leaving poor psychological QOL , women with total score from (>12-24) were specified as leaving average psychological QOL and women with total score from (>24-36)were specified as leaving good psychological QOL)

3- Two Arabic Weekly log:

Arabic Weekly log was used by researcher to follow the compliance of the study subject to the E & N regimen; one log to record how many minutes women exercised per week and type of exercise. The other to record the regularity of program diet.

4- Woman's follow up card:

Researchers' constructed Arabic card to assess the outcome measures: (i) change in menstrual cycle; (ii) change in anthropometric measurements (body mass index (BMI) (normal 19-24 kg), and waist and hip circumference / waist and hip ratio).; and (iii) changes in the endocrine parameters, insulin sensitivity (fasting insulin concentration and serum endocrinology for testosterone); (iv) change in hirsutism. (*Assessment of degree of hirsutism:* This was done by means of *Ferriman and Gallwey scoring system, 1961*.This system grades hair growth over nine body areas from 1-4, which quantifies the extent of hair growth in nine anatomical sites, scoring 0 (no hair) to 4 (maximal growth), with a maximum score of 36; personal perception of reduction in hirsutism; effects of intervention.

5- Educational Arabic leaflet:

Educational Arabic leaflet constructed by the principle investigator, was distributed to guide the women. The leaflet included concept, symptoms, diagnosis, long-term health risks of PCOS and lifestyle modifications to relieve PCOS.

Administrative Design And Ethical Considerations:

An official approval was obtained from the Maternal & Neonatal Health Nursing department counsels that were approved by the Faculty of Nursing, Ain Shams University Counsel. The aim of the study was explained to each woman before applying the tools . An oral consent was obtained from each woman to participate in the study, after ensuring that data collected will be treated confidentially. Women were informed that they have the right to withdraw from the study at any time without giving a reason.

Intervention:

Phase 1: there was introductory phase for researchers with cases to explain the aim of study and obtain the oral approval to participate in the study. Every case was interviewed to assess women personal, menstrual, reproductive and gynecological history, in addition to follow up card was used to assess baseline measures related to PCOS in a time ranged from 10 to 15 at from the first session.

Phase 2: group of cases were gathered for blood sample to assess hormonal baseline profile by trained nurses. The samples were transported to laboratory (Royal Lab) in coded serum containers.

Phase 3: Then the education session was done on groups for a mean duration of 25 minutes range (20-30 min) for group one (EN) and a mean of 20 minutes range (15-25 min) for group 2 (N).

The education session was conducted on small groups (4-5 subjects) with an emphasis on Lifestyle modifications; stress management with dietary and exercise interventions or with dietary intervention only. (NE) group was asked to follow the following

instructions: Moderate exercise on a regular basis (≥30 min/day) e.g Aerobic exercise &/or walking. Dietary modification, heart-healthy diet/an energy-restricted diet (1200-1600 kcal/day according to cases' weight) through either a low or high protein diet) e.g increase vegetables, fruits, nuts, beans, and whole grains, limits foods that are high in saturated fat, such as meats, cheeses, and fried foods. (fat ≤30% daily intake, decrease saturated fat and glycaemic load, increase fibers and polyunsaturated fat). Reduction the effect of psychosocial stressors through stress management by relaxation technique, & dealing with stressors. (N) group asked to follow the previous instructions except daily exercises. **An educational Arabic leaflet** constructed by the principle investigator, reviewed and modified by gynecologist, nutritionist and mental health professional was distributed after instructions to guide the women.

Phase 4: Weekly follow up was done by telephone & meeting in outpatient clinics. The follow up regularity were recorded in Two Arabic Weekly log; one to record how many minutes women exercised per week and type of exercise and the other to record the regularity of program diet, to ensure program diet & exercise. Reinstruction & referral for nutritionist/gynecologist if indicated. A home phone call system was used to facilitate follow up and tracing cases.

Phase 5: After 6 months, researchers evaluated the women anthropometry measures, menstrual cycle, selected hormones; fasting insulin & free testosterone levels (a blood sample was took using the same technique as in the baseline assessment), and change in hirsutism.

Statistical analysis:

Data entry and statistical analysis were done using Statistical Packages for Social Science version 18 (PASW). Quality control was done at the stages of coding and data entry. Data were presented using descriptive statistics in the form of frequencies and percentages for qualitative variables, and means and standard deviations for quantitative variables. Qualitative/quantitative variables were compared using MacNemar for the qualitative variable, while paired t-test, & Pearson Correlation coefficient test for quantitative variable. Statistical significance was considered at p-value <0.05, highly significant difference obtained at $p < 0.0l$ and non significant difference obtained at $p > 0.05$.

3. Results:
Table (1)

This table reveals the socio-demographic characteristics of the subjects under study. The women age ranged between <25 – >35 (18-47 yr) with mean age 28.7 (± 6.7). Married women represented 87.5 % of the studies sample with mean duration of marriage (4.2 ± 3.5 years). 37.5% of the studied females completed their secondary education , while 32.8% of them had low education and 29.7% only completed their university education. Working females represented 32.8 % of the studied sample.

Table (2)

This table shows that the mean sample age of menarche is 13.0 (± 1.1), their mean duration of menstrual rhythm is 51.1 (± 26.0) days, while the menstrual duration has a mean of 5.0 (± 1.4) days. Concerning duration of PCOS among the studied sample; 1-5 years, less than 1 year, more than 5 years represented 39.1 %, 34.9 %, 25.0 % respectively. 60.9 % of the studied sample seeks medical consultation. About half (54.7 %) of the studied sample have PCOS cases in their families.

Figure (2)

The regularity of the menstrual cycle over the time-course of the study increased; both groups (N &EN) shows significant improvements in menstrual frequency and notes significant reduction in menstrual problems.

Figure (3)

This figure shows significant changes in lifestyle habits which have an impact on psychological measures as decrease caffeine consumption, practice sport & using one or more of the intervention measures (relaxation technique, ventilation, facing problems……..)

Table (3)

This table illustrates that the mean number of pregnancy among the study sample is 1.9 (±1.0), 55.3 % of ever pregnant women suffered from pregnancy complications. While the mean number of delivery is 1.6 (± 0.8), 12.9 % of ever delivered women suffered from delivery complications. The mean number of children among married women is 1.6 (± 0.8).

Table (4) & Table (5)

This table reveals at the end of the study period, highly significant improvement post intervention than pre intervention regarding PCOS indicators, in which the mean score related each item decreased in post than pre. There is a significant decrease in weight loss in terms of BMI, waist and hip girth. A trend towards an improved hormonal profile, fasting insulin level ($p = 0.000$) & free testosterone ($p = 0.035$) occurred in both groups. There is a significant reduction in hirsutism total score ($p = 0.000$). However, the improvement with insignificant difference between 2 groups.

Table (6)

This table confirmed a significant strong positive correlation between the drop in BMI score and both testosterone level (r= 0.81; $p < 0.001$), and insulin level (r=0.76; $P < 0.001$). The reduction in hirsutism total

score is moderately correlated (r= 0.58; *p* <0.001) with the change in the BMI (*p* <0.001).

Table (1): General Characteristics of the Study Sample

General Characteristics	(n =64)	
	No	%
Age in completed years		
• < 25	20	31.3
• 25- 35	35	54.7
• > 35	9	14.1
Mean age ± SD	28.7 (±6.7)	
Marital status		
• Single	8	12.5
• Married	56	87.5
Duration of marriage (n= 56) Mean years ± SD	4.2 (±3.5)	
Education		
• Low education	21	32.8
• Secondary education	24	37.5
• University education	19	29.7
Occupation		
• Housewife	43	67.2
• Working for cash	15	23.4
• Student	6	9.4

Table (2): Menstrual & gynecological history of the study sample

Items	(n =64)	
	No	%
Menarche Mean age ± SD	13 (±1.1)	
Menstrual rhythm Mean days ± SD	51.1 (±26.0)	
Menstrual duration Mean days ± SD	5.0 (±1.4)	
Family history of diabetes	16	25.0
Family history of PCOS	35	54.7
Duration of PCOS		
• Less than 1 year	22	34.9
• 1-5 year	25	39.1
• More than 5 year	16	25.0
Reaction to PCOS symptoms		
• Medical consultation	39	60.9
• Relative consultation	12	18.8
• Nothing	13	10.3

Table (3): Obstetrical history of married women (n= 56)

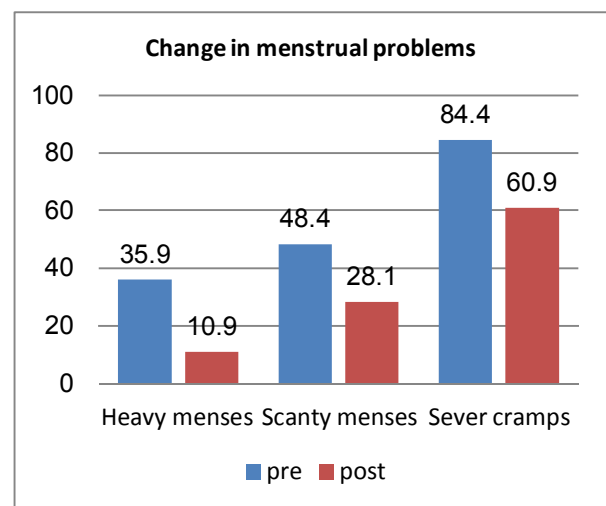| Items	No	%
Number of pregnancy (n=38) Mean ± SD	1.9 (±1.0)	
Previous pregnancy complications (n=38)	21	55.3
Number of delivery (n=31) Mean ± SD	1.6 (±0.8)	
Previous delivery complications (n=31)	4	12.9
Number of children (n=31) Mean ± SD	1.6 (±0.8)	

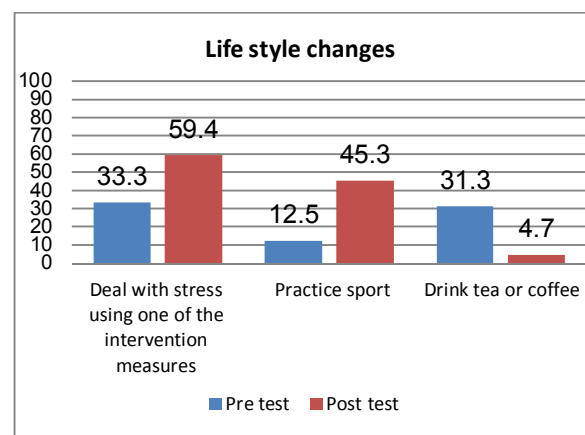**Figure (2): Change in menstrual problems pre & post intervention**

Figure (3): Change in lifestyle habits pre & post intervention

Table (4): change in PCOS indicators of the study sam ple pre & post intervention

Items	Pre-Intervention (n= 64)%	Post-Intervention (n=64)%	*P* value
Weight loss			
• BMI (Mean ± SD)	33.8 (±5.6)	30.4 (±5.1)	0.000
% obese/ morbid obese (BMI 30+)	49 (76.6%)	28 (43.8%)	0.000
• Waist circumference (Mean±SD)	95.8 (±10.3)	88.1 (±8.2)	0.000
% high risk waist (88+ cm)	51 (79.7%)	31 (48.4%)	0.000
• Hip circumference (Mean±SD)	112.5 (±10.5)	104.3 (±9.3)	0.000
• Waist and hip ratio (Mean±SD)	0.85 (± 0.06)	0.85 (±0.05)	0.288
Investigations			
• Fasting insulin concentration **uIU/ml** (Mean±SD)	6.9 (±1.8)	6.2 (2.0)	0.000
• Free testosterone **pg/ml** (Mean±SD)	3.2(±0.9)	2.7 (±1.0)	0.035
Hirsutism total score (Mean±SD)	13.1 (±6.5)	10.5 (±5.2)	0.000

Table (5): Comparison between the change in PCOS indictors in (diet and ex) group versus (diet only).

	Mean (±SD) change in Diet and Ex group **(n=31)**	Mean (±SD) change in Diet Only **(n=33)**	*P*-value
BMI	-3.5 (±1.5)	-3.4 (± 1.7)	0.689
Waist circumference	-7.9 (±5.0)	-7.4 (±5.6)	0.669
Hip Circumference	-9.3 (±5.1)	-7.3 (±5.7)	0.148
Waist Hip ratio	0.0016(±0.05)	-0.0099 (±0.04)	0.457
Insulin level	-0.88 (±1.1)	-0.53 (±0.6)	0.114
Testosterone level	-0.63 (±0.6)	-0.49 (±0.4)	0.331
Hirsuitism score	-2.2 (±2.2)	-3.2 (±3.4)	0.184

Table (6): Correlation between change in the BMI (post- pre) score and change in the indicators

Items	Pearson Correlation coefficient	*P*-value
Change in insulin level	0.76	0.000
Change in Testosterone level	0.81	0.000
Change in Hirsutism score	0.58	0.000

4. Discussion:

Polycystic ovarian syndrome cannot be cured except surgery; however, it can be managed to the point where symptoms no longer manifest (or are at least less severe). Unfortunately, excess weight can further aggravate insulin resistance and hormonal imbalances. As these are key symptoms of PCOS, sufferers may find it quite difficult to lose weight. This can cause the symptoms to progressively become more severe if weight continues to increase and the disorder is left untreated. A healthy lifestyle will still help improve fertility and symptom severity in these cases. Lifestyle modification programs with an emphasis on behavioral management and dietary and exercise interventions have been successful in improving menstrual and reproductive features in PCOS. Keeping a healthy weight by eating healthy foods and exercising is another way women can help manage PCOS *(Reaven., 2005& Tang et al., 2006)*

There are still research questions to be answered especially on the role of exercise and behavioral strategies to improve the feasibility and sustainability of lifestyle change. In support to the previous concepts the research team designed the present study.

The present results showed the women compliance as nearly all of the study women followed the diet (an energy-restricted diet 1200-1600 kcal/day according to case's weight), half of them followed stress management & third of them followed exercise regimen on a regular basis (≥30 min/day). This compliance for 6 months resulted in significant reduction in their anthropometric measures/weight loss; 78 % of the study sample was obese, the intervention decreased this percent to 44 %, this means that the intervention successes to decrease the percentage of obesity by 34 percentage point. This may be explained by the fact that the majority of women had a wish to conceive and may therefore have had a greater incentive to adhere to the protocol.

Weight loss for PCOS sufferers may be difficult, but it's not impossible. A combination of regular cardiovascular exercise and resistance training is recommended. At least three to four times per week for at least 30 minutes each session will help to keep body fat low. On trial to compare the effectiveness of exercise and nutritional counseling (EN) versus nutritional counseling (N) only on hormonal, menstrual, and reproductive function on women with PCOS. Our study found no significant difference between the 2 groups. Both groups showed significant improvements in anthropometric measures and PCOS features. Similar to several studies have attempted to establish

the role of exercise *(Bruner et al., 2006)* in the treatment of obese PCOS patients. None found significant differences when different diets, associated or not with exercise, were compared.

The results of this study support the hypothesis that it is possible to improve menstrual function and fertility in overweight/obese women with PCOS. By using a lifestyle program that sets realistic weight loss and exercise goals, subjects were able to sustain an improvement in carbohydrate metabolism over a 6-month period and hence improve their likelihood of pregnancy, 6 cases out of 72 enrolled got pregnant. Following the 6 month intervention, the instruction done at the present study showed direct positive effect on women menstrual & reproductive features. The regularity of the menstrual cycle over the time-course of the study increased; both groups (N &EN) shows significant improvements in menstrual frequency and significant reduction in menstrual problems. As well as 6 (10.7 %) out of 56 married women become pregnant (three cases in each arm of the study).

In the study by *Kiddy et al., 1992* discussed earlier, about 40% of obese women with PCOS who lost >5% of initial body weight with caloric restriction achieved spontaneous pregnancy. Another trial *Moran et al., 2003* compared the effects of an energy-restricted diet (~1400 kcal/day) through either a low or high protein diet in 28 obese PCOS subjects over 12 weeks. Subjects were also advised to increase exercise to a minimum of 3 times weekly though no information was reported as to the actual duration and/or intensity achieved. Average weight loss was 7.5% (with abdominal fat decreasing 12.5%), and 3 of the 20 subjects actively trying to conceive did so (two in the high and one in the low-protein group) for a rate of 15%. Thus, lifestyle modification needs to be stressed in the treatment of infertility. Similarly, the study done by *Tang et al., 2006* who reported that weight loss alone through lifestyle changes improves menstrual frequency & ovulation.

Investigating other indicators of PCOS feature improvement, the present finding revealed significant decrease in free testosterone and insulin levels occurred in both groups of intervention (N & EN). Hirsutism total score change was statistically significant, as there is a significant reduction in hirsutism total score. In addition to, the study result confirmed a significant strong positive correlation between the drop in BMI score and both insulin level and testosterone level, while the reduction in hirsutism total score is moderately correlated with the change in the BMI. This in accordance with *(Pasquali et al., 2003& Moran et al., 2006)*, who stated that 5%–10% loss of initial weight appears to reverse the hormone disorders associated with PCOS and thus improve menstrual pattern, induction of ovulation improve fertility & pregnancy rates, decrease androgens, and

improvement of insulin resistance. This coincides with a study done by *Escobar-Morreale et al., 2005* on morbidly obese PCOS women, who noted that weight loss was paralleled by a decrease in hirsutism score, testosterone and dehydroepiandrosterone sulfate; amelioration of insulin resistance occurred and ovulatory cycles were also restored.

Supporting the same point by *(Linderbaum., 2010)* who mentioned weight reduction in obese patients diagnosed with PCOS has shown to alleviate some symptoms. It helps in reducing hirsutism and acne in patients that have PCOS. Also weight reduction is encouraged as the first-line of therapy when infertility is believed to be connected to PCOS. Some studies show that a 5% reduction in body mass can restore ovulation and fertility.*(Stankiewicz, 2006, Norman, 2006, Pillai et al., 2007, Raisbeck., 2009, & Linderbaum., 2010)*

Similar to the findings of the studies done by *(, Polson et al., 1989, Hamilton et al., 1993, Andersen et al., 1995 & Wahrenberg et al., 1999)* whom observe differences, Short-term weight loss strategies using very low calorie diets (<500kcal\day) for 4 weeks have achieved 6.6-9% loss of initial body weight and have been shown to decrease serum insulin levels, OGTT stimulated-insulin and insulin sensitivity on the clamp test in patients with PCOS.

This finding was assured by few studies have combined energy restriction with physical activity. More recently a 6-month lifestyle modification was performed in a group of obese anovulatory PCOS women and obese ovulatory controls *(Huber-Burchholz et al., 1999)*. The group program included 1 hour of weekly supervised exercise with encouragement to do a further two hours per week as well as one hour of diet and lifestyle education *(Gaby., 2008)*. In this study, mean weight loss was only 2-5% of body weight however 9/15 still became ovulatory. This was associated with an improvement in insulin sensitivity of 71% using the "gold standard" euglycaemic hyperinsulinemic clamp. Significant improvements in fasting insulin, waist circumference and central abdominal fat (but not in androgen levels) were also seen in those that responded. There was no improvement in any of these measures in non-responders who remained anovulatory.

In congruent with Previous studies have recommended weight loss as an effective method of inducing ovulation in obese women with menstrual disturbances *(, Hamilton Fairley et al., 1993, Clark et al., 1995, Hollmann et al., 1996, Hollmann et al., 1997, & Clark et al., 1998)*, but there have been few studies that have attempted to explain the mechanism of the return of ovulation or have used sustainable diet and exercise programs. In previous study *Clark et al., 1995*, the average weight loss was only 6.3 kg, which was a small percentage (<10%) of the starting weight.

Despite this, 12 of 13 subjects resumed ovulation, and 11 became pregnant. *Hollmann et al., 1996* reported a weight loss of less than 10% with menstrual period improvement in 80% and pregnancy in 29%. Other results emphasize that large changes in fasting insulin can be induced in a group of women in whom unimpressive changes in weight resulted, but increased use of exercise and sensible eating patterns achieved metabolic changes sufficient to alter reproductive function. The loss of a small volume of critical intra-abdominal fat, which may be only a small percentage of the total body fat may explain these results. In addition, calorie restriction may lower lipid availability and improve sensitivity independent of changes in body composition.

Cronin et al. have developed a health-related quality-of-life questionnaire *1998* for patients with PCOS, updated *2007*; in which emotional and mood issues play a prominent role. Because National Institutes of Health (NIH) guidelines for reduction of weight emphasize the importance of behavior therapy and attention to psychological adjustment, any lifestyle modification program should address behavior therapy and a better understanding of the psychological background of subjects with PCOS. The present findings coincides with results of several investigators whom shown that subjects with PCOS have higher levels of stress and a more negative self-image than controls *(NIH., 1998)*. With adjustment of lifestyle habits; the intervention of the present study showed improvement on women's psychological Health related quality of life and correlates with PCOS indicators improvement. Similarly, *Galletly et al., 1996* reported that the instructional interventions used to teach stress management measures, result in a significant improvement in psychological measures, including self-esteem, anxiety, mean depression scores and scores on the general health questionnaire.

In summary, our results indicate that lifestyle modification through exercise, stress management and sensible eating patterns can lead to improved reproductive/hormonal features in PCOS women.

Conclusion & Recommendations:

Finally, the present study drew attention to a critical point that lifestyle modification with weight loss leads to improved hormonal profile, which restores ovulation and the best initial management for overweight & obese women seeking to improve their reproductive function.

In the light of the study findings, the following recommendations are suggested:

1. Didactic center for PCOS cases inside infertility/gynecological clinics to ensure lifestyle modification including dealing with stressors
2. Future research should focus on the optimal dietary strategies and exercise regimens for PCOS treatment and the relative efficacy and appropriate use of lifestyle management versus anti-obesity pharmacologic agents and surgery.
3. Further studies are still needed to determine the effect stress management only on PCOS features & other on larger sample size

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