



ISSN: 2230-9926

Available online at <http://www.journalijdr.com>

IJDR

International Journal of Development Research
Vol. 09, Issue, 02, pp.25965-25973, February, 2019



ORIGINAL RESEARCH ARTICLE

OPEN ACCESS

COMPARING THE EFFECTIVENESS OF HERBAL REMEDIES AND LIFESTYLE MODIFICATION ON MINIMIZING POLYCYSTIC OVARIAN SYNDROME SYMPTOMS

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ARTICLE INFO

Article History:

Received 20th November, 2018
Received in revised form
03rd December, 2018
Accepted 06th January, 2019
Published online 28th February, 2019

Key Words:

Herbal remedies,
Lifestyle modification,
Symptoms, Polycystic Ovary Syndrome.

ABSTRACT

Polycystic ovary syndrome (PCOS) is a common, complex reproductive problem that affects women in reproductive age. It is characterized by menstrual irregularities, hyperandrogenism and polycystic ovaries. Lifestyle modification is a first-line intervention. Women often seek adjunct therapies including herbal remedies. So, the aim of this study was to compare the effectiveness of lifestyle modification plus herbal remedies, with lifestyle modification alone on minimizing PCOS symptoms and weight loss. One hundred twenty women with PCOS were recruited for the study (60 each group) from outpatient gynecological clinic at Al Kasr Alani hospital, workplaces, and colleges, Cairo, Egypt, utilizing quasi-experimental design. After 6 months interventions, women in the herbal group reported a reduction in oligomenorrhoea (30%) compared to (48.3%) in lifestyle alone group ($p < 0.04$) and regulation of menstruation (61.7%) compared to (41.7%) ($p < 0.02$). Other significant improvements were found for body mass index ($p < 0.01$); waist circumference ($p < 0.002$); W/H circumference ($p < 0.015$); acne score ($p < 0.003$); and Hirsutism score ($p < 0.01$). This study provides evidence of effectiveness and safety of the combined herbal remedies and lifestyle modification on overweight and obese women with PCOS.

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Citation: Nagwa A. Afefy and Afaf Ebrahim Abd Elrehim. 2019. "Comparing the effectiveness of herbal remedies and lifestyle modification on minimizing polycystic ovarian syndrome symptoms", *International Journal of Development Research*, 09, (02), 25965-25973.

INTRODUCTION

Polycystic ovary syndrome (PCOS) is one of the most common gynecological disorders that affect between 5 - 10% of women who are of reproductive age and characterized by endocrine, metabolic, and genetic disorders, chronic absence of ovulation of polycystic ovary, and hyperandrogenism (Barbosa, Bianca, Cunha, Rosso, Wanderley, Arbex, 2016). Changes in endocrine hormones include increased levels of androgen, estrogen, and prolactin and decreased level of progesterone; metabolic disorders include insulin resistance, and type 2 diabetes (Jelodar and Askari, 2012). In addition, some women experience physical changes due to the presence of male hormones. These include menstrual disorders, Hirsutism, acne, and infertility. In Egypt, a cross-sectional observational study conducted on 1450 women visiting the outpatient clinic of Minia University Maternity Hospital, included 620 middle-aged fertile women with an intrauterine contraceptive device and gave birth more than 2 years previously and 830 with primary or secondary infertility reported that the prevalence of

PCOS in the fertile women was 14% and 37.5% in the secondary infertile women. The cause of infertility is lack of ovulation in approximately 75% of the cases (Sanad, 2014). Research evidence has shown that insulin resistance has an important implication in the pathogenesis of PCOS and the use of insulin-sensitizing drugs is an effective approach in the management of PCOS (Bhuvaneshwari, Poornima, Averal, 2015). Drug therapy is effective in the treatment of PCOS but it may cause some side effects after prolonged usage. With regards to the side effects of such drugs, it is essential to identify alternative strategies to manage such infertility problems. If women diagnosed early and managed properly with the lifestyle modification, the onset of Type2 diabetes mellitus and its resultant risk of coronary artery disease may be delayed or prevented (Bency Baby, Remya, Rani, Rasheed, Azeem, 2017). Currently the standard care treatment for women with PCOS ranges from lifestyle modification to pharmacological interventions. Lifestyle modification has been adopted as the first line of treatment to manage PCOS in overweight and obese women through diet, weight loss, and exercise (Nahuis, Oosterhuis, Hompes, Van Wely, Mol, Van der Veen, 2013; Moran, Pasquali, Teede, Hoeger, Norman, 2009). As a result a surge in clinical studies involving dietary

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restriction alone or in combination with physical activity programs have been indicate that a reduction in body weight of at least 5% leads to significant improvements in menstrual cycle, ovulation and biochemical hyperandrogenism in terms of the reproductive complaints and improved glucose tolerance and reduced risk for cardiovascular disease (Moran, Hutchison, Norman, Teede, 2011). Abazar, Taghian, Mardanian, Forozandeh, (2015) studied the effects of aerobic exercise on plasma lipoproteins in overweight and obese women with polycystic ovary syndrome, reported that after 12 weeks of exercise, BMI, waist- hip ratio, fat rate, weight and fat mass and triglyceride were significantly reduced. Moreover, a five to ten percent loss in body weight over a period of six months regardless of body mass index may be associated with improvement in central obesity, hyperandrogenism and ovulation rate (Legro, 2017). There has been a special attention to medicinal plants since ancient times and today, with numerous studies performed, worthwhile and beneficial medicinal plants are discovered. Many herbal plants have got significant activity in PCOS with fewer side effects (Bency Baby, et al. 2017). The aim of herbal treatment is to enable the body to readjust the excess levels of hormones to normal levels and loss weight, so that the menstrual cycle can occur in a normal manner (Kashani, Mohammadi, Heidari, Akhondzadeh, 2015). There are some herbs that are very helpful in treating PCOS, such as Green tea, jeera powder (cumin seed powder), black seed oil, Chia Seeds, Anise, Fenugreek Seeds, Fennel seeds, Cinnamon powder, Flax seed, Evening Primrose Oil, Curcuma turmeric etc., have been highly esteemed sources which have the advantages to reduce PCOS and also having hypoglycaemic and anti-obesity effect (Chitra, Dhivya, Derera, 2017).

Significance of the Study: Polycystic ovary syndrome (PCOS) is a common endocrine and metabolic disorder that affecting more than one in five women during reproductive period (Feldman, 2014). Conventional therapies are effective in the prevention and treatment of PCO but it might be a lifelong treatment. Prolonged usage of drug therapy can causes severe adverse effects. These numerous adverse effects and high cost, lead to search for alternative remedies in the management of PCOS. Recently, much researches have been investigated the impact of the lifestyle modification in PCOS women and suggested that modest weight loss, even as little as 5% from baseline body weight can positively affect hyperinsulinemia (Legro, 2017). As a result, it causes a decrease of androgens and normalization of menstrual cycles. However, there are barriers to success this form of self-care. Herbal remedies can return the body to a state of natural balance compared to synthetic drugs. Researches evidence of various herbal extracts used in the management of PCOS are promising and can be used as an important source of new therapies for human disease (Hosseini, Leila, Ebrahim, Nazanin, Farzad, Elham, et al. 2015). This stimulates the current study to compare the effectiveness of lifestyle modification plus herbal remedies, with lifestyle modification alone on minimizing PCOS symptoms and weight loss.

Conceptual Framework: The current study was based on health belief model. It is a health protection model that provides a framework to explain why some people take specific actions to avoid or treat illness, whereas others fail to protect themselves (Stanhope & Lancaster, 2016; Pender et al 2006). This model states that the probability that a person will take appropriate health care actions depends on the person's

value of health, perceptions about disease, and perceived threats of disease. The main constructs of the HBM comprise: 1) Perceived susceptibility; 2) Perceived severity; 3) Perceived benefits and; 4) Perceived barriers.

SUBJECTS AND METHODS

Objectives

- Assess impact of lifestyle modification plus herbal remedies on minimizing PCOS symptoms and weight loss.
- Assess impact of lifestyle modification alone on minimizing PCOS symptoms and weight loss.
- Comparing the effectiveness of interventions on both groups.

Research Hypothesis

- There will be a significant weight loss for women in both groups.
- Women who follow lifestyle modification plus herbal remedies will report less polycystic ovarian syndrome symptoms than those who follow lifestyle modification alone.

Design: A quasi-experimental (pre-post test) design was used to compare the effectiveness of lifestyle modification plus herbal remedies, with lifestyle modification alone on minimizing PCOS symptoms and weight loss.

Study sample and setting: This study included 120 women aged 18–44 years, overweight or obese, with either 2 of the 3 symptoms of PCOS as per Rotterdam criteria (ESHRE, 2012) namely, menstrual irregularity, clinical hyperandrogenism (acne and Hirsutism), who gave consent to participate in the study. Women taking oral contraception to regulate menstrual bleeding or antidepressants, having other medical disorders like thyroid diseases, hyperprolactinemia, and not willing to participate in the study were excluded. Women were recruited from community settings including outpatient gynecological clinic at al Kasr Alani hospital, workplaces, and colleges, Cairo, Egypt. Sample was randomly assigned to lifestyle modification (diet and exercise) plus herbal remedies group or lifestyle modification alone group.

Recruitment of participants and randomization: After official permission was obtained to conduct the study, two steps selection process was used to ensure the randomization. The first of which was identifying the random sample. This step was done on the admission of women who met the eligibility criteria. Potential participants were recruited by direct announcement and poster at the outpatient's clinic and the entrance of Cairo University. Then the researchers assessed every participant for the illegibility criteria. The second step of the randomization started with the women being assigned to the lifestyle modification plus herbal remedies group or the lifestyle modification alone group utilizing computer generated random numbers. Each number (from one to 120) was inserted separately into opaque envelopes by the researchers and these 120 sealed opaque envelopes were used for groups' assignment.

Sample size: The sample size was estimated to 120 women completing the study. This estimation was based on studies

reporting similar outcomes in women with PCOS for lifestyle interventions (Arentz, Smith, Abbott and Bensoussan, 2014; Moran, *et al.*, 2011). As the study progressed, there was attrition for lifestyle modification plus herbal remedies group (12 cases), and for lifestyle modification alone group (9 cases). The researchers replaced them to reach the sample size (120).

Data collection: Data collection tool was developed by the researchers based on extensive electronic review of literatures which consisted of four parts: 1) Socio-demographic characteristics 2) gynecological history; 3) physical assessment and evaluation tool (pre-post test); and 4) Women's compliance. *The first and second parts of the questionnaire* were socio demographic characteristics such as age, educational level, occupation, marital status, as well as gynecological history which included family history of PCOS, age of menarche, and menstrual history (pre-post) which included history of menstrual regularity, oligomenorrhea, and amenorrheaect. *The third part* was assessed twice once before intervention (pre test) as a baseline data and once after six months intervention (post test).

This included three sections:

Section (1): anthropometrical data as body weight (kg) and height (meter), BMI kg/m², waist and hip circumference (centimeters) and waist to hip ratio (W: H). Waist circumference (WC) was measured at the midpoint between the lower margin of the last palpable rib and the top of the iliac crest, using a stretch-resistant tape that provides a constant 100 g tension. Hip circumference (HC) was measured around the widest portion of the buttocks, with the tape parallel to the floor. WC/HC ratio was obtained by dividing both.

Section (2): Degree of acne; Acne Evaluation was performed on the face and back according to the Global Acne Grading Scale (GAGS) (Doshi, Zaheer, Stiller, 1997). The GAGS considers six locations on the face and chest/upper back, with a factor for each location based roughly on surface area, distribution, and density of pilosebaceous units. Each of the six locations is graded separately on a 0–4 scale, with the most severe lesion within a location determining the local score. These grading scores are then multiplied by the factor of each location (forehead ×2, right cheek ×2, left cheek ×2, nose ×1, chin ×1, chest and upper back ×3). The global score is the summation of all the local scores (= grades × factors). The global scores are subdivided into categories: no active acne lesions (score = 0), mild active acne lesions (score = 1–18), moderate active acne lesions (score = 19–30), severe active acne lesions (score = 31–38), and very severe acne lesions (score > 39).

Section (3): Degree of Hirsutism was assessed using the modified Ferriman-Gallwey (mf-G) scoring method. A score of 1 to 4 is given for nine areas of the body. A total score less than 8 is considered normal, a score of 8 to 15 indicates mild Hirsutism, and a score greater than 15 indicates moderate or severe Hirsutism. A score of 0 indicates absence of terminal hair (Gallwey, 1962). *The fourth part* was Women's compliance; women were asked about their compliance to the given instructions.

Validity and Reliability of the Tool

Face and content validity of the questionnaire were assessed by 3 PhD faculty members who are expert in nursing field and

obstetrical department. Some modifications were carried out according to the panel judgment on clarity of the sentences and appropriateness of the content. Reliability test was assessed by applying the questionnaire on 10 women as a pilot study to check validity, reliability, feasibility and applicability of the questionnaire using test-retest.

Procedure: After approvals to conduct this study was obtained, the researchers introduced themselves to the women who met the inclusion criteria and informed them about the purpose of the study, benefit, and risk in order to obtain their acceptance to participate in the study as well as gain their cooperation. Oral agreement was obtained from each woman who agreed to participate in the study. The researchers constructed and prepared different data collection tools, power point presentation and booklet. Data collection was carried out through three phases: interviewing and assessment phase, implementation phase, and evaluation phase. Data collected over a period of six months.

Interviewing and assessment phase: In this phase, self-administered questionnaire containing socio-demographic characteristics, gynecological history, symptoms of PCOS were carried out for each woman. A baseline data of BMI kg/m², waist and hip, waist to hip ratio (W: H) circumference as well as acne and Hirsutism degree were carried out by the researchers (pre and post intervention). The questionnaire was written in Arabic language and documented the answer in the tools utilized.

Implementation phase: In this phase, the interventions were administered for six months for both groups. Both groups were advised to modify their lifestyle. The lifestyle modifications was guided by attending dietary and exercise behaviors session that aimed to induce weight loss or prevent weight gain through calorie-controlled diet within a healthy food choice setting and exercise in order to achieve an average weight loss of 0.5 kg per week. Each participant was given a diary having prescribed caloric diet to be taken and hours of physical exercise to be done. Eating a relatively low fat diet, eating breakfast almost every day, weighing themselves regularly. Regarding exercise, all women were advised to raise physical activity during daily life (e.g., going to the store on foot instead of by car, taking the stairs instead of the elevator). Also, do physical exercise for at least 150 min per week including 60 min of moderate activity (60 to 70% of maximum heart rate). The exercise included 24 weeks for 3 sessions a week, each session for 60 min and consumes at least 2000ml of drinking water per day. The women were instructed to do simple calorie-burning activities like brisk walking, swimming or cycling. Women had access to the researchers throughout the study, and they invited to attend exercise sessions and helped to construct their own personalized lifestyle plan. For lifestyle modification plus Herbal remedies group. The same diet and exercise guideline was provided, in-addition, participants had received a session about the different types of herbal that they can use and explained the effect of each type on PCOS through PowerPoint presentation and providing a hand out booklet. Herbal remedies included eight types: green tea, flax seeds, anise, cinnamon, chia seed, black seed oil, fennel, and fenugreek seed. These remedies had been chosen based on evidence of its effect on PCOS included to improve insulin sensitivity and menstrual regularity (Dou, Zheng, Li, Gui, Chen, & Guo, 2018; Hajimonfarednejad, Nimrouzi, Heydari, Zarshenas, Raee, Jahromi 2018; Wang, Anderson,

Graham, Chu, Sauer, Guarnaccia, 2007). The participants advised to have three types once a day throughout the study.

Follow up phase: Participants were followed up by phone every 4 weeks for up to 24 weeks to know their compliance towards the intervention program and were counseled accordingly. Participant compliance was assessed by number of self-reported of herbal types at 6 months. Women's compliance with the exercise and dietary intervention was assessed fortnightly and during an interview at week 24. Women self-reported the intensity of exercise (mild, moderate or vigorous) and number of minutes per week, dietary compliance was assessed through the average number of self-reported servings of vegetables and fruit per day and number of high energy, nutrient sparse meals per week. Moreover, women were assessed for the research outcome: (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); (iii) change in acne degree; and (iv) Change in Hirsutism score.

Ethical considerations: All official permissions to carry out the study were secured from pertinent authorities. Verbal agreements were taken from all participants before data collection and they were informed that the data will be anonymous and confidential. All participants were informed about the purpose of the study, ensuring that the collected data would be used only for the purpose of the present study, as well as for their benefit. The participants were informed that the participation is voluntary and they can withdraw from the study at any time. Women who agreed to participate in the study gave their acceptance after have being provided an information sheet containing the aim and details of the study and informed consent form.

Statistical Analysis: Data was coded, tabulated, and analysed by using SPSS version 20 statistical software. According to study aim the descriptive statistics were inform of means, standard deviations, frequency, and percentage. Inferential statistics were inform of T test, and Chi Square test. Statistical significance was considered at p-value <0.05.

RESULTS

This study was conducted to compare the effectiveness of lifestyle modification plus herbal remedies, with lifestyle modification alone on minimizing PCOS symptoms and weight loss. One hundred and twenty women were enrolled into the study from October 2017 till May 2018. All women in both groups (60 each) were instructed to follow life style modification programs (diet and exercise) in addition using herbal remedies for one group.

The results of the study is devided into three parts as the following:

Part one: Baseline demographic, anthropometric, as well as PCO data.

Part 2: Objective one (Assess impact of lifestyle modification plus herbal remedies on minimizing PCOS symptoms and weight loss).

Part 3: Objective two (Assess impact of lifestyle modification alone on minimizing PCOS symptoms and weight loss).

Part 4: Comparing the effectiveness of interventions on both groups.

Part one: Baseline demographic, anthropometric, as well as PCO Data

Table (1) shows that, the sampleage range was 18-44years old and about half of the sample (43% plus herbal group and 45% for lifestyle modification alone) belonged to age group of 27-36 years. Almost half of them(48%&45% respectively) were overweight. Near half (41%) of herbal group were students at university compared with more than one third (38%) in lifestyle alone and about two third in both group were single (58.3% and 63.3% respectively). There was no statistical significant difference between groups regarding socio-demographic data (Table, 1). Regarding menstrual baseline history, table (2) shows that the mean menarche age of the herbal group was (13.29±0.81) years, with a mean menstrual cycle length (90.47±96.49) days, and a mean menstrual duration (7.51± 1.87) days. Near half (41%) and (48%) had family history of PCOS and diabetes respectively. Regarding, the lifestyle modification alone group, the current result revealed that, mean menarche age was (13.24±0.69) years, with a mean menstrual cycle length (91.12±96.62) days, and mean menstrual duration (7.35± 2.01) days. Near half (45%) had a family history of PCOS and 38% had family history of diabetes. There was no statistical significance differences between both in all items. Before interventions, there were no statistical significant mean difference between both groups regarding anthrompomtric data as well as acne and Hirsutism score (table, 3). While after six months interventions, despite there were significant improvement in both groups, there were statistical significant mean difference between both groups regarding body weight, BMI, Waist circumference, W/H ratio, acne score and Hirsutism score (p= 0.000, p=0.000, p= 0.001, p= 0.015, 0.003, 0.001 respectively). As the mean body weight and BMI in lifestyle modification plus herbal remedies was (64.53±5.24 and 25.12±1.51) compared with (77.25±5.88 and 26.36±1.14) for lifestyle modification alone. Also. The mean acne score and hirsutim score for lifestyle modification plus herbal was (14.23± 3.12 and 11.87 ± 1.46), while for lifestyle modification alone was (15.69±5.16 and 13.26 ±1.56). Exercising more than 150 minutes per week defined as 60-70% of maximum heart rate and unable to engage in conversation. Health diets defined as two servings of fruit and five of vegetables per day, and low carbohydrates. Regarding to life style characteristics of both groups, table (4) shows that, no statistical significant differences between groups in all life style characteristics before and after interventions, except for herbal use after interventions (p<0.000). As the majority in both groups exercised more than 150 minutes per week (81.6% and 71.6% respectively) (p=0.19) and were consuming healthy diets (85% and 88.3% respectively) (p= 0.62) after interventions. Regarding menstrual changes, table (5) revealed there was no statistically significant differences between both groups before interventions However, after six months interventions, despite there was a reduction and improvement in menstrual rythm in both groups, the current results had shownen a statistical significance differences between them regarding menstrual regularity and oligomenorrhoea. As more than two third (61.7%) in herbal group had regular menstruation compared to 41.7% in lifestyle modification alone (p<0.02). Also, there was a reduction in oligomneorrhoea approximately halved from 65% to 30% in herbal group compared to 37% to 29% in lifestyle modification alone

Table 1. Frequency Distribution of the Socio-demographic Data of the Sample

Characteristics	Lifestyle Modification Plus Herbal remedies N = 60		Lifestyle Modification alone N = 60		P
	Freq.	%	Freq.	%	
	Age				
18-26 years	19	31.7	18	30.0	0.54
27-36 years	26	43.3	27	45.0	
37-44 years	15	25.0	15	25.0	
BMI					
Overweight (25.0-29.9)	31	51.7	33	55.0	0.71
Obese (30 or more)	29	48.3	27	45.0	
Educational level					
Secondary school	7	11.7	9	15.0	0.53
University	28	46.6	22	36.7	
Graduate	25	41.7	29	48.3	
Occupation					
Student	25	41.7	23	38.3	0.89
Employer	22	36.7	22	36.7	
House wife	13	21.6	15	25.0	
Marital status					
Single	35	58.3	38	63.3	0.57
Married	25	41.7	22	36.7	

Table 2. Frequency Distribution of the Studied Sample According Menstrual Baseline History

Characteristics	Lifestyle Modification Plus Herbal remedies N = 60		Lifestyle Modification alone N = 60		P value
	Freq.	%	Freq.	%	
	Menstrual history				
Menarche age \pm SD	13.29+0.81		13.24+0.69		0.71
Menstrual duration					
Normal (3-7 days)	23	38.3	26	43.3	0.57
Abnormal (> 7 days)	37	61.7	34	56.7	
Mean menstrual duration (days, \pm SD)	7.51+1.87		7.35+2.01		0.63
Menstrual cycle length					
21-35 days	9	15.0	11	18.3	0.74
35-45 days	22	36.7	19	31.7	
45-60 days	10	16.7	13	21.7	
> 60 days	7	11.6	5	8.3	
> 180 days	12	20.0	12	20.0	
Mean menstrual cycle length (days \pm SD)	90.47+96.49		91.12+96.62		
History					
Family History of PCO	25	41.7	27	45.0	0.71
Family History of Diabetes	29	48.3	23	38.3	0.74

Table 3. Comparing the Effect of Six Months Interventions on both Groups according to BodyWeight in Kilograms, BMI, Waist Circumference, W/H Ratio, Acne and Hirsutism Score

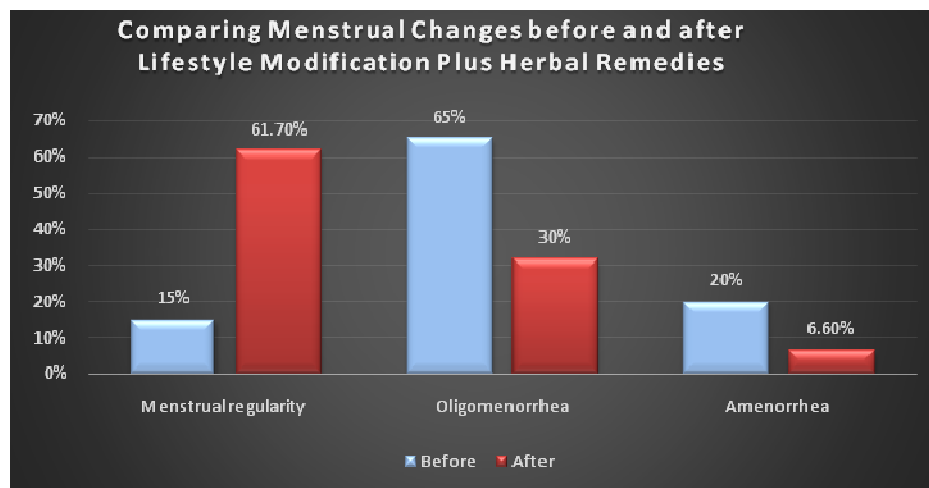
Variable	Lifestyle Modification Plus Herbal remedies N = 60		Lifestyle Modification alone N = 60		P. value
Body weight in kilograms					
Pre- interventions	85.41+7.55		84.54+6.07		0.44
Post- interventions	64.53+5.24		77.25+5.88		0.000
Mean BMI (kg/m ² \pm SD)					
Pre- interventions	28.74+3.03		28.69+3.09		0.92
Post- interventions	25.12+1.51		26.36+1.14		<0.002
Mean Waist circumference (cm \pm SD)					
Pre- interventions	95.1+8.3		94.2+9.16		0.63
Post- interventions	86.31+8.42		87.61+8.71		<0.001
Mean Waist to Hip ratio (\pm SD)					
Pre- interventions	0.86+0.03		0.85+ 0.4		0.12
Post- interventions	0.82 +0.01		0.84 +0.5		<0.015
Mean Acne score + SD					
Pre- interventions	17.30+9.60		16.79+9.84		0.59
Post- interventions	14.23+ 3.12		15.69+5.16		<0.003
Mean Hirsutismscore					
Pre- interventions	15.41+5.04		16.10+4.24		0.89
Post- interventions	11.87 \pm 1.46		13.26 +1.56		<0.001

Table 4. Comparing Lifestyle Characteristics Before and After Six Months Interventions between Both Groups

Life style Characteristics	Lifestyle Modification Plus Herbal remedies N = 60		Lifestyle Modification alone N = 60		P value
	Freq.	%	Freq.	%	
	Exercising more than 150 minutes per week				
Pre- interventions	23	38.3	22	45.0	0.57
Post- interventions	49	81.6	43	71.6	0.19
Consuming health diets					
Pre- interventions	28	46.6	27	45.0	0.59
Post- interventions	51	85.0	53	88.3	0.62
Using herbal remedies					
Pre- interventions	11	18.3	8	13.3	0.45
Post- interventions	53	88.3	11	18.3	0.000

Table 5. Comparing the Effect of Six Months Intervention on Both Groups According to Menstrual Changes

Menstrual changes	Lifestyle Modification Plus Herbal remedies N = 60		Lifestyle Modification alone N = 60		P value
	Freq.	%	Freq.	%	
	Menstrual regularity				
Pre- interventions	9	15.0	11	18.3	0.62
Post- interventions	37	61.7	25	41.7	0.028
Oligomenorrhea					
Pre- interventions	39	65.0	37	61.7	0.71
Post- interventions	18	30.0	29	48.3	0.04
Amenorrhea					
Pre- interventions	12	20.0	12	20.0	1.000
Post- interventions	4	6.6	8	13.3	0.22

**Fig. 1. Comparing Menstrual Changes before and after Lifestyle Modification plus Herbal Remedies**

($p < 0.04$). Regarding Amenorrhea, both groups had shown an improvement without statistical significance differences ($p = 0.22$) Table (5).

Part 4: Comparing the effectiveness of Interventions on both Groups

When comparing the effect of lifestyle modification plus herbal remedies before and after interventions on menstrual rhythm, Figure (1) Illustrates that, two third (61.7%) of the sample menstruated regularly after six months of interventions compared to 15% at baseline with statistically significant differences ($p < 0.000$). Women who had oligomenorrhea and amenorrhea (65% and 20% respectively) before intervention, they were approximately halved (30% and 6.6% respectively) with statistically significant differences ($p < 0.000$) for oligomenorrhea and ($p < 0.03$) for amenorrhea (Fig.1). Regarding to, lifestyle modification alone, Figure (2) Illustrates that, near half (41.7%) of the sample menstruated

regularly after six months of interventions compared to 18.3% at baseline ($p < 0.003$). More than two third (61.7%) had oligomenorrhea and 20% had amenorrhea before interventions. Despite these percentages were decreased after interventions (48.3% and 13.3% respectively) there were no statistically significant differences ($p < 0.14$) for oligomenorrhea and for amenorrhea ($p < 0.32$) (Fig.2).

DISCUSSION

Polycystic ovarian syndrome (PCOS) is a common endocrine system disorder in women of reproductive age. Lifestyle modifications (diet and exercise) and herbal remedies are equally important on symptoms of polycystic ovarian syndrome through losing weight and consequently improving hyperandrogenism, insulin sensitivity and normalization of menstrual cycles (Nair, Nambisan, Radha, Leelamma, 2017). Therefore, this study was carried out to compare the effectiveness of lifestyle modification plus herbal remedies,

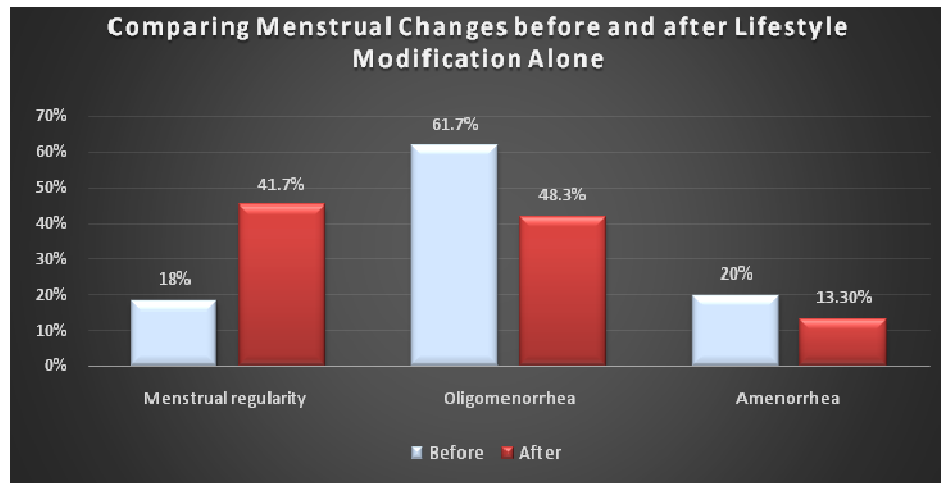


Fig. 2. Comparing Menstrual Changes before and after Lifestyle Modification Alone

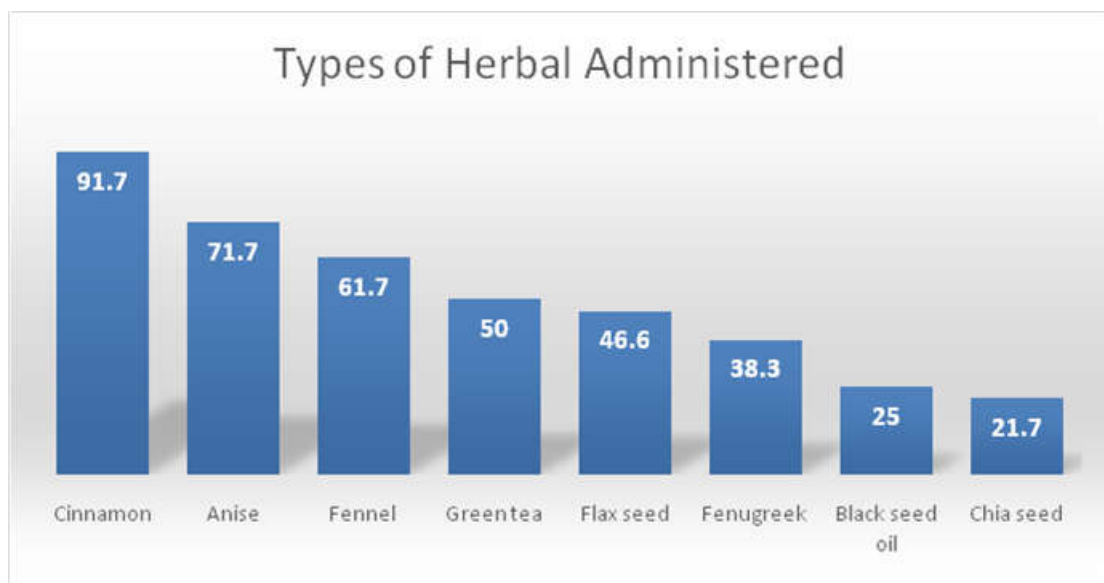


Figure 3. Percentage of Lifestyle Modification plus Herbal Remedies according to Types of Herbal Administered

with lifestyle modification alone on minimizing PCOS symptoms and weight loss. The current result had shown that, before interventions, the general baseline characteristics of both groups were similar with no statistical significance differences regarding socio-demographic, anthropometric as well as hyperandrogenism data. While after six months interventions, there were changes in body weight, BMI, waist circumference, W/H ratio, mean Acne score, and mean Hirsutism score for both groups. Surprisingly these changes were statistically significant differences ($p < 0.000$, $p < 0.000$, $p < 0.001$, $p < 0.015$, $p < 0.003$ and $p < 0.001$ respectively). This explained by the fact that herbal remedies facilitate weight loss when accompanied with life style modification. This finding is the same line of Abdelmenim and Emam (2016) who evaluate the effect of lifestyle changes on symptoms of polycystic ovarian syndrome in obese girls. They found highly significant decreases in waist circumference ($P < .001$), highly significant reduction in Hirsutism total score ($p < .001$) and total acne grade ($p < .001$) after one year of lifestyle changes. Also, Ahmed, Salem, and Sweed, (2012) studied the effect of lifestyle modifications on polycystic ovarian syndrome symptoms. They found a significant reduction in sample anthropometric measures as more than three quarter of the studied sample was obese, the intervention decreased this percent to less than one half, this mean that the intervention

successes to decrease the percentage of obesity by more than one third. Similar study done by Maki, Reeves, Farmer, Yasunaga, Matsuo, Katsuragi, *et al.* (2009) stated that after three months intervention, the women's weight in the intervention group was reduced by 2.4%; however, this reduction was not significant. Nair, *et al.*, (2017) studied effectiveness of lifestyle modification package among overweight and obese adolescent girls with polycystic ovary syndrome. They reported that more than two third of the participants lost their weight, their BMI were changed with statistically significant difference ($p < 0.001$). Waist circumference significantly decreased from 103.3 ± 12.3 cm to 97.6 ± 13 cm ($P < 0.01$) for all participants during the dietary intervention period. Moreover, Thomson, Buckley, Noakes, Clifton, Norman, Brinkworth, (2008), studied the effect of addition of exercise to energy restricted diet, which provided more beneficial changes in body composition with an approximately 45% greater reduction in fat mass. After six months interventions, despite there was change in Hirsutism score in both groups, the results had shown a significant statistical differences between groups. Clark, Rudolph, Gerber, Glick, Shalita, Lowenstein, (2014), mentioned that, the degree of Hirsutism is influenced not only by androgen levels but also the insulin levels and insulin resistance. Therefore, lifestyle changes and herbal remedies may have a positive effect on the

speed of hair growth. Farzana, Sulaiman, Ruckmani, Vijayalakshmi, Lakshmi, Ranjini *et al.*, (2015) reported that flaxseed might indeed help regulate androgen levels in women with PCOS. A significant decrease in androgen levels and hirsutism degree were observed in the study. Findings suggest that flaxseed may have a profound impact on testosterone levels, and may diminish symptoms associated with hyperandrogenism, such as Hirsutism. Regarding menstrual changes, the current study revealed significant changes in menstrual cycle regularity in both groups. As before interventions, only less than one quartile (15%, and 18.3%) in both groups had regular menstruation, while after interventions, more than two third in combined group reported regular menstruation versus more than one half-in life style alone group. In addition, there was a reduction in oligomenorrhoea and amenorrhoea. This finding was matched with Arentz, Smith, Abbott, Fahey, Cheema, and Bensoussan (2017) who compared the effectiveness and safety of a lifestyle intervention plus herbal medicine against lifestyle alone in overweight women with PCOS. They reported that, there were statistical and clinical significant improvement for a lifestyle intervention plus herbal combination compared with lifestyle intervention alone. As there was a reduction of PCOS symptoms including: a reduction in the number of days of the menstrual cycle from 106 to 62 days ($p < 0.01$); reduction in oligomenorrhoea of 32.9% ($p < 0.01$) and fasting insulin compared with control group. In addition, there was a significant improvement for body mass index ($p < 0.01$) and anthropometry measures. Menstrual cycle regulation is consistently associated with loss of body weight. The aim of herbal treatment is to enable the body to readjust the excess levels of hormones to more 'normal' levels so that, the menstrual cycle can occur in a 'normal' manner (Kamel, 2013). Cinnamon considered as a very effective home remedy for PCOS and its symptoms. It can help normalize the monthly menstrual cycle; increase of insulin sensitivity, control blood sugar levels and facilitates weight loss as well (Ried, 2015; Arentz, Smith, Abbott & Bensoussan, 2014).

Current study revealed the most herbal administered by the participants was Cinnamon followed by Anise. Moreover, Farzana *et al.*, (2015) reported that flaxseed supplementation may diminish symptoms associated with hyperandrogenism, such as Hirsutism and improve the frequency of menstrual cycles. Moreover, a trial was conducted by Swaroop, Jaipurkar, Gupta, Bagchi, Kumar, Preuss, *et al.*, (2015) in women suffering from PCOS over a period of 90 consecutive days following fenugreek administration. They concluded that, there was a significant improvement in menstrual cycle following fenugreek administration resulted in significant increases in LH and FSH. Approximately 46% of the participants showed reduction in cyst size. No significant adverse effects were observed. Supporting the same point by Lass, Kleber, Winkel, Wunsch, Reinehr (2011) and Ornstein, Copperman, Jacobson (2011), who concluded that weight loss due to lifestyle intervention was associated with an improvement in menstrual irregularities. The participants who lost weight were 3 to 4 times more likely to have improvement in their menstrual function ($P < 0.001$). Moran, *et al.* (2011) assessed the effectiveness of lifestyle treatment in improving reproductive, anthropometric (weight and body composition), metabolic and quality of life factors in PCOS women and found that lifestyle intervention, provided benefits when compared to minimal treatment for Hirsutism.

They also concluded that medium to long-term lifestyle intervention resulted in significant reduction in weight. Weight loss for PCOS sufferers may be difficult, but it is not impossible. A combination of lifestyle modification and herbal remedies can help to keep body fat low, and consequently improve the anthropometric measures and PCOS features.

Conclusion

The present study drew attention to a critical point that Lifestyle modifications along with home remedies are simple, cost effective interventions in the management of overweight and obese women with PCOS through improving their BMI and regularization of menstrual cycles more than Lifestyle modifications alone.

Recommendations

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

Implication for Research

- Further studies are needed to determine the effect of herbal remedies only on hormonal profile and insulin level using larger sample.
- Future research is needed to explain the specific clinical effects of each component of the intervention and to examine the relationships between herbal remedies and lifestyle modifications.
- Conduct research by multidisciplinary team including a pharmacist, obstetrician, and nurses to differentiate the effects of the herbal remedies and reduced body weight and this may further explain the mechanism of the herbal remedies separately to the effects of lifestyle modification.
- The similar study can be conducted with large samples over longer durations for better generalization and examine the sustainability of the outcomes.

Implication for Practice

- Didactic center for PCOS cases inside infertility/gynecological clinics to ensure lifestyle modification and appropriate use of herbal remedies.
- Nurse has a crucial role to guide and counseling women with PCOS to modify their lifestyle to lose weight and to equip them with adequate knowledge about PCOS features.

Acknowledgements

The authors express their gratitude and thanks towards all who directly or indirectly helped them to complete this study and their support in each step of the study. Authors would like to extend their sincere gratitude to the director of outpatient clinic and nursing staff at AlKasr AlAni hospital for helping them in recruiting the study sample. We would also like to extend our heartfelt thanks to our colleagues at Faculty of nursing Cairo University for their continued motivation and support.

Funding: No funding sources.

Conflict of interest: No conflict of interest.

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