

DOI: <http://dx.doi.org/10.18203/2320-1770.ijrcog20182890>

Original Research Article

## Holistic approach in the management of PCOS: a pilot study of an online PCOS-reversal program

Manthan N. Mehta<sup>1\*</sup>, Mahesh Jayaraman<sup>2</sup>, Sharda Agarwal<sup>2</sup>

<sup>1</sup>Department of Pharmacology, Topiwala National Medical College and BYL Nair Charitable Hospital, Mumbai, Maharashtra, India

<sup>2</sup>PCOS Expert Panel, Sepalika, Mumbai, Maharashtra, India

**Received:** 15 May 2018

**Accepted:** 05 June 2018

**\*Correspondence:**

Dr. Manthan N. Mehta,

E-mail: [drmanthanmehta@gmail.com](mailto:drmanthanmehta@gmail.com)

**Copyright:** © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

### ABSTRACT

**Background:** Polycystic ovary syndrome (PCOS) is a complex disorder that can be managed but not permanently cured. Each woman has her own PCOS symptoms and its own root causes. A number of medications are prescribed to women with PCOS. However, a holistic approach could be the best way forward in managing a disease as complex as PCOS. Authors conducted this pilot study called the Sepalika 5-petal PCOS reversal program which consisted of individualized diet plans, magnet acupotherapy, fitness regimens, dietary supplements and herbal products to evaluate whether these interventions improve PCOS symptoms, insulin resistance and hyperandrogenism.

**Methods:** A total of 30 patients were recruited online from all parts of India using the PCOS symptom quiz. Various baseline investigations were performed at recruitment. They were suggested personalized diet plans, followed by exercise videos, magnetic acupotherapy and herbal and micronutrient supplements. The program spanned over a period of 90 days and patients outlook and quality of life were also assessed at the end of the program.

**Results:** The main goal of most participants was improvement in weight and energy issues, and regularization of periods. Each of these goals were achieved in all participants of the program. Patient-reported outcomes showed a definite improvement in the quality of life of the participants at the end of 90 days.

**Conclusions:** PCOS is a physical - sexual, psychological and social syndrome; therefore, it is necessary to taking a more holistic approach to patient care beyond treating physical symptoms. Larger studies with more objective and subjective endpoints is the way forward.

**Keywords:** Infertility, Integrative Medicine, Polycystic ovaries, Patient support

### INTRODUCTION

Polycystic ovary syndrome (PCOS) is a common, complex endocrine, metabolic and reproductive disorder affecting up to 17.8% of reproductive aged women.<sup>1</sup> Estimates of prevalence range from 2.2% to as high as 26%, depending on the diagnostic criteria used and the ethnicity of the population under study. A recent survey found a 9.13% prevalence in south Indian adolescent girls.<sup>2</sup> Polycystic Ovarian Syndrome (PCOS) has been associated with a constellation of symptoms that can

damage self-esteem in young women, including obesity, hirsutism, acne, diabetes risk, and worries about future fertility.<sup>3</sup> Hyperinsulinemia either contributes to or worsens all of these conditions, and increases androgens in women with PCOS.<sup>4</sup> Despite the high prevalence of insulin resistance, impaired glucose tolerance and type 2 diabetes mellitus in women with PCOS, there is no consensus on the best long-term management of these conditions.<sup>5</sup> An insight into the metabolic implications of PCOS is limited. This may be attributed to the lack of uniform diagnostic criteria, the heterogeneity of the

condition and the presence of confounders including obesity.<sup>6</sup> It is important for women with PCOS to understand the health risks and complications associated with this disease.<sup>3</sup>

Lifestyle modifications including dietary changes, increased exercise and weight loss are appropriate first line interventions and form the foundation for treating women with PCOS. Lifestyle modifications may reduce the incidence of diabetes, cardiovascular disease and cancer.<sup>6</sup> Goals for management of PCOS places strong emphasis on a multidisciplinary approach as pharmacological treatments appear to be only symptom oriented. Conventional medical treatment is limited by the prevalence of contraindications to such drugs in some women with PCOS, non-effectiveness in some circumstances, side effects and by preferences of women with PCOS for alternatives to pharmacological management, given the complex nature of the disease.<sup>1</sup> Therefore, it is important to evaluate other non-pharmacological treatment strategies because most women with PCOS require long-term treatment.<sup>5</sup>

An 8-week study by Phy et al. using a diet eliminating insulinemic foods resulted in anthropometric improvements including weight loss, a reduction in waist circumference, and body fat loss in an overweight and obese PCOS population. This diet also led to improvements in insulin sensitivity as determined by HOMA-IR and a reduction in total and free testosterone in women with PCOS. These improvements are promising, especially since weight loss is difficult in a PCOS population.<sup>5</sup>

Various studies have shown that physical exercises in the form of yoga and others are useful decreasing AMH, LH, testosterone, and mFG scores and increasing menstrual frequency targeting the hormonal imbalance in PCOS women.<sup>2</sup>

Herbal medicines are known to contain pharmacologically active constituents with physiological effects on female endocrinology and have been positively associated with reduced incidence of various complex diseases. They have complex interactions with the body systems both, biochemically and by altering organ function.<sup>1</sup>

The complexity of the disorder along with a multitude of treatment options ranging from lifestyle modifications to pharmacological management to alternative therapies provides an opportunity for health care providers to develop plans of management that incorporate a holistic approach reflecting the multi-layered needs of each woman.

A study done by Crete et al suggests that women with PCOS face many challenges in managing their disorder and desire to gain control, balance, and well-being through a comprehensive treatment plan.<sup>7</sup>

With this background in mind, we conducted this pilot study called the Sepalika 5-petal PCOS reversal program which consisted of individualized diet plans, magnet acutherapy, fitness regimens, dietary supplements and herbal products to evaluate whether these interventions improve PCOS symptoms, insulin resistance and hyperandrogenism.

## METHODS

Thirty women in the reproductive age group from 15-45 years all over India were recruited online in the Sepalika five-petal PCOS reversal pilot program. Inclusion criteria were defined by the diagnosis of PCOS using the PCOS-Symptom quiz on the Sepalika website. The symptom quiz was carefully designed by the expert panel and included questions under the subheadings of menstrual health, urogenitary health, digestive health, diet, weight issues, energy problems, mental and emotional health, and other miscellaneous symptoms. The quiz was validated by the PCOS Expert Panel and Gynaecologists and fertility experts. Detailed medical history of all participants were obtained including ongoing and previous treatments undertaken for PCOS. Participants were asked about their main health goal and the reason for joining this program. Demographics and baseline anthropometry measurements were performed. Baseline investigations such as Complete Blood Indices, Thyroid profile, Male and Female Hormonal panels, Iron studies, Vitamin D assay were performed for all patients. Other necessary investigations such as lipid profile, cortisol levels, etc. were performed on a case to case basis. The primary end point of this online reversal program was improvement in patient-reported outcomes with respect to PCOS symptoms at the end of 90 days. The overall acceptance of the online program was also recorded.

### *Flow of the program*

Women who were accepted into the programme filled an online form, listing their current symptoms, medications, diet and exercise habits. Special attention was also paid to metabolic health symptoms like energy levels, moods, digestion, etc. Baseline investigations, including hormonal investigations and vitamin and mineral profiles were done on the 3rd day of the period by women on the programme and the results shared with the experts via email.

The first call with a member of the medical team included further questioning when needed and an explanation of the expected prognosis. Vitamins and minerals (such as iron, Vitamin D3 etc.) that were prescribed were explained fully to the patient.

Participants received the magnet-based acupressure kit via courier and learnt how to use it via video demonstrations sent to them. Most of them learnt this easily and intuitively and magnet therapists would check location accuracy of magnets regularly, to ensure

effectiveness of the therapy. The diet plan too was sent via mail. Videos of the exercise regimen, that included yoga and parts of the Aviva method were sent to participants who just had to follow along with the experts in the video. High levels of compliance were noted on all petals of the 5-petal programme.

Counselling, especially on lifestyle changes that were part of the programme was given utmost importance and women were allowed to ask questions and clear doubts via whatsapp messages at any point on the programme. Any questions/situations that needed immediate medical attention was escalated and the patient received a telephonic consult with a medical expert. The Nutritionist had fortnightly reviews with patients to evaluate progress and make course corrections if needed.

Regular report cards on progress were sent to the patient, to ensure encouragement and further compliance. Patients spoke to an expert from the team every 15 days, to ensure continued adherence to the programme. They also reported onset of natural periods, details of symptoms like less painful periods, better flow, reduced hair fall, reduction in acne etc. A health discussion group was also formed for the women, so they could celebrate each others' progress, ask questions that peers and experts answered, share healthy recipes and participate in group detox programmes, etc.

Recruitment → Call → Baseline investigations → Diet plan → Videos → Magnets → Supplements

**RESULTS**

Thirty women from different parts of India belonging to different age-groups completed the Sepalika 5-petal online PCOS reversal program. Mean age of the participants was 28.25 years. The mean weight at baseline was 70.42 kg. Mean height of the participants

was 160.53 cm. The mean waist and hip circumference at baseline was 36 and 49.31 inches respectively. Previous reports and medical prescriptions including supplements was retrieved from all participants. At the time of enrolment into the program, five participants were receiving metformin in the range of 500 mg to 1gm per day and two others had received the drug in the past. Four participants were receiving Aldactone and one of them was on this drug in the past and had discontinued prior to enrolment. Most of them were receiving some form of supplements, such as multivitamins, calcium, etc. Four participants were receiving Myo-inositol as a supplement for PCOS. Three of them had tried some form of alternative treatment besides conventional medical treatment for relief of PCOS symptoms. Eight of the thirty participants had received multiple cycles of Oral Contraceptive Pills to regularize their menses. Fourteen participants were married and the average years since marriage were 7.25. Of them, five had children. Three of them had children by the use of assisted reproductive techniques, mainly in-vitro fertilization (IVF).

The average number of days of menstrual bleeding were 4.76 (range 2-12) days. The average gap between two menstrual periods was 47.30 days. Most of them had a history of normal bleeding (n=19). Few of them (n=7) had heavy bleeding and others (n=4) had scanty bleeding. More than half of them (n=19) complained of pain and discomfort, ten of them before periods and nine of them during menses. At the monthly follow up and the end of the program, all the women complaining of pain and discomfort, rated it between 1 and 3 (where 1= Not severe and 5= Very severe) which was between 2 and 5 at baseline. The usual gap between menstrual periods was reduced from an average of 47.30 days to 34.67 days. Participants reported a natural period without the use of contraceptive pills. The periods lasted for an average of 3.89 days (range 3-7 days) as opposed to the wide variation at baseline.

**Table 1: Comparison of Menstrual Cycles at Baseline and End of Treatment (90 days).**

Parameter	Baseline	End of Treatment (90 days)
Average gap between two menstrual cycles (days)	47.30	34.67
Average number of days of menstrual bleeding	4.76	3.89
Range of number of days of menstrual bleeding	2-12	3-7
Severity of pain and discomfort before or during menstrual cycle (On a scale of 1 to 5; 1= Not severe; 5= Very severe)	2-5	1-3

Most of the women in the program rarely exercised prior to joining the five-petal program. 21 of them complained of breathlessness or feeling tired when they walked fast or went up a staircase. At the monthly follow up and the end of the program, most of the women (17 of 21) complaining of fatigue (in the form of breathlessness and tiredness), rated it between 1 and 3 (where 1= Not severe

and 5= Very severe) which was between 1 and 5 at baseline. Four of them did not feel any change in this symptom.

Eighteen of the thirty participants reported acne. Most of them complained of acne on the face (n=11) and others on the back (n=7). At the end of the program, eight of

them reported a decrease in severity (Reduction in score by one to two points) of acne.

Ten participants complained of hair loss. Loss of hair from the crown region only was reported in three participants and the other seven reported an overall hair loss. The severity of hair loss was reported from 3 to 5 at baseline which dropped by 1-3 points in most of the participants (n=8). Excess hair growth was reported by all participants especially in the face, abdomen and chest region. There was marginal change in this aspect at the end of the program. However, some reduction in the areas covered by excess hair was noted.

There was a definite reduction in craving for sweet or salty foods as compared to baseline. The severity was reduced by one to three points on the five-pointer severity scale. Fourteen women complained of mood swings and anxiety issues at enrolment which was marginally reduced by one point on the severity scale in eight of them.

On the Quality of Life scale, improvements in overall energy levels, sleep quality and memory function were noted. It was rated from three to five in most participants (1= Very poor and 5=Very good). Compliance to the program was within acceptable limits of 10% non-compliance to either of the five petals of the program. Overall acceptance of the program also rated between three and five (1= Very poor and 5=Very good).

## DISCUSSION

The findings of this 90 days online pilot PCOS reversal program suggest an improvement in menstrual health, energy issues, acne, along with overall physical and emotional well-being. The program was holistic in nature and included individualization of diet plans, physical exercise, personalized magnet therapy protocols, dietary supplements and ayurvedic medications. The main goal of most participants was improvement in weight and energy issues, and regularization of periods. At the end of the program, most participants achieved a natural period. A significant reduction in the average gap between two periods was noted. Menstrual irregularities have consequences on women's intimate relations, cultural and social concerns and other aspects of their reproductive and general health.<sup>8</sup> Studies in different cultural settings have suggested that menstrual problems are one of the greatest concerns reported by women suffering from PCOS.<sup>8</sup> An overall improvement in menstrual health at the end of this program is definitely a positive step towards improving the quality of life in women diagnosed with PCOS.

Guidelines suggest that lifestyle modification is the first form of therapy, combining behavioural (reduction of psychosocial stressors), dietary, and exercise management.<sup>9</sup> The importance of dietary changes cannot be overstressed. Effective approaches to nutrition and diet

improve endocrine features, reproductive function and cardiometabolic risk profile - even without marked weight loss.<sup>10</sup> Reduced-energy diets (500–1000 kcal/day reduction) are effective options for weight loss and can reduce body weight by 7% to 10% over a period of 6 to 12 months. This study was of limited duration (90 days) and thus, overall reduction in weight was not one of the outcome measures. Guidelines recommend alternative dietary options (increasing dietary protein, reducing glycemic index, reducing carbohydrate) may be successful for achieving and sustaining a reduced weight but more research is needed in PCOS.<sup>9</sup> Present program followed the low-carbohydrate high fat (LCHF) approach which is in line with the new alternative recommendations. The structure and support within a weight-management program is crucial and may be more important than the dietary composition. Individualization of the program, intensive follow-up and monitoring by a physician, and support from the physician, family, spouse, and peers will improve retention.<sup>9</sup> The Sepalika 5-petal program was tailor-made and individualized. Using appropriate technology, regular follow-up and monitoring was done. Support was provided by the experts on the panel of the program. The compliance to the diet plan was noted at the end of the program and was within acceptable limits.

There is surprisingly scant literature on the role of exercise in managing patients with PCOS. Current recommendations suggest that structured exercise is an important component of a weight-loss regime; the aim is >30 minutes per /day.<sup>9</sup> A realistic approach to exercise depends on the assessment of the patient's current exercise habits, preferences regarding type of exercise, and inclination to undertake exercise.<sup>10</sup> Keeping this in mind, the exercise program was based on the AVIVA method and included Bollywood dance numbers to make it interesting for the participants. The types of exercises were frequently changed to avoid boredom.

Acupuncture, which is one of the main treatment modalities of traditional Chinese medicine, is increasingly being used in the area of reproductive endocrinology and infertility in many different parts of the world.<sup>5</sup> The Sepalika 5-petal program individualized magnetic acupathy protocols for each of its participants under the guidance of experts with close follow-up and monitoring. Improvement in energy issues could be attributed to this arm of the program. It is a routine practice in alternative medicine with great results.

PCOS is a life-long condition and although the exact cause is yet to be identified, it is believed to have epigenetic origins, influenced by the uterine environment and behavioural factors.<sup>1</sup> Herbal medicines are complex interventions with the potential for various interactions between compounds. Effects within the body may also exhibit complexity by simultaneous interactions with various body systems, both biochemically and by altering organ function.<sup>1</sup> Certain herbal medicine preparations

exhibit direct effects on reproductive endocrinology for the treatment of women with irregular menstruation, hyperandrogenism and PCOS. Improvement on various fronts was observed at the end of this pilot program.

Various studies have shown that use of dietary supplements such as zinc, iron, Vitamin D, chromium, magnesium, myo-inositol, etc. have promising results in improving PCOS symptoms. Present study has also shown subjective improvement in symptoms of PCOS in all participants.

PCOS impacts patients' lives and psychological health. Post diagnosis, patients with PCOS undergo multiple tests and hospital visits, with associated anxiety. Studies indicate diminished health related quality of life (HRQoL), marital and social difficulties, depression and suicidal ideation among patients with PCOS. Poor QoL is likely to be a risk factor for other poor outcomes. For example, in one study, 14 % of women suffering from PCOS reported suicidal ideation.<sup>8</sup> In present study, all the participants rated an improvement in overall well-being and quality of life.

This was a pilot study with only thirty participants and did not have any objective endpoints in terms of laboratory parameters or physical examination. However, this was a unique online program for reversal of PCOS symptoms. The program was based on a holistic approach to the disease and concentrated on improvement in PCOS symptoms leading to a better quality of life.

## CONCLUSION

PCOS is a physical - sexual, psychological and social syndrome; therefore, it is necessary to taking a more holistic approach to patient care beyond treating physical symptoms. PCOS patients present a challenge to providers across disciplines. Physical and psychosocial effects of living with PCOS are well-documented. The findings of this pilot study suggest that women with PCOS can gain control, balance, and well-being through a comprehensive treatment plan. The Sepalika five-petal program looks at targeting the disease from its roots. The high prevalence of this disorder provides an opportunity to develop plans of management that incorporate a holistic approach rather than a conventional approach. Larger studies with more objective and subjective endpoints is the way forward.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee*

## REFERENCES

1. Arentz S, Abbott JA, Smith CA, Bensoussan A. Herbal medicine for the management of polycystic ovary syndrome (PCOS) and associated oligo/amenorrhoea and hyperandrogenism; a review of the laboratory evidence for effects with corroborative clinical findings. *BMC Complement Altern Med.* 2014;14:511.
2. Nidhi R, Padmalatha V, Nagarathna R, Amritanshu R. Effects of a holistic yoga program on endocrine parameters in adolescents with polycystic ovarian syndrome: a randomized controlled trial. *J Altern Complement Med.* 2013;19(2):153-60.
3. Pereira K, Kreider KE. Caring for women with polycystic ovary syndrome. *Nurse Pract.* 2017;42(2):39-47.
4. Phy JL, Pohlmeier AM, Cooper JA, Watkins P, Spallholz J, Harris KS, Berenson AB, Boylan M. Low starch/low dairy diet results in successful treatment of obesity and co-morbidities linked to polycystic ovary syndrome (PCOS). *J Obesity Weight Loss Therapy.* 2015;5(2).
5. Zheng Y, Stener-Victorin E, Ng EH, Li J, Wu X, Ma H. How does acupuncture affect insulin sensitivity in women with polycystic ovary syndrome and insulin resistance? Study protocol of a prospective pilot study. *Br Med J open.* 2015;5(4):e007757.
6. Bates GW Jr, Propst AM. Polycystic ovarian syndrome management options. *Obstet Gynecol Clin North Am.* 2012;39(4):495-506.
7. Crete J, Adamshick P. Managing polycystic ovary syndrome: what our patients are telling us. *J Holist Nurs.* 201;29(4):256-66.
8. Taghavi SA, Bazarganipour F, Hugh-Jones S, Hosseini N. Health-related quality of life in Iranian women with polycystic ovary syndrome: a qualitative study. *Br Med C Women's Health.* 2015;15(1):111.
9. Bates GW, Legro RS. Longterm management of Polycystic Ovarian Syndrome (PCOS). *Mol Cell Endocrinol.* 2013;373(1-2):91-7.
10. Farshchi H, Rane A, Love A, Kennedy RL. Diet and nutrition in polycystic ovary syndrome (PCOS): pointers for nutritional management. *J Obstet Gynaecol.* 2007;27(8):762-73.

**Cite this article as:** Mehta MN, Jayaraman M, Agarwal S. Holistic approach in the management of PCOS: a pilot study of an online PCOS-reversal program. *Int J Reprod Contracept Obstet Gynecol* 2018;7:2829-33.