



IJAYUSH
International Journal of AYUSH
AYURVEDA, YOGA, UNANI, SIDDHA AND HOMEOPATHY
<http://internationaljournal.org.in/journal/index.php/ijayush/>

International Journal
Panacea
Research library
ISSN: 2349 7025

Original Research Article

Volume 13 Issue 9

September 2024

EFFECTIVENESS OF AYURVEDIC REGIMENS IN MANAGING POLYCYSTIC OVARIAN SYNDROME AND RELATED COMORBIDITIES: AN OBSERVATIONAL STUDY

Shalini Singh¹, Vedpriya Arya², Rajesh Kumar Mishra², *Satyendra Kumar Rajput¹

^{*1}Department of Pharmaceutical Sciences, Gurukula Kangri (Deemed to be University), Haridwar-249404, India

²Patanjali Herbal Research Department, Patanjali Research Foundation, Haridwar-249405, India

Corresponding Author: satyendra.rajput@gkv.ac.in; Mobile No: +91-9990054327

ABSTRACT

Polycystic ovarian syndrome (PCOS) is a common endocrine disorder affecting 8-13% of women of reproductive age worldwide, characterized by irregular menstrual cycles, hyperandrogenism, and polycystic ovaries, with an estimated 70% of cases remaining undiagnosed. This observational study aimed to assess the efficacy of Ayurvedic regimens in managing PCOS and associated comorbidities, highlighting the potential of integrative approaches in women's health. The study was conducted in the Out-patient department of Streeroga and Prasuti Tantra at Patanjali Bhartiya Ayurvedigyan Evam Anusandhana Sansthan and, included 50 women aged 18-45 diagnosed with PCOS, who were treated with individualized Ayurvedic interventions over six months. Ethical approval was obtained from the Institutional Ethics Committee. Data collection was performed using a three-part questionnaire, and Quality of Life (QoL) scores were analyzed using One-Way ANOVA, with supplementary analyses conducted using Chi-Square tests and power analysis. Results demonstrated that Ayurvedic herbs, specifically Cinnamon and Shatavari, were associated with a 39.13% improvement in QoL scores among PCOS patients after three months of treatment. ANOVA indicated statistically significant differences in QoL scores pre-and post-treatment. However, the study's statistical power was modest, and Chi-Square tests did not reveal significant differences between pre-and post-treatment assessments. The findings suggest that Ayurvedic interventions, including herbal remedies, dietary modifications, Panchakarma therapies, yoga, and lifestyle changes, may significantly enhance QoL in women with PCOS. Nonetheless, the study recommends further research with larger sample sizes and randomized controlled trials to substantiate these preliminary findings.

KEYWORDS: PCOS, Women's health, Insulin resistance, Ayurveda, QoL

INTRODUCTION

Polycystic ovarian syndrome (PCOS), known as '*Soothaga Vaayu*' in Siddha literature, is a prevalent endocrine disorder in women of reproductive age, characterized by irregular menstrual cycles, hyperandrogenism, and polycystic ovaries. It affects 8-13% of reproductive-age women globally, with up to 70% undiagnosed [1]. The condition's prevalence is increasing due to unhealthy lifestyles, poor nutrition, and mental stress, which contribute to both physical and mental health issues [2]. PCOS is associated with comorbidities such as obesity, insulin resistance, type 2 diabetes, cardiovascular diseases, and infertility [3,4]. In modern Science, PCOS can be diagnosed using the modified Rotterdam criteria if at least two of the following are present: clinical or biochemical hyperandrogenism, oligo-anovulation, or polycystic ovarian morphology on ultrasound, with other disorders excluded [5]. In Ayurveda, the diagnosis of PCOS involves evaluating body contents (*Dushya* or *Sapta Dhatu*), etiological factors (*Nidana*), clinical symptoms (*Lakshana*), and pathogenesis (*Samprapti*) [6]. Classified within the *Yonivyapada* category, PCOD accounts for over 70% of gynecological issues described by *Acharya Sushruta*, *Acharya Charak*, and *Acharya Vagbhata* [7]. Conditions such as *Vandhya*, *Arajaska*, *Nashtartava*, *Artavakshaya*, and *Pushpagni jathaharini* exhibit symptoms similar to PCOS. *Acharya Sushruta's* descriptions of *Viddha Lakshana*, *Ksheena Artava*, *Nashtartava*, and *Artava-vahastrotas* match the clinical features of PCOS [8]. The condition involves fluid accumulation in enlarged ovaries and is linked to *Rakta Gulma*, as described by *Acharya Charak* in *Chikitsa Sthana* [9].

Clinically, PCOS is characterized by irregular menstrual cycles, infertility, hirsutism, obesity, acne, and ovulatory dysfunction [10]. Hormonal imbalances involving luteinizing hormone (LH) and follicle-stimulating hormone (FSH) disrupt follicular development [11]. *Samprapti* describes worsened *Vata* blocking *Artavvaha Srotasa*, leading to *Rakta Gulma* [12]. Incorrect lifestyles and faulty diets contribute to PCOS, with androgen exposure causing genetic issues. Ayurvedic perspectives link PCOS to *Dosha* and *Dhatu* imbalances, causing conditions like amenorrhoea, reproductive disorders, and infertility [13]. Conventional treatments for PCOS, including lifestyle modifications, hormonal contraceptives, insulin sensitizers, and anti-androgens, have limited efficacy and potential side effects [14,15]. Ayurveda offers a holistic approach, using herbal formulations like *Ashwagandha* (*Withania somnifera* (L.) Dunal), *Shatavari* (*Asparagus racemosus* Willd.), and *Guduchi* (*Tinospora*

cordifolia (Willd.) Hook. f. and Thoms.) for their adaptogenic, anti-inflammatory, and insulin-sensitizing properties, along with dietary modifications, lifestyle changes, and detoxification [16]. This observational study aims to evaluate Ayurvedic regimens for PCOS management, highlighting their potential benefits and supporting the integration of traditional practices into modern healthcare paradigms.

METHODOLOGY

Ethical consideration

This study was approved by the Institutional Ethics Committee (IEC) at Patanjali Research Foundation (IEC approved no: **PAC/IEC/2023/6/15**). Patients were treated ethically under the Declaration of Helsinki [17], with a total study period of 6 months and before data collection, patients provided written informed consent.

Study design

This observational study comprises 50 volunteers who participated between October 2023 and April 2024, suffering from Soothaga Vaayu (PCOS), and related factors such as irregular menstruation, ovarian cyst, and infertility for the individualized in-depth evaluation. The entire study was conducted in the Out-patient department of Streeroga and Prasuti Tantra at Patanjali Bhartiya Ayurvedigyan Evam Anusandhana Sansthan, Haridwar, Uttarakhand, India, who met the inclusion and exclusion criteria, were chosen at random for this observational study, regardless of gender, religion, occupation, or other factors. Participants were clinically diagnosed with PCOS based on ultrasonography (USG), and hormonal reports, and their ages ranged from 18 to 45 years. Women were thoroughly informed about the study's aims before they were asked to participate voluntarily. Participants were also informed that completing and submitting the questionnaire would be interpreted as an agreement to participate in this study. Data were handled with the highest level of anonymity and confidentiality. Regular follow-ups were conducted to assess changes in symptoms, hormonal levels, and comorbidities over a specified duration. This study implemented several criteria for inclusion and exclusion (**Figure 1**). A STROBE, flow chart of the investigation is shown in **Figure 2**.

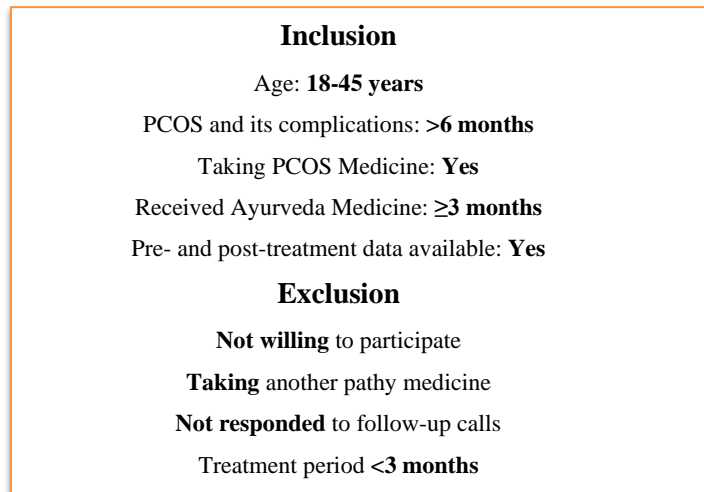


Figure 1: Inclusion/exclusion criteria for participants taking part in this study

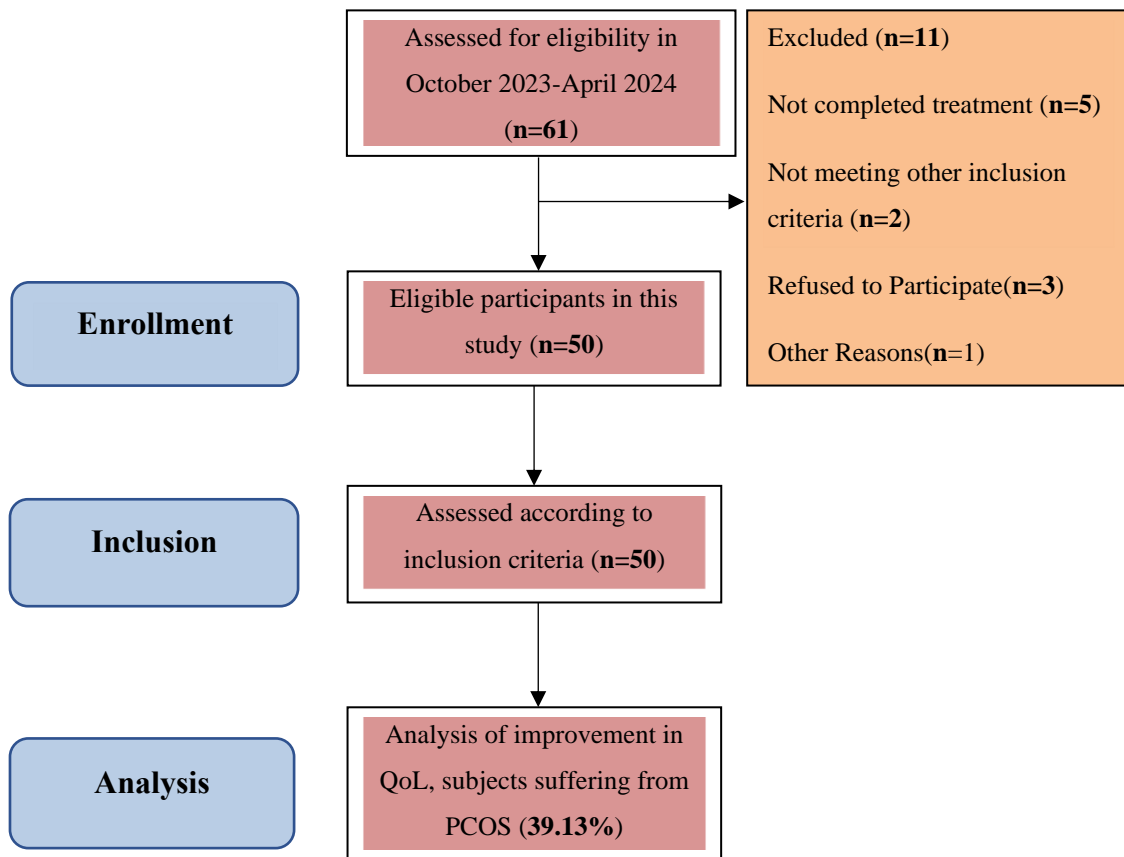


Figure 2: Flow diagram of the study based on STROBE guidelines [18].

Questionnaire

There were three sections in the questionnaire. Demographic data, including gender, age, living situation, religion, and course of study, were included in the first part. The risk assessment questionnaire, which has 20 questions in the second half, is paired with a 4-point Likert scale, where 4 represents the worst health and 1 represents excellence function [19]. The third section assessed the Self-administered Polycystic Ovary Syndrome Questionnaire (PCOSQ) sheet is typically designed to determine the symptoms and impact of PCOS on patients. PCOSQ is a disease-specific quality-of-life measure for women with PCOS that comprises 26 questions spanning a variety of areas such as emotions, body hair, weight, infertility, and menstruation issues, to capture the impact of PCOS on women's lives thoroughly. Each question is associated with a 7-point Likert-type scale in which 7 represents the optimal function and 1 represents the poorest function [20]. Questions involve concerns such as visible hair growth, infertility, and disappointment. The PCOSQ consists of five domains: emotions (eight items), body hair (five items), weight (five items), infertility difficulties (four items), and menstrual problems. Cronbach's alpha was greater than 0.7 when the PCOSQ was verified [21].

Sample size determination and power validation

The target population was identified, and eligibility criteria were applied, leading to an initial assessment of 61 participants between October 2023 and April 2024. After exclusions based on treatment completion, inclusion criteria, and participant consent, 50 eligible participants were enrolled. The sample size was calculated to achieve sufficient power to detect a clinically meaningful improvement in the Quality of Life (QoL) among the subjects. Based on preliminary data and literature, an expected effect size (difference in QoL scores pre- and post-intervention) was estimated. The alpha level was set at 0.05, corresponding to a 5% risk of Type I error (false positive). A power of 0.80 (80%) was chosen, indicating a 20% risk of Type II error (false negative). An anticipated dropout rate was factored in, based on historical data, ensuring that the final sample size would still be adequate after accounting for potential dropouts. A post-hoc power analysis was performed using the actual data collected from the 50 participants. This analysis confirmed whether the study maintained the intended power of 80% or higher. Sensitivity analysis was carried out to assess the robustness of the study

findings. This involved varying key assumptions (such as effect size and standard deviation) to examine the impact on the study's power.

Intervention

A range of herbs and formulations are part of the prescribed Ayurvedic regimen for PCOS participants, which aims to treat the condition's complex symptoms and underlying causes, as mentioned in **Table 1**. Ashwagandha churna prepared from the powdered root or extract of *W. somnifera*, is advised to be taken twice a day after meals for three to six months. The suggested dose is $\frac{1}{4}$ to $\frac{1}{2}$ teaspoon cooked in two cups of water. PCOS patients who experience hormonal imbalances associated with stress find ashwagandha, an adaptogenic herb, particularly helpful in lowering stress, balancing hormones, and enhancing general vigor [22]. *A. racemosus* root, or Shatavari churna, is recommended to be taken twice a day after lunch and dinner at a comparable dosage of $\frac{1}{4}$ to $\frac{1}{2}$ teaspoon with milk for three months. Shatavari is a useful herb for treating PCOS symptoms because of its phytoestrogenic qualities, which promote reproductive health and help regulate menstrual cycles [23]. For three to six months, 300 mg of Guduchi churna—which contains the stem powder or extract of *T. cordifolia*—is taken three times a day. Due to its immunomodulatory and anti-inflammatory properties, guduchi churna lessens systemic inflammation, frequently linked to PCOS [24]. Also, Triphala churna, a combination of three fruits (*Amalaki*, *Bibhitaki*, and *Haritaki*), is advised to be eaten once or twice a day for three to six months at a dose of $\frac{1}{2}$ to 2 teaspoons with lukewarm water. Moreover, Triphala is a potent detoxifier that promotes digestive health [25], which is extremely significant for PCOS sufferers because gut health is linked to hormonal balance. Aloe vera juice from *Aloe barbadensis* Mill. must be taken with water on an empty stomach in the morning, once a day, for two to three months. Aloe vera juice helps to regulate blood glucose levels, which is useful for PCOS patients who frequently have insulin resistance [26]. One teaspoon to one-third of a teaspoon, given once daily for three to six months, is the recommended dosage for cinnamon in the form of *Cinnamomum verum* J.Presl powder or extract. Cinnamon is widely known for its capacity to raise blood sugar levels and enhance insulin sensitivity, which helps control one of the main problems associated with PCOS [27]. *Momordica charantia* L. bitter gourd juice is recommended for three to six months at a dose of thirty milliliters per day. Juice from bitter gourds is hypoglycemic and can help control insulin resistance, which is a typical issue with PCOS [28].

For a duration of three to six months, one tablet of Chandraprabha Vati, herbal supplement with many constituents, is recommended to be taken twice or three times a day. It is frequently used for its rejuvenating qualities, which may help to manage the symptoms of PCOS [29]. Additionally, it is advised to take 1 to 2 tablets twice a day for 3 to 6 months of Kanchanar Guggulu, herbal tablet that contains Guggulu (*Commiphora mukul* (Hook. ex Stocks) Engl.) and Kanchanar (*Bauhinia variegata* L.). Furthermore, Kanchanar Guggulu helps control glandular swellings, which are frequently linked to hormonal imbalances in PCOS, and it promotes thyroid function [30]. The powdered bark of *Crateva nurvala* Buch. - Ham. used to make Varuna churna, is recommended to be consumed daily after meals for three to six months, at a dose of ½ to 1 teaspoon. Due to its beneficial effects on the urinary tract and ability to assist in the removal of toxins, Varuna has long been utilized to maintain hormonal balance in PCOS [31]. For three months, it is advised to take two tablets of Cystogrit vati, which contains Heerak bhasma, Mukta shukti, Mukta sindoor, Moti pishti, Tamra bhasma, and Kanchanar haldi (*Bauhinia variegata*), twice a day after meals. It helps in managing ovarian cysts and regulating menstrual cycles, addressing some of the core symptoms of PCOS [32]. Ashokarishta, a liquid formulation with ingredients such as *Ashok Chaal* (*Saraca asoca* (Roxb.) W.J.de Wilde), *Gur*, *Dhaiphool*, *Kalajeera*, *Motha*, *Sonth*, *Daru Haldi* (*Berberis aristata* DC.), *Neelkamal* (*Nymphaea nouchali* Burm.f.), *Haritaki* (*Terminalia chebula* Retz.), *Baheda* (*T. bellirica* (Gaertn.) Roxb.), *Amla* (*Emblica officinalis* Gaertn.), *Aam Guthli* (*Mangifera indica* L.), *Jeera*, *Basak Panchang*, and *Lalchandani* (*Pterocarpus santalinus* Blanco), is prescribed at a dose of 5 to 10 ml with an equal amount of water, taken twice daily after meals for 3 to 6 months. Subsequently, Ashokarishta is also particularly effective in regulating menstrual cycles and alleviating symptoms of menstrual problems [33]. Raj Pravartini Vati, which contains Kanya (Aloe vera), Kaseesa (Purified Blue Vitriole), Tankana (Borax), and Ramatha (Asafoetida), is recommended at a dose of 1 to 2 tablets, taken twice a day before or after meals for 3 to 6 months. It promotes menstrual health and improves the management of menstrual irregularities that are typical among PCOS patients [34].

Table No. 1 Some Ayurvedic remedies for PCOS and associated conditions

Medicines	Composition	Dosage	Duration	Time of administration
-----------	-------------	--------	----------	------------------------

Ashwagandha churna	<i>Withania somnifera</i> (Root powder or extract)	¼-1/2 teaspoon boiled in 2 cups of water	3-6 months	Twice a day after a meal
Shatavari churna	<i>Asparagus racemosus</i> (Root powder or extract)	¼-1/2 teaspoon with milk	3-6 months	Twice a day after lunch and dinner
Guduchi churna	<i>Tinospora cordifolia</i> (Stem powder or extract)	300 mg	3-6 months	3 times a day
Triphala churna	Powder of three fruits (Amalaki, Bibhitaki, Haritaki)	1/2-2 teaspoon with lukewarm water	3-6 months	Once or twice a day
Aloe Vera Juice	<i>Aloe barbadensis</i> (Juice)	2-3 teaspoons with water	2-3 months	On an empty stomach in the morning, once a day
Cinnamon	<i>Cinnamomum verum</i> (Powder or extract)	1/2 to 1 teaspoon	3-6 months	Once in a day
Bitter Gourd Juice	<i>Momordica charantia</i> (Juice or extract)	30 ml of juice	3-6 months	Daily
Chandraprabha Vati	Herbal tablet containing multiple ingredients	1 tablet	3-6 months	Twice or thrice daily
Kanchanar Guggulu	Herbal tablet containing Kanchanar (<i>Bauhinia variegata</i>) and Guggulu (<i>Commiphora mukul</i>)	1-2 tablets	3-6 months	Twice daily
Varuna	<i>Crateva nurvala</i> (Bark powder)	½-1 teaspoon	3-6 months	Daily after meal
Cystogrit Vati	Kanchanar haldi (<i>B. variegata</i>), Shila sindoor, Mukta shukti, Moti pishti, Tamra bhasma, Heerak bhasma	2 tablets with lukewarm water	3 months	Twice a day after a meal

Ashokarishta	Ashok Chaal (<i>Saraca asoca</i>), Gur, Dhaiphool, Kalajeera, Motha, Sonth, Daru Haldi (<i>Berberis aristata</i>), Neelkamal (<i>Nymphaea nouchali</i>), Haritaki (<i>Terminalia chebula</i>), Baheda (<i>T. bellirica</i>), Amla (<i>Emblica officinalis</i>), Aam Guthli (<i>Mangifera indica</i>), Jeera, Basak Panchang, Lalchandani (<i>Pterocarpus santalinus</i>)	5-10 ml with an equal amount of water	3-6 months	Twice daily after a meal
Raj Pravartini vati	Kanya (<i>Aloe vera</i>), Kaseesa (Purified Blue Vitriole), Tankana (Borax), Ramatha (Asafoetida)	1-2 tablet	3-6 months	Twice a day before or after the meal

Statistics

The statistical analysis for this study involved meticulous data collection and initial analysis using industry-standard software programs such as Microsoft Excel 365 (USA), GraphPad PRISM (USA), and SPSS (USA). To compare the means of three or more independent (unrelated) groups, we employed One-Way ANOVA, which helps determine if there is a statistically significant difference in the effectiveness of Ayurvedic regimens among different PCOS participants. Power analysis was conducted to determine the necessary sample size required to detect an effect of a given size with a specified degree of confidence, ensuring that the study is adequately powered to detect differences pre- and post-treatment for related (paired) samples. The Chi-Square test was used to examine the association between two categorical variables. In the context of this observational study, it helped determine if there was a significant association between Ayurvedic treatment and categorical outcomes such as menstrual regularity or the presence of acne. SPSS software was used for all statistical analyses to ensure robust and reliable results.

Results

Cinnamon and Shatavari provide notable benefits for managing PCOS and its associated factors among the Ayurvedic herbs and formulations used in treatment. Cinnamon enhances

insulin sensitivity and helps regulate blood sugar levels, addressing the common insulin resistance in PCOS. It also supports weight management and reduces the risk of type 2 diabetes while its anti-inflammatory properties help alleviate PCOS symptoms. Shatavari, on the other hand, supports hormonal balance and regulates menstrual cycles, directly addressing fertility issues and reproductive health challenges associated with PCOS. Additionally, Shatavari promotes overall hormonal well-being, contributing to an improved QoL for individuals with PCOS. The effect of Ayurvedic therapies on participants' QoL throughout three months with PCOS (**Figure 3**). The X-axis indicates the study's time points (baseline, one month, two months, and three months), while the Y-axis shows QoL ratings on a scale of 0 to 100, with higher scores indicating greater QoL. At baseline, the average QoL score is 50, reflecting the individuals' starting state. After one month of Ayurvedic therapy, the score increases to 60, suggesting a positive response to the medication. This positive trend continues, with the QoL score increasing to 70 after two months and 80 at the end of three months. Following various ayurvedic interventions, participants' QoL improved by approximately 39.13%. The analysis revealed that the mean ratings for pre-treatment, post-treatment, and both follow-up sessions ranged widely.

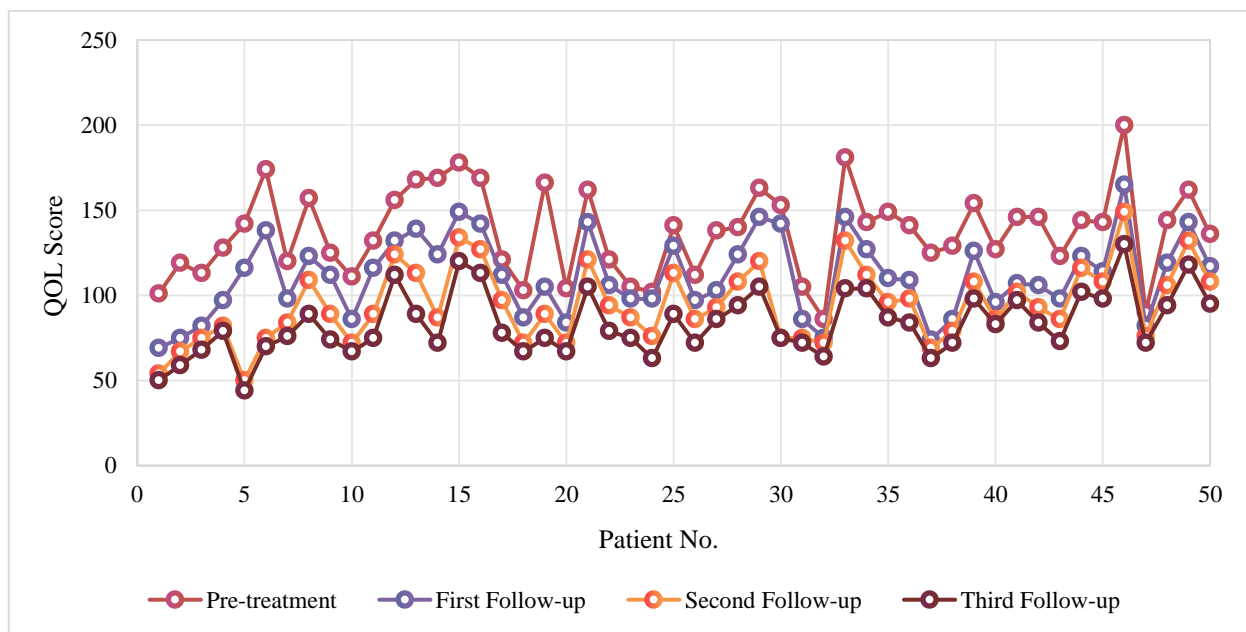


Figure 3: Effect of Ayurvedic medication in improving QoL in PCOS participants.

For the post-treatment period, the analysis indicates that the total squares between groups is 25,090.780 with 40 degrees of freedom, yielding a mean square of 627.270. The F-value is

4.456, with a significance level (of $p=0.011$), showing a statistically significant difference between pre-and post-treatment scores. The within-group total of squares is 1,267.000, with 9 degrees of freedom and a mean square of 140.778. The total sum of squares is 26,357.780, with 49 degrees of freedom. At the first follow-up, the total of squares between groups is 22,061.620 with 40 degrees of freedom, for a mean square of 551.541. The F-value is 3.682, and the p-value is 0.021, indicating a significant difference between pre-treatment and follow-up 1 score. The total squares between groups are 1,348.000, with 9 degrees of freedom, and the mean square is 149.778. The total number of squares is 23,409.620, with 49 degrees of freedom. The second follow-up demonstrates significant effects, with the between-group sum of squares at 1,036,182.280 with 40 degrees of freedom, resulting in a mean square of 25,904.557. The F-value is significantly higher (204.959), with $p<0.001$, demonstrating a highly significant difference between pre-treatment and follow-up two scores. The within-group total of squares is 1,137.500, with 9 degrees of freedom, and the mean square is 126.389. The entire sum of squares is 1,037,319.780, with 49 degrees of freedom. As a result, ANOVA results show that pre-treatment and post-treatment scores differ significantly between pre-treatment scores and scores at both follow-up intervals (**Table 2**). At the second follow-up, the significance of these differences increases markedly, suggesting a strong and sustained impact of the treatment.

Table No. 2 Analysis of variance between pre-treatment and post-treatment follow-up 1 & 2.

		Sum of Squares	Df	Mean Square	F	Significance
Post-treatment	Between Groups	25090.780	40	627.270	4.456	0.011
	Within Groups	1267.000	9	140.778		
	Total	26357.780	49			
Follow-up 1	Between Groups	22061.620	40	551.541	3.682	0.021
	Within Groups	1348.000	9	149.778		
	Total	23409.620	49			
Follow-up 2	Between Groups	1036182.280	40	25904.557	204.959	<0.001

	Within Groups	1137.500	9	126.389		
	Total	1037319.780	49			

The result of the power analysis for a Spearman correlation using Fisher's z-transformation is given in **Table 3**. A sample size of 1539 was used for the analysis. A modest amount of statistical power was shown by the actual power obtained in the study, which was reported as 0.500. One of the test assumptions was a two-sided test with alternative and null hypotheses. For both hypotheses, 0.05 was the significance threshold. With variance estimate done according to Bonett and Wright's suggested procedure, the power was obtained using Fisher's z-transformation and a normal approximation.

Table No. 3 Power analysis based on Fisher's z-transformation

	N	Actual Power ^b	Test Assumptions			
			Power	Null	Alternative	Significance
Spearman Correlation^a	1539	0.500	0.5	0	0.05	0.05

a. Two-sided test; b. Based on Fisher's z-transformation and normal approximation.

The linear regression analysis findings reveal a significant correlation between specific factors and the efficiency of Ayurvedic medicines (**Figure 4**). The regression line in the graph has a positive or negative slope, depending on the variable during analysis.

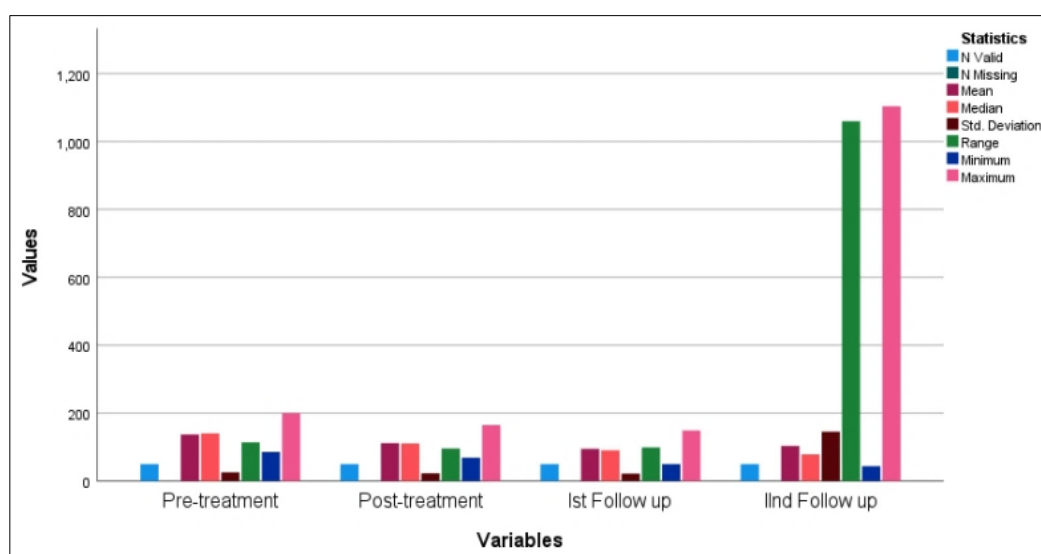


Figure 4: Linear regression of different variables on the Ayurvedic treatment.

The Pearson Chi-Square test gave a statistic of 1372.917 with 1320 degrees of freedom (df) and a non-significant p-value of 0.152 (2-sided), showing no significant difference between pre-and post-treatment assessments (**Table 4**). Similarly, the Likelihood Ratio Chi-Square test gave a non-significant p-value of 1.000. In contrast, the Linear-by-Linear Association test found a significant linear relationship between treatments ($p=0.000$), albeit with a test statistic of 37.973 and 1 df. For instance, the results included cautionary remarks stating that all cells had anticipated counts below 5, indicating potential limitations in the chi-square test's validity due to sparse predicted cell frequencies.

Table No. 4 Chi-square tests between pre- and post-treatments.

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	1372.917 ^a	1320	0.152
Likelihood Ratio	320.841	1320	1.000
Linear-by-Linear Association	37.973	1	0.000
No. of valid cases	50		

a. 1394 cells (100%) have an expected count of less than 5. The minimum expected count is 0.02.

The progression of patients receiving treatment with Ayurveda medicines by comparing their conditions at four different phases (**Figure 5**). The pre-treatment **5 (a)** serves as a baseline, demonstrating the patients' initial health status before beginning Ayurvedic treatment, including clinical information along with symptom severity metrics specific to the illness being treated. The post-treatment **5 (b)** shows the immediate outcomes after completing the Ayurveda treatment regimen, including a comparison to the pre-treatment baseline and any immediate improvements or changes in clinical and symptomatic parameters. The first follow-up **5 (c)** represents the initial follow-up assessment performed at a predetermined interval following treatment to assess the short-term retention of therapeutic results. This comprises a comparison of the same clinical signs and symptoms

examined before and after therapy to establish the short-term durability of treatment effects. The second follow-up 5 (d) displays the subsequent follow-up examination, which was performed at a later time to examine the long-term efficacy and stability of treatment outcomes. This study contributes to a better understanding of Ayurveda therapy's long-term effects and efficacy by comparing the results to the previous phases. All these combine to provide a comprehensive, chronological examination of the treatment's impact, delivering insights into both immediate and long-term therapeutic consequences.

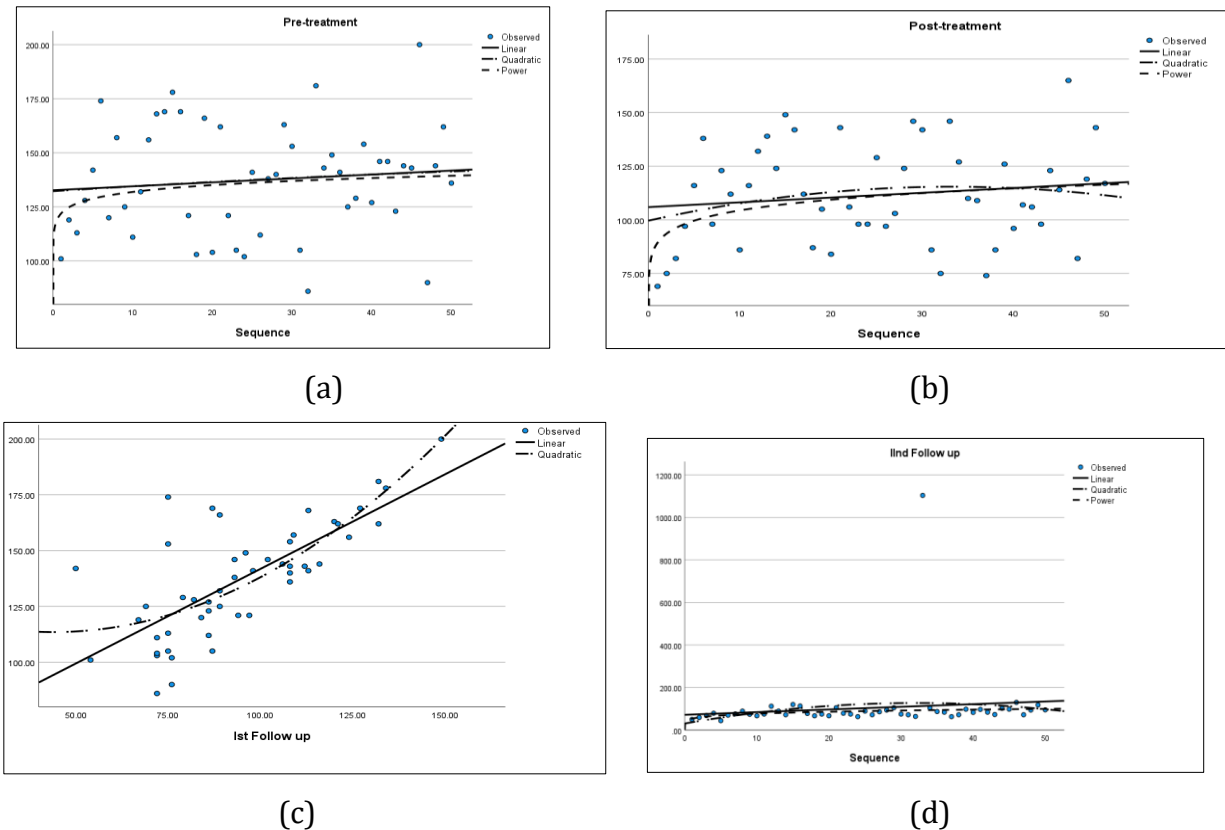


Figure 5: Effects of Ayurveda treatment on different timelines: (a) pre-treatment; (b) post-treatment; (c) 1st follow-up; (d) 2nd follow-up

DISCUSSION

The study conducted at Patanjali Bhartiya Ayurvedigyan Evam Anusandhana Sansthan revealed a significant improvement in the QoL for women with PCOS following Ayurvedic therapy. Participants demonstrated an initial mean QoL score of 50, which increased to 60 after one month, 70 after two months, and 80 after three months, indicating an overall improvement of approximately 39.13%. These findings were statistically significant, as evidenced by One-Way ANOVA, which indicated significant differences between pre-treatment and post-

treatment QoL scores ($p=0.011$), with further significant changes observed at the one-month ($p=0.021$) and three-month ($p<0.001$) follow-ups. Additionally, the Chi-Square test revealed a significant association between Ayurvedic treatments and improvements in menstrual regularity and acne ($p=0.000$). Linear regression analysis further underscored significant correlations between various clinical parameters and the efficacy of the Ayurvedic interventions. The strengths of the study include the use of a comprehensive Ayurvedic approach tailored to individual symptoms, aligning with Ayurveda's holistic principles of balance and systemic harmony. The application of robust statistical methods, including One-Way ANOVA, Chi-Square tests, and linear regression, provided strong evidence for the efficacy of these therapies. A power analysis confirmed that the sample size was sufficient to detect clinically relevant changes, with a statistical power of 80%. However, the study has several limitations. The relatively small sample size of 50 participants limits the generalizability of the results. Moreover, the observational study design lacks the rigorous control of a randomized controlled trial (RCT), which would provide stronger evidence of causality and reduce potential biases. The reliability of the Chi-Square test may also have been compromised by sparse cell frequencies, potentially affecting the assessment of categorical outcomes.

CONCLUSION

This study provides evidence that Ayurvedic regimens, particularly Cinnamon and Shatavari, significantly enhance the QoL for women with PCOS over three months. The statistical analysis, including One-Way ANOVA, supports the sustained efficacy of these treatments, despite the study's limited statistical power. In conclusion, these results are congruent with Ayurveda's holistic framework, which seeks to restore systemic balance and harmony through individualized therapeutic approaches. Future research should involve larger, randomized controlled trials to corroborate these findings and elucidate the mechanisms underlying the effects of Ayurvedic therapies. Furthermore, the integration of Ayurvedic treatments with conventional therapeutic methods may optimize management strategies for PCOS and improve patient outcomes. This study highlights the potential of Ayurveda as an effective complementary or alternative modality for PCOS management and for enhancing women's overall health.

ACKNOWLEDGMENT

The authors would like to express their gratitude to the revered Swami Ramdev and Acharya Balkrishna for their inspiration and valuable support. The authors also extend their thanks to all participants involved in this study. The authors are appreciative of the guidance and assistance provided by Dr. Prashant Katiyar, Dr. Neha Verma, Dr. Monika Chauhan, Mrs. Shalini Mishra, and Ms. Maneesha Rana throughout the study. Additionally, the authors acknowledge with gratitude the facilities provided by Patanjali Bhartiya Ayurvedic Evam Anusandhana Sansthan, and Patanjali Research Foundation, Haridwar for the successful conduct of this research.

FUNDING INFORMATION

Not available.

CONFLICT OF INTEREST STATEMENT

All authors declared that they have no conflicts of interest.

ETHICAL APPROVAL

This study was approved by the Institutional Ethics Committee at Patanjali Research Foundation (IEC No: PAC/IEC/2023/6/15) on June 15, 2023, and was conducted following the Declaration of Helsinki. The study lasted 6 months, and written informed consent was obtained from all participants.

REFERENCES

1. WHO. 2024. Available from <https://www.who.int/news-room/fact-sheets/detail/polycystic-ovary-syndrome#:~:text=Key%20facts,a%20leading%20cause%20of%20infertility>.
2. Farhud DD. Impact of lifestyle on health. Iranian Journal of Public Health. 2015;44(11):1442.
3. Jabeen A, Yamini V, Amberina AR, Eshwar MD, Vadakedath S, Begum GS, Kandi V. Polycystic ovarian syndrome: Prevalence, predisposing factors, and awareness among adolescent and young girls of South India. Cureus. 2022 Aug;14(8).
4. Gupta A. Aṣṭāṅga-saṅgraha. Reprint Edition. Varanasi (India): Chaukhambha Krishna Das Academy. As. Ut. 2005; 38:32.
5. Christ JP, Cedars MI. Current guidelines for diagnosing PCOS. Diagnostics. 2023 Mar 15;13(6):1113.
6. Tripathi B. Aṣṭāṅghṛdayam. Reprint Edition. Delhi (India): Chaukhambha Sanskrit Pratishthan. Aṣ. Ut. 2011; 33:27-28.

7. Sharma AR. Suśruta-saṁhitā Vol. III. Reprint Edition. Varanasi (India): Chaukhambha Surbharati Prakashan. Su. Ut. 2012a; 38:4.
8. Śāstrī K, Chaturvedi GN. Caraka-saṁhitā. Reprint Edition. Varanasi (India): Chaukhambha Bharati Academy. Ca.Ci. 2011a; 5:11.
9. Sharma AR. Suśruta-saṁhitā Vol. III. Reprint Edition. Varanasi (India): Chaukhambha Surbharati Prakashan. Su. Ut. 2012b; 38:10-11.
10. Witchel SF, Oberfield SE, Peña AS. Polycystic ovary syndrome: pathophysiology, presentation, and treatment with emphasis on adolescent girls. *Journal of the Endocrine Society*. 2019 Aug;3(8):1545-1573.
11. Raju GA, Chavan R, Deenadayal M, Gunasheela D, Gutgutia R, Haripriya G, Govindarajan M, Patel NH, Patki AS. Luteinizing hormone and follicle stimulating hormone synergy: A review of role in controlled ovarian hyper-stimulation. *Journal of Human Reproductive Sciences*. 2013 Oct 1;6(4):227-234.
12. Sharma AR. Suśruta-saṁhitā Vol. III. Reprint Edition. Varanasi (India): Chaukhambha Surbharati Prakashan. Su. Ut. 2012c; 3:4.
13. Śāstrī K, Chaturvedi GN. Caraka-saṁhitā. Reprint Edition. Varanasi (India): Chaukhambha Bharati Academy. Ca.Ci. 2011b; 30:8.
14. Badawy A, Elnashar A. Treatment options for polycystic ovary syndrome. *International Journal of Women's Health*. 2011 Feb 8:25-35.
15. Akre S, Sharma K, Chakole S, Wanjari MB. Recent advances in the management of polycystic ovary syndrome: A review article. *Cureus*. 2022 Aug;14(8).
16. Siriwardene SD, Karunathilaka LA, Kodituwakku ND, Karunarathne YA. Clinical efficacy of Ayurveda treatment regimen on Subfertility with polycystic ovarian syndrome (PCOS). *AYU (An international quarterly journal of research in Ayurveda)*. 2010 Jan 1;31(1):24-27.
17. World Medical Association. Declaration of Helsinki: Ethical principles for medical research involving human subjects. *JAMA*. 2013;310(20):2191-2194.
18. Von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: Guidelines for reporting observational studies. *The Lancet*. 2007 Oct 20;370(9596):1453-1457.
19. Priyanka PS, Priya RS, Menaka R, Anbu N. A Cross-Sectional Observational Study on Awareness and Belief in Siddha Treatment for Soothaga Vaayu (PCOS) among women attending the outpatient department. *International Journal of Translational Research in Indian Medicine*. 2019 Jan;1(1):25-32.
20. Cronin L, Guyatt G, Griffith L, Wong E, Azziz R, Futterweit W, Cook D, Dunaif A. Development of a health-related quality-of-life questionnaire (PCOSQ) for women with polycystic ovary syndrome (PCOS). *The Journal of Clinical Endocrinology & Metabolism*. 1998 Jun 1;83(6):1976-1987.
21. Jones GL, Benes K, Clark TL, Denham R, Holder MG, Haynes TJ, Mulgrew NC, Shepherd KE, Wilkinson VH, Singh M, Balen A. The polycystic ovary syndrome health-related

- quality of life questionnaire (PCOSQ): A validation. *Human Reproduction*. 2004 Feb 1;19(2):371-377.
22. Buduru P, Kumaramangalam B, Sharma S. Ayurvedic management of infertility due to polycystic ovaries and tubal block: A case study. *Journal of Ayurveda*. 2022 Apr 1;16(2):170-174.
 23. Dhankani MA, Patil HJ, Dhankani AR. A systematic review: Ayurvedic herbal medicine for women with polycystic ovary syndrome. In *Medical Sciences Forum 2023 Apr 21 (Vol. 21, No. 1, p. 46)*. MDPI.
 24. Rani R, Sharma AK, Chitme HR. Therapeutic Effect of *Tinospora cordifolia* (Willd) Extracts on Letrozole-Induced Polycystic Ovarian Syndrome and its Complications in Murine Model. *Clinical Medicine Insights: Endocrinology and Diabetes*. 2023 Oct; 16:11795514231203864.
 25. Peterson CT, Denniston K, Chopra D. Therapeutic uses of triphala in ayurvedic medicine. *The Journal of Alternative and Complementary Medicine*. 2017 Aug 1;23(8):607-614.
 26. Lakshmi JN, Babu AN, Kiran SM, Nori LP, Hassan N, Ashames A, Bhandare RR, Shaik AB. Herbs as a source for the treatment of polycystic ovarian syndrome: A systematic review. *BioTech*. 2023 Jan 3;12(1):4.
 27. Dou L, Zheng Y, Li L, Gui X, Chen Y, Yu M, Guo Y. The effect of cinnamon on polycystic ovary syndrome in a mouse model. *Reproductive Biology and Endocrinology*. 2018 Dec; 16:1-10.
 28. Selvakumar G, Shathirapathiy G, Jainraj R, Paul PY. Immediate effect of bitter gourd, ash gourd, Knol-khol juices on blood sugar levels of patients with type 2 diabetes mellitus: A pilot study. *Journal of Traditional and Complementary Medicine*. 2017 Oct 1;7(4):526-531.
 29. Jagani P, Moharana PK, Soumya EA. A Critical Review on Chandraprabha Vati-An Ayurvedic Formulation. *Journal of Ayurveda and Integrated Medical Sciences*. 2022;7(11):136-144.
 30. Singh S, Singh RP, Chaudhari SD, Sonar GV. Effect of Kanchnar Guggul, Flaxseeds, And Spearmint to Reduce Testosterone Level in PCOS and PCOD. *International Journal of Pharmaceutical Research and Applications*. 2023;8(4):989-997.
 31. Jung W, Choi H, Kim J, Kim J, Kim W, Nurkolis F, Kim B. Effects of natural products on polycystic ovary syndrome: From traditional medicine to modern drug discovery. *Heliyon*. 2023 Oct 11.
 32. Sokiya G, Painuly P, Sharma G. An Ayurvedic methodology for managing PCOD-A Case Report. *Journal of Ayurveda and Integrated Medical Sciences*. 2024 Jun 16;9(4):304-309.
 33. Rawat N, Barla MA, Roushan R. Ayurvedic approach for management of uterine fibroid: A case report. *Journal of Research in Ayurvedic Sciences*. 2019 Jan 1;3(1):34-38.
 34. Chauhan M, Makeem R. Clinical Efficacy of Rajah Pravartini Vati in the Management of Artava Kshaya (Oligomenorrhoea). *International Ayurvedic Medical Journal*. 2020:2480-2485.