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The Effect of Lifestyle Correction Based on Body Composition Intervention on Clinical Efficacy: a Prospective Comparative Randomized Study of Polycystic Ovary Syndrome Patients

Zhang Xin-Yuan*, Fu Ling-Ling, Song Ke, He Ting-Ting, Yang Jing, Chang Jun, Su Li Meng Wu Jun, Li Jie, Yao Lei, Zhang Yan, Liu Jiang-Ling
Urumqi First People's Hospital, Xinjiang, China

ABSTRACT

AIM. To study the clinical effect of body composition-based lifestyle intervention in patients with polycystic ovary syndrome (PCOS).
MATERIAL AND METHODS. In the period of November, 2020 – July, 2021, 91 patients diagnosed with PCOS in the First People's Hospital of Urumqi were prospectively selected and divided into a control group (46 cases) and an experimental group (45 cases) according to random number method. The patients in the control group were treated with Drospirenone and Ethinylestradiol tablets (II), while the patients in the experimental group were treated with Drospirenone and Ethinylestradiol tablets (II) and lifestyle adjustment based on body composition. The changes of the indices before and after 3 months of treatment were compared between the two groups.
RESULTS. The indices of PCOS patients in the two groups after treatment (except 1 basal metabolic rate and muscle weight, 2. FSH and 3. HDL) were decreased, and the decrease in the experimental group was more significant ($P < 0.05$). Patients in the experimental group had significantly increased spontaneous ovulation and pregnancy rate / Conducive to ovulation and pregnancy.
CONCLUSION. In PCOS patients, the combination of Drospirenone and Ethinylestradiol tablets (II) and lifestyle intervention based on human body components can improve reproductive hormone, glucose metabolism and insulin resistance more effectively, which is beneficial to spontaneous ovulation and pregnancy, and reduce the weight of patients.
KEYWORDS: body composition, life style, polycystic ovary syndrome, Anti-Mullerian hormone, Insulin resistance

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***For correspondence:** Zhang Xin-Yuan, e-mail: 790723751@qq.com

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Влияние изменения образа жизни на основе коррекции состава тела на клиническую эффективность: проспективное сравнительное рандомизированное исследование пациентов с синдромом поликистозных яичников

Чжан Синь-Юань, Фу Линг-Линг, Сонг Ке, Хэ Тинг-Тинг, Ян Цзин, Чан Цзюнь, Су Ли Мэн, Ву Цзюнь, Ли Цзе, Яо Лэй, Чжан Янь, Лю Цзян-Лин
Первая народная больница Урумчи, Синьцзян, Китай

РЕЗЮМЕ

ВВЕДЕНИЕ. Синдром поликистозных яичников – это эндокринно-метаболическое заболевание, показатели по распространённости которого постоянно растут. Он характеризуется различными клиническими составляющими, основными из которых являются избыток андрогенов, олиго-ановуляторное бесплодие, поликистоз яичников, инсулинорезистентность (ИР) и кардиометаболические изменения.
ЦЕЛЬ. Изучить клинический эффект корректировки образа жизни на основе состава тела у пациенток с синдромом поликистозных яичников.

МАТЕРИАЛ И МЕТОДЫ. В период с ноября 2020 года по июль 2021 года 91 пациентка с диагнозом синдрома поликистозных яичников в Первой народной больнице Урумчи была проспективно отобрана и разделена на контрольную (46 человек) и экспериментальную (45 человек) группы в соответствии с методом случайных чисел. Пациентки контрольной группы принимали таблетки дроспиренона и этинилэстрадиола (II), а пациентки экспериментальной группы – таблетки дроспиренона и этинилэстрадиола (II) и проходили корректировку образа жизни в зависимости от состава тела. Изменения индексов до и после 3 месяцев лечения сравнивались между двумя группами.

РЕЗУЛЬТАТЫ. Показатели пациентов с синдромом поликистозных яичников в двух группах после лечения (за исключением 1 базальной скорости метаболизма и веса мышц, 2. гонадотропный гормон и 3. ЛПВП) снизились, причем снижение в экспериментальной группе было более значительным (P < 0,05). У пациенток в экспериментальной группе значительно повысился уровень спонтанной овуляции и беременности.

ЗАКЛЮЧЕНИЕ. У пациенток с синдромом поликистоза яичников комбинация таблеток Дроспиренона и Этинилэстрадиола (II) и изменения образа жизни на основе на основе коррекции состава тела может значительно улучшить репродуктивный гормон, метаболизм глюкозы и резистентность к инсулину, что благоприятно для спонтанной овуляции и беременности, а также снизить вес пациенток.

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***Для корреспонденции:** Чжан Синь-Юань, e-mail: 790723751@qq.com

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INTRODUCTION

PCOS affects 5-18% of women, and is a reproductive, metabolic, and psychological condition with impacts across the lifespan [1]. The prevalence of PCOS is between 6 and 15% globally [2]. In view of pathophysiological characteristics, the factors accounting for PCOS heterogeneity mainly include obesity, insulin resistance, abdominal adiposity, and so on [3]. According to various data, the risk of miscarriage in PCOS women is three times higher than the risk of miscarriage in healthy women [4].

There are still many controversies about the definite diagnosis and specific treatment measures of PCOS. In recent years, PCOS is often treated with simple drugs, but the research on obesity and reproduction caused by external factors, such as unhealthy lifestyle, obesity, high-fat diet and mental stress. Compared with other medical methods, adapting to lifestyle, exercise and diet is an economical, convenient and safe way [5]. Antimueller hormone, also known as Müllerian inhibitory substance (MIS), is a glycoprotein homodimer in the transforming growth factor-β superfamily. Levels of anti-Mullerian hormone (AMH) [6], a marker of ovarian aging. In the ovary, AMH inhibits steroid synthesis, inhibits primordial follicle recruitment, reduces follicle stimulating hormone (FSH) synthesis, decreases FSH synthesis will affect aromatase activation, is not conducive to the transformation of androgen to estrogen, and androgen excess will hinder follicular development [7]. The serum AMH level of PCOS patients is 2-3 times higher than that of normal women of childbearing age. Women with high AMH level (≥ 4.45ng/mL) are 9.35 times more likely to suffer from PCOS than those with low AMH level. In recent years, with the continuous improvement of AMH detection technology, the relationship between AMH and PCOS has attracted much attention. In order to study the pathogenesis of PCOS patients, 91 PCOS patients diagnosed in our hospital between November 2020 to July 2021 were prospectively selected. Effects of lifestyle intervention based on human body composition on body composition, metabolism and reproductive function, spontaneous ovulation and pregnancy rate of PCOS patients were studied. To establish the correlation between AMH index and human insulin resistance index, further reveal the clinical value of lifestyle intervention based on human body composition for PCOS patients, and lay the foundation for the long-term management of PCOS patients.

A prospective study was conducted on 91 PCOS patients diagnosed by gynecology in our hospital from November 2020 to July 2021, aged between 18 and 40 years inclusive. The control group was 46 cases, age 21-39 years old, mean (27.10±2.53) years old; body mass index 19-25 kg /m^2, mean (21.86±1.42) kg /m^2; the experimental group was 45 cases, age 22-40 years old, mean (28.39±2.70) years old; body mass index 19-26 kg /m^2, mean (21.92±1.47) kg /m^2 ; two groups of general data comparison (P > 0.05), comparable.

The subjects were divided into insulin resistance group (HOMA-IR>1.95)-42 cases and non-insulin resistance group (HOMA-IR≤1.95) – 49 cases, according to HOMA-IR value from the general sample of patients.

The age of the insulin resistance group was 21-38 years old, average age (28.02±3.11) years old; the age of the non-insulin resistance group was 22-39 years old, average age (27.50±2.95) years old; two groups of general data comparison (P>0.05), comparable.

Inclusion criteria:

1. All in line with the 2018 edition of the International Guidelines for the Diagnosis and Treatment of PCOS [9]; 2. 25kg /m^2≤BMI (BMI<30 kg/m^2); 3. The functions of important organs such as heart, liver and kidney were normal; 4. All participants agreed to participate in this study and signed the informed consent form, which was approved by the Medical Ethics Committee.

Exclusion criteria:

1. Reproductive system lesions; 2. Malignant tumor; 3. Other endocrine system diseases; 4. Unable to strictly implement and record diet and exercise according to

the regulations; 5. Patients with severe neuropsychiatric diseases cannot cooperate with this study properly; 6. Patients receiving sex hormones or affecting glucose and lipid metabolism during the observation period.

MATERIAL AND METHODS

In this study, 91 patients with PCOS in our hospital were selected as research objects, and the patients were randomly divided into experimental group (45 cases) and control group (46 cases) by prospective randomized controlled case study. Patients in the control group were simply treated with Drospirenone and Ethinyl Estradiol tablets (II) (oral administration started on the first day of menstruation, 1 tablet/day, cycle of 28 days, for three consecutive months). Patients in experimental group were assisted with lifestyle intervention based on human components on the basis of the control group (Specifically at 1.2.2.1). Both groups needed follow-up (physical composition, diet, exercise, endocrine metabolism, reproductive hormone levels, spontaneous recovery of ovulation and pregnancy rate). The subjects were further divided into insulin resistance group (HOMA-IR>1.95) with 42 cases and non-insulin resistance group (HOMA-IR≤1.95) with 49 cases according to HOMA-IR values. BMI and Serological indicators: hormone six items, AMH, Fasting plasma glucose (FPG), fasting insulin (FIN), total cholesterol (TC), triglyceride (TG), low density lipoprotein cholesterol (LDL-C), and high density lipoprotein cholesterol (HDL-C) of the two groups were compared, and the correlation between AMH level and HOMA-IR was compared. During this period, 4 cases in the control group lost the follow-up rate of 8.00% and 5 cases in the experimental group lost the follow-up rate of 10.00%, because they failed to adhere to the drug treatment and life intervention.

Human-based lifestyle intervention methods

To popularize PCOS-related knowledge to patients, including the harm of PCOS, treatment methods and related precautions; to inform patients about the influence of body weight on the condition, it is suggested that patients should control body weight reasonably and make individualized nutritional intervention plan according to body weight, energy and food preference. It is recommended that food intake of 1200-1500 kg calories per day or a 30% energy intake gap be maintained, while daily intake of protein not less than 1.2g/kg, dietary fiber 30-40g, fat intake of 20-30%, carbohydrate intake of 40-50%, and daily drinking water not less than 1.5L. Nutritionists introduced the method of food exchange points to patients in detail to enrich their food types. Studies have also suggested [10] that for PCOS patients 30% or 500~750kcal (1kcal = 4.184kJ) of energy should be reduced daily on the basis of a low-calorie diet to reduce body weight, which can be customized individually and flexibly. Therefore, Calorie consumption should be determined after individual assessment and adjusted timely according to the patient's condition.

Appropriate exercise mode was selected according to the patient's physical exercise function: the parameters of the patient's muscle, joint, nerve, and anti-fracture ability were understood in detail. The individualized exercise mode and exercise intensity were formulated according to the patient's functional state, and the patients were required to take 30-60 minutes of walking, jogging, cycling or other aerobic exercise every day. The patients were strongly recommended aerobic activity at least 30 minutes per day (cycling, speed walking, swimming, etc.) in the home environment. Attention should be paid to the prohibition of dangerous sports during exercise.

Human body composition analyzer (Sihai Huachen NQA-PI individual nutrition analyzer) was used to measure the body composition data of patients. Prohibit intense exercise within 6 hours before the test, the test day to minimize drinking water and eating, avoid affecting the body composition test results. During the measurement, the patients were asked to take off shoes and socks, put their feet on the foot electrode, stand on the test bench, and keep their body relaxed. The hands were evenly applied to the hand electrode. The patients were asked to maintain the correct posture and start the data test. The basic metabolic rate, overall water, intracellular fluid, extracellular fluid, PBF, fat weight, defatted weight and muscle weight were measured.

Follow-up management method: each patient was included in the PCOS WeChat group composed of gynecological doctors and nursing staff. To personalize lifestyle advice for women with polycystic ovary syndrome (PCOS), there were no such women detailed information regarding dietary intake, eating behavior, physical activity levels, and quality of life (QoL) may be useful [11]. To understand the diet and exercise status of patients in the treatment process and carry out remote guidance, regularly distribute popular science information in WeChat group, improve the level of disease knowledge of patients and improve their treatment compliance. At the same time, patients can also exchange experience in disease treatment in WeChat group, supervise and encourage each other, which is conducive to improving patients' treatment confidence. Issue diet diary and exercise diary, patients are required to keep the diary carefully and follow up once a month. According to the changes of diet, exercise diary, weight and body composition of patients, adjust the nutrition intervention plan. After 3 months of life intervention, the body weight and body composition of the patients were re-measured and laboratory tests were performed.

Observation indices:

1. Collect fasting basal metabolic rate, total water, intracellular fluid, total extracellular fluid, body fat percentage (PBF), fat weight, fat-free weight, muscle weight, body weight, body mass index, waist circumference before and after life intervention;

2. All patients were fasting for 12 hours before and after life intervention, venous blood was drawn at 10:00 a. m., and venous blood hormone six items and AMH were collected on the 2nd–5th day of menarche;

3. Fasting plasma glucose (FPG), fasting insulin (FIN), total cholesterol (TC), triglyceride (TG), low density lipoprotein cholesterol (LDL-C), and high-density lipoprotein cholesterol (HDL-C) were collected on the same day. Insulin resistance index: insulin resistance index (HOMA-IR = FPG ×FIN/22.5) was calculated by steady-state model to evaluate the degree of insulin resistance in peripheral tissues.

4. From the 8th to the 10th day of menstruation, ultrasonography was used to monitor the follicles and the

examination showed that there were yolk sac in the uterus to judge the pregnancy, The indicators and pregnancy of the two groups were recorded and the relevant statistical records were made. Statistical methods SPSS 26.0 software was used for analysis. Measurement data were expressed as (±s) using t test. The enumeration data were expressed as rate (%), and$\chi 2$ test was used; Pearson's linear method was used for correlation analysis. The single group was compared before and after treatment by f test, $P < 0.05$ was considered statistically significant.

RESULTS AND DISCUSSION

There was no significant difference in the body composition indices between the two groups before and after treatment (P>0.05). After treatment, the total water, intracellular fluid, total extracellular fluid, body fat percentage, fat mass and fat-free weight of the two groups decreased and the decrease in the experimental group was more significant (P>0.05) (Table 1).

Table 1. *Comparison of body composition of PCOS patients before and after treatment (n±s)*

Ground	Number of samples	Before and after treatment	Basic metabolic rate (kJ/d)	Overall water (kg)	Intra-cellular fluid (kg)	Overall extra-cellular fluid (kg)	Body fat percentage (%)	Fat (kg)	Defatted weight (kg)	Muscle weight (kg)
Experi-mental group	45	Before treatment	6350.45 ± 653.29	35.59 ± 4.16	19.48 ± 2.87	15.89 ± 2.25	36.71 ± 4.66	21.92 ± 1.47	48.57 ± 6.45	45.61 ± 6.32
		After treatment	5900.46 ± 780.13	31.02 ± 4.20[ab]	16.90 ± 2.76[ab]	14.96 ± 2.23[ab]	32.37 ± 4.11[ab]	22.28 ± 8.31[ab]	46.31 ± 6.27[ab]	42.43 ± 5.89
Control group	46	Before treatment	6345.57 ± 652.21	35.81 ± 4.53	19.48 ± 2.78	15.87 ± 2.26	34.41 ± 4.34	21.86 ± 1.42	48.64 ± 6.36	45.62 ± 6.36
		After treatment	6035.82 ± 701.31	33.08 ± 4.30[a]	18.57 ± 2.62[a]	15.11 ± 2.34[a]	36.80 ± 4.22[a]	24.06 ± 8.29[a]	47.53 ± 6.45[a]	43.78 ± 5.92

Note: *Comparison with the same group before treatment; aP<0.05; Comparison with control group after the treatment; bP<0.05*

There was no significant difference in anthropometric indicators and reproductive hormones between the two groups before and after treatment (P>0.05). After treatment, the body weight, waist circumference, BMI, T and LH levels of the two groups were decreased and the decrease in the experimental group was more significant (P>0.05) (Table 2.).

Table 2. *Comparison of anthropometric and reproductive serological indices between the two groups of PCOS patients before and after treatment (n±s)*

Ground	Number of samples	Before and after treatment	Body weight(kg)	Waistline(cm)	BMI(Kg/cm^2)	T(nmlo/L)	LH(IU/L)	FSH(IU/L)
Experi-mental group	45	Before treatment	65.59 ± 8.01	91.95 ± 6.30	26.10 ± 2.01	2.66 ± 0.41	11.87 ± 1.09	4.52 ± 1.11
		After treatment	58.21 ± 7.62[ab]	84.63 ± 6.73[ab]	21.87 ± 1.08[ab]	2.40 ± 0.22[ab]	4.02 ± 2.10[ab]	4.10 ± 0.93
Control group	46	Before treatment	65.38 ± 7.63	91.30 ± 6.11	26.65 ± 2.03	2.56 ± 0.34	10.30 ± 2.11	4.49 ± 1.21
		After treatment	64.44 ± 6.32[a]	90.01 ± 5.03[a]	25.02 ± 1.64[a]	1.90 ± 0.32[a]	5.58 ± 2.06[a]	4.30 ± 1.03

Note*: Comparison with the same group before treatment; aP<0.05; Comparison with control group after treatment: p<0.05. Hormone data was collected on the 2nd–5th day of menarche*

There was no significant difference in endocrine indices between the two groups before and after treatment (P > 0.05). After treatment, the levels of FPG, FIN, TG, TC and LDL-C in the two groups decreased, and the decrease in the experimental group was more significant (p<0.05) (Table 3.).

Table 3. *Comparison of endocrine indices before and after treatment between the two groups of PCOS patients (n, ± s)*

Ground	Number of cases	Before and after treatment	FPG (mmol/L)	FIN(μIU/L)	TG (mmol/L)	TC (mmol/L)	HDL-C(mmol/L)	LDL-C(mmol/L)
Experimental group	45	Before treatment	5.29 ± 0.60	13.59 ± 2.21	2.10 ± 0.78	4.72 ± 0.75	1.13 ± 0.26	2.98 ± 0.61
		After treatment	3.95 ± 0.13[ab]	5.11 ± 1.32[ab]	1.39 ± 0.52[ab]	4.10 ± 0.77[ab]	1.11 ± 0.29	2.28 ± 0.52[ab]
Control group	46	Before treatment	5.32 ± 0.75	12.33 ± 2.54	2.11 ± 0.81	4.75 ± 0.60	1.15 ± 0.27	2.96 ± 0.59
		After treatment	5.01 ± 0.15[a]	12.22 ± 2.03[a]	1.71 ± 0.46[a]	4.49 ± 0.61[a]	1.11 ± 0.30	2.69 ± 0.57[a]

Note: *Comparison with the same group before treatment: aP<0.05; Comparison with control group after treatment; bP<0.05*

Compared with the control group, the success rates of spontaneous ovulation and pregnancy in the experimental group were significantly higher than those in the control group and the difference between the two groups was statistically significant (P < 0.05) (Table 4.).

Table 4. *Comparison of spontaneous ovulation and pregnancy success rate after treatment between the two groups of PCOS patients (n%)*

Ground	Number of cases	Autonomous ovulation rate		Success rate of pregnancy	
		Number of cases (n)	Self-help ovulation rate (%)	Number of cases (n)	Pregnancy success rate (%)
Experimental group	45	39	86.67	24	53.33
Control group	46	30	65.22	16	34.78

Note: *Comparison of two groups P<0.05*

BMI, FPG, FIN and AMH levels in the insulin resistance group were higher than those in the non-insulin resistance group and the difference was statistically significant (p<0.05)(Table 5).

Table 5. *Comparison of BMI and serum indices between insulin resistance group and non-insulin resistance group in PCOS patients (n ± s)*

Groups	Case number	BMI (Kg/cm2)	FPG (mmol/L)	FIN (μIU/L)	T (nmlo/L)	A M H (ng/ml)
Insulin resistance group	42	26.20 ± 2.01	5.24 ± 0.50	17.51 ± 8.01	0.73 ± 0.15	10.21 ± 4.50
Non-insulin resistance group	49	23.35 ± 2.23	4.30 ± 0.85	12.20 ± 4.56	0.62 ± 0.15	6.64 ± 3.23
t		4.732	3.653	2.845	1.366	3.142
p		0.000	0.000	0.005	0.165	0.001

Correlation analysis between AMH and HOMA-IR in PCOS patients Pearson linear correlation analysis showed that AMH level was positively correlated with HOMA-IR level (P < 0.05), as shown in Table 6.

Table 6. *Association between AMH level and HOMA-IR*

Project	A M H	
	r	P
HOMA-IR	0.463	0.026

Background polycystic ovary syndrome (PCOS) is characterized by reproductive disorder and increased risk of metabolic syndrome [12]. Due to the complex causes of the disease, the clinical manifestations are mostly polymorphism, such as menstrual disorder, rare ovulation, obesity, ovarian polycystic change and hyperandrogen expression such as acne. Studies have shown that insulin resistance is an important link in the pathogenesis of PCOS. In recent years, the incidence of PCOS has increased significantly, which seriously threatens women's health [13]. The etiology and pathogenesis of PCOS are still unclear. Excessive ovarian secretion of AMH is an important feature of PCOS. AMH is closely related to the number of antral follicles and ovulation disorders. The determination of serum AMH has good diagnostic potential for the diagnosis of PCOS, and is also a new indicator for predicting the therapeutic response of PCOS patients. However, there are still some limitations regarding markers for the independent diagnosis of PCOS [14]. Studies have shown that insulin resistance (IR) is another basic feature of PCOS, which is a key link in the pathogenesis of PCOS.

However, the specific mechanism of IR leading to PCOS has not yet been fully studied, which may be associated with the weak response of target organs to insulin and cause physiological changes. In order to maintain blood glucose, the body secretes more insulin to cause hyperinsulinemia [15]. At present, the Canadian Association of Obstetrics and Gynecology Doctors (SOGC) in 2018 recommended lifestyle interventions (including diet control, exercise, behavioral intervention) for PCOS guidelines, regulating menstrual cycles and improving clinical symptoms, including short-acting oral contraceptives [16]. Hajivandi Leila's [17] study shows that inappropriate dietary behavior was the most important risk factor for obesity in all age groups in PCOS patients. Lifestyle intervention based on human components is the most accurate, effective and scientific way of life intervention for PCOS patients. It is a convenient, safe and effective intervention method to adjust the living habits of patients, improve various unhealthy lifestyles, moderate exercise and adjust the diet structure [18]. It also improves health-related quality of life and quality of life in overweight or obese PCOS patients.

Dietz de Loos Alexandra L.P. [19] suggests that all women with polycystic ovary syndrome receive three lifestyle interventions before pregnancy, with a goal of weight loss of 5-10%. Weight loss had a significant positive effect on the incidence of ovulation dysfunction and hyperandrogenism. The characteristics and symptoms of PCOS in all groups were improved, although these improvements were more pronounced in lifestyle intervention group. Weight loss itself leads to improvements in the diagnosis and phenotype of PCOS.

The results of this study showed that there was no significant difference in human components and (reproductive) endocrine indices between the two groups before treatment ($P > 0.05$). After treatment, the total water content, intracellular fluid, total extracellular fluid, body fat percentage, fat content and defatted weight of the two groups were decreased. Weight, waist circumference, BMI, T and LH levels decreased; fPG, FIN, TG, TC and LDL-C were decreased; and the experimental group decreased more significantly ($p<0.05$). BMI, FPG, FIN and AMH levels in the insulin resistance group were higher than those in the non-insulin resistance group, and the difference was statistically significant ($p<0.05$). Pearson linear correlation analysis showed that AMH level was significantly positively correlated with HOMA-IR level ($p<0.05$). It showed that the increase of BMI, FPG, FIN and AMH levels in PCOS patients will further aggravate insulin resistance, which leads to endocrine disorders and abnormal glucose metabolism. AMH was related to HOMA-IR level and was significantly positively correlated. AMH increased with the increase of HOMA-IR. For obese PCOS patients with high BMI, no matter whether a series of clinical reproductive indicators such as AMH are normal or not, they still need to change their lifestyle and reduce their weight, which further helps to reduce insulin resistance [20]. This study improved endocrine metabolism and obesity in PCOS patients by lifestyle intervention based on body composition. Especially for obese PCOS is the most economical and effective treatment. All PCOS patients, regardless of obesity or not, weight loss should become the first choice in many treatments. For obese and infertile women with PCOS, weight loss can be placed in a crucial and critical position, and weight loss can be combined with other treatments.

We have found that a scientific diet and a regular exercise pattern can help treat patients with PCOS and can really improve their health and reduce adverse effects.

CONCLUSION

To sum up, lifestyle interventions based on human body component can effectively improve endocrine metabolism, promote ovulation and increase fertility in PCOS patients, which has better clinical value and improves patients' quality of life and truly improves their health.

ADDITIONAL INFORMATION

Information about the authors:
Zhang Xin-Yuan, Master degree, Deputy Chief Physician of Obstetrics and Gynecology, First People ' s Hospital of Urumqi, China.
E-mail: 790723751@qq.com
Fu Ling-Ling, Bachelor's degree, Attending Physician of Obstetrics and Gynecology Department, First People's Hospital of Urumqi, China.
E-mail: 270581330@qq.com
Song Ke, Bachelor's degree, Attending Physician of Obstetrics and Gynecology Department, First People's Hospital of Urumqi, China.
E-mail: 1471078383@qq.com
He Ting-Ting, Master degree, Attending Physician of Obstetrics and Gynecology Department, First People's Hospital of Urumqi, China.
E-mail: 65856670@qq.com
Yang Jing, Master degree, Deputy Chief Physician of Obstetrics and Gynecology, First People' s Hospital of Urumqi, China.
E-mail: 457160642@qq.com
Chang Jun, Bachelor's degree, Attending Physician of Obstetrics and Gynecology Department, First People's Hospital of Urumqi, China.
E-mail: 279055996@qq.com
Su Li Meng Wu Jun, Master degree, Attending Physician of Obstetrics and Gynecology Department, First People 's Hospital of Urumqi, China.
E-mail: 254229104@qq.com

Li Jie, Master degree, Deputy Chief of Pediatrics, First People' s Hospital of Urumqi, China.
E-mail: 19208291@qq.com
Yao Lei, Bachelor degree, Ultrasound Physician, First People's Hospital of Urumqi, China.
E-mail: 33019734@qq.com
Zhang Yan, Bachelor degree, Laboratory Physicians, First People's Hospital of Urumqi, China.
E-mail: 1017537634@qq.com
Liu Jiang-Ling, Chief Physician, Director of Hospital, First People's Hospital of Urumqi, China.
E-mail: 790723751@qq.com

Authors' contribution:
All authors confirm their authorship according to the ICMJE criteria (all authors contributed to the conception, study design and preparation of the article, read and approved the final version before publication).
Special contribution:
Zhang X.Y. – design and development of the protocol;
Zhang X.Y., Fu L.L., Song K., He T.T., Su L.M.W.J., Chang J., Yang J., Li J., Yao L., Zhang Y., Liu J.L. – data collection;
Zhang X.Y.- complete data analysis independently.

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The authors state that all the procedures used in this paper comply with the ethical standards of the institutions that carried out the study and comply with the Helsinki Declaration as revised in 2013.
Consent for Publication:
Consent of patients (their representatives) to the processing and publication of non-personalized data was obtained.

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