Open Access Journal
International Journal of Nutrition & Lifestyle
https://doi.org/10.69859/ijnl.2025.v5i3002
ISSN: 2583-3499 (Online)
Volume 5, Issue 3, Sep 2025

Original Research Article

Study on impact of dietary intervention and use of functional foods in reducing symptoms of PCOS

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Abstract

Polycystic Ovary Syndrome (PCOS) is a prevalent endocrine disorder. This study was undertaken to evaluate the effectiveness of dietary intervention and functional foods in mitigating PCOS symptoms. A sample size of 40 women, ages 17 to 33, diagnosed with PCOS were selected. Twenty participants were assigned to the Standard group, who received structured dietary counselling. The other 20 participants were assigned to the Experimental group, who received the same standard care with daily supplements of 20 g black raisins and 10g soaked fenugreek seeds for three months. Anthropometric measurements and clinical parameters were evaluated at baseline and after 3 months of intervention. BMI, insulin sensitivity, and menstrual regularity all showed significant improvements in both groups ($p<0.05$ for within-group changes). In particular, the experimental group's mean weight loss was -5.30 ± 2.9 kg ($p < 0.0001$) and their BMI was reduced by -2.05 ± 0.97 kg/m² ($p < 0.0001$), which was significantly lower than the Standard group. The Experimental group experienced a complete normalization of menstrual cycles by the end of three months. Insulin resistance decreased significantly from 4.2 to 2.5 and the mean hirsutism score decreased significantly from 7.4 to 4.2 in the experimental group, indicating a more effective metabolic impact of functional foods. The results of this study showed that dietary intervention together with functional foods significantly improved symptoms of PCOS.

Keywords: Polycystic Ovary Syndrome (PCOS), Dietary intervention, Lifestyle modification, Fenugreek seeds, Black raisins

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Received on: 20 June 2025 - Accepted 06 Sep 2025 - Published: 30 Sep 2025

Citation for the paper: Maheshwari M, Bansal V. Study on impact of dietary intervention and use of functional foods in reducing symptoms of PCOS. International journal of nutrition & lifestyle 2025; 5(3): 134-146. DOI: 10.69859/ijnl.2025.v5i3002

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Introduction

The menstrual cycle is a coordinated sequence of hormonal and structural changes that occur roughly every 28 days in reproductive-aged women. It is regulated by the Hypothalamic-Pituitary-Ovarian (HPO) axis, which ensures proper ovulation and endometrial preparation for potential implantation.

A common hormonal condition that affects women of reproductive age, polycystic ovarian syndrome (PCOS) is characterized by a confluence of endocrine, metabolic, and reproductive problems. Symptoms like acne, irregular hair growth, and irregular menstruation can result from insulin resistance, elevated insulin levels, and excess androgens. In addition to having polycystic ovaries that are visible on ultrasound, women with PCOS may have irregular or absent ovulation, which makes conception challenging. Weight gain and poor fat metabolism are common, as are hormonal imbalances like a high LH to FSH ratio. Long-term health problems such as high-risk pregnancies, type 2 diabetes mellitus, dyslipidemia, endometriosis, and cardiovascular problems can result from PCOS if it is not treated [1].

About 10-15% of women suffer from PCOS, a common endocrine disorder. PCOS is a common endocrine disorder, impacting roughly 10–15% of women globally who are of reproductive age. It manifests as a variety of symptoms that differ from person to person. After ruling out other conditions like congenital adrenal hyperplasia, Cushing's syndrome, and androgen-secreting tumours, PCOS is diagnosed based on the Rotterdam 2003 criteria when at least two of the following three characteristics are present: oligo/anovulation, clinical or biochemical hyperandrogenism, and polycystic ovarian morphology. Environmental, hormonal, and genetic factors are all involved in the syndrome's multifactorial genesis [2].

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Criteria	Description
Oligo and/or anovulation	Infrequent or absent ovulation often causing irregular menstrual cycles
Hyperandrogenism	Hirsutism/ acne and/ or biochemical signs (elevated androgens)
Polycystic ovaries	> 12 follicles (2-9 mm each) of each ovary or increased ovarian volume (> 10 mL)

Table 1: Rotterdam Criteria, Modified 2003

According to new research, lifestyle choices are crucial for the development and treatment of PCOS. Hormonal balance and metabolic parameters in afflicted individuals are significantly impacted by dietary practices, levels of physical activity, and body weight. Papavasiliou & Papakonstantinou (2017) state that dietary support specifically designed to lower inflammation and insulin resistance is essential for easing PCOS symptoms [1]. In a similar vein, Pasquali and Gambineri (2002) stressed that changing one's lifestyle is still the first line of treatment for PCOS's metabolic and reproductive characteristics [3].

They described how metabolic disorders that result in complications like diabetes, infertility, and cardiovascular diseases are exacerbated by poor diet, inactivity, and stress. Despite the impact of genetic factors, it was underlined that women can effectively manage PCOS symptoms by implementing healthy eating habits, taking supplements, maintaining an active lifestyle, and managing stress [4]. Ovulatory function and metabolic markers have been demonstrated to improve with dietary interventions, especially those that involve calorie restriction, low glycemic index foods, and balanced macronutrient composition. Hypocaloric diets have been shown by Jarrett and Lujan (2016) to increase the frequency of ovulation in obese women with PCOS [5]. Additionally, findings from McCulloch (2016) emphasized how dietary decisions, exercise, stress reduction, and supplements work in concert to address the root causes of the disorder [6].

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The integration of holistic lifestyle changes to achieve significant symptom reduction, hormonal balance, and improved quality of life for women with PCOS is further supported by recent clinical findings, such as those compiled in the review by Cincione et al. (2021) and in the study by Eslamian et al. (2021) [7] [8]. While there was no discernible impact on insulin resistance or hormone levels, Bashtian et al. (2013) found that fenugreek seed extract significantly improved menstrual cycle regularity and decreased polycystic ovaries in women with polycystic ovarian syndrome [9].

According to a study by Williamson & Carughi (2010), raisins can have higher concentrations of the healthy polyphenols quercetin, kaempferol, and phenolic acids than grapes. Raisins may lower insulin, according to limited human studies, influence glycemic index, improve satiety, and affect oxidative biomarkers. However, more research is needed to confirm the bioavailability and health effects of these compounds [10].

Emerging Evidence for Functional Foods in PCOS: In a previous study, Bashtian et al. (2013) [9] found that fenugreek seed extract improved menstrual cycle regularity and decreased the appearance of polycystic ovaries. HOMA-IR decreases, on the other hand, showed that the combined intervention of the current study, which included fenugreek seeds, black raisins, and extensive lifestyle changes, significantly improved insulin sensitivity.

Therefore, the present study was planned with the aim to study the impact of dietary intervention and lifestyle modification in reducing symptoms of PCOS.

Objectives

- To study anthropometry of PCOS patients pre and post intervention
- To study clinical signs of patients pre and post intervention

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Research Methodology

The research methodology has been divided into four distinct phases

Phase 1: Study Design, Locale, Sample Size, and Sample Selection

Study Design: It was a Randomized Controlled Trial (RCT)

Locale of the study: Mahatma Gandhi Medical College & Hospital (MGMCH), Jaipur.

Sample size: A total of 60 female participants diagnosed with PCOS will be recruited, divided equally into:

- Group 1: 30 participants
- Group 2: 30 participants

Sample Selection:

Inclusion Criteria:

- Females aged 16 to 40 years, representing the reproductive age group
- Confirmed diagnosis of PCOS based on Rotterdam criteria (presence of two of the following three: oligo/anovulation, hyperandrogenism, polycystic ovaries on ultrasound)
- Willingness to participate and provide informed consent
- No known food allergies

Exclusion Criteria:

- Age below 16 or above 40
- Presence of medical conditions (e.g., thyroid disorders, diabetes, Cushing's syndrome), medications, or dietary restrictions that may interfere with study outcomes
- Known allergies to the functional foods used
- Diagnosed eating disorders or severe mental health issues
- Plan to relocate from Jaipur during the study period

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- Inability to comply with the intervention and data collection protocols

Discontinuation criteria: Participants may be withdrawn from the study if they:

- Are non-compliant with the intervention protocol over an extended period
- Develop adverse reactions or intolerance to the functional food products provided
- Voluntarily withdraw consent at any point

Phase 2: Development and Standardization of the Dietary Intervention and Lifestyle Modification protocol

A customized counselling plan was developed for diet and lifestyle based on:

- Standard dietary recommendations for PCOS (e.g., low-GI foods, anti-inflammatory diet)
- National and international guidelines on PCOS management
- Recent research findings from peer-reviewed studies
- The Ayurvedic principles of Ahar (diet), Vihar (physical activity) and Nidra (sleep) for a holistic approach

Development of Functional Food Regimen

A combination of functional foods known to support PCOS management (fenugreek seeds, black raisins) were included in Group 2's daily diet. Serving sizes were standardised as 10g for fenugreek seeds and 20g for black raisins which were given for 90 days. These foods were chosen for their potential benefits in improving insulin sensitivity, menstrual regularity, hormonal balance and weight management**.**

Phase 3: Intervention and Data Collection Phase

Baseline data for both groups acted as control for comparison with post-intervention outcomes. The intervention lasted for 3 months. Data was collected at: Baseline (before intervention) and 3 months post intervention.

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Data Collection Components:

Data collection was done for following components -

1. Anthropometric Measurements: Height (cm), weight (kg), Body Mass Index (BMI), waist circumference, hip circumference, waist-to-hip ratio (WHR)

2. Clinical Signs of PCOS: menstrual irregularity (delayed/excessive), hirsutism, acne, acanthosis nigricans (insulin resistance marker), unexplained weight gain, stress-related symptoms: anxiety, depression (via simple screening questionnaire), eating disorder presence

Compliance Monitoring:

A compliance form was developed to track participants' adherence to dietary recommendations, consumption of functional foods (Group 2) and lifestyle modification practices. This form was recorded monthly, both in physical and Google Form format, depending on participants' preference and accessibility.

Phase 4: Data Analysis

All data will be tabulated using Microsoft Excel, cleaned, and then analyzed using appropriate statistical software (e.g., SPSS, R, or GraphPad).

Ethical Considerations: Ethical approval will be obtained from the Institutional Ethics Committee (IEC) of MGUMST, Jaipur. Informed consent was obtained from all participants.

Results & Discussion

Although sample size was 60 women but due to drop outs or non-compliance, 40 samples were finally included in the study. The results & discussion section has been bifurcated under following headings -

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A. Baseline Characteristics of Study Participants

Twenty participants were assigned to the Standard Care group, which received structured dietary counselling. The other twenty participants were assigned to the Experimental Care group, which received the same standard care with daily supplements of 20g black raisins and 10g soaked fenugreek seeds.

Mean age, baseline weight, Body Mass Index (BMI), waist circumference (WC), hip circumference (HC), and waist-to-hip ratio (WHR) did not significantly differ between the two groups, according to statistical analysis ($p > 0.05$ for all baseline measures). Although anthropometric measures like weight (71.6 ± 9.4 kg vs. 60.1 ± 7.2 kg) and BMI (27.9 ± 3.4 kg/m² vs. 21.7 ± 2.5 kg/m²) showed somewhat higher mean values for the Experimental group, the corresponding p-values (ranging from 0.07 to 0.15), confirm that these numerical differences were not statistically significant.

Parameter	Control Group (n=20) Mean ± SD	Experimental Group (n=20) Mean ± SD	p-value
Mean Age (years)	22.8 ± 3.0	24.3 ± 3.9	0.15
Weight (kg)	60.1 ± 7.2	71.6 ± 9.4	0.09
BMI (kg/m²)	21.7 ± 2.5	27.9 ± 3.4	0.08
Waist circumference (cm)	76.8 ± 4.1	92.6 ± 5.8	0.07
Hip circumference (cm)	95.0 ± 6.8	109.8 ± 9.2	0.07
WHR	0.82 ± 0.03	0.85 ± 0.04	0.09

Table 2: Age & anthropometric measurements of participants at baseline (control vs. Experimental Group)

B. Comparison of anthropometric parameters in both the groups with baseline as well as intercomparison of both the groups post intervention

Significant and differential changes in anthropometric parameters were observed between the two groups over the 3-month intervention period.

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Weight (Kg): The mean weight of the Standard Group increased by a non-significant amount (+0.95 ± 3.1 kg; p = 0.19). In spite of receiving standard dietary counselling. This suggests that standard advice alone may not be enough to help PCOS patients lose weight quickly, underscoring the inherent challenges of managing weight in this population. The Experimental Group, on the other hand, experienced a highly significant mean weight reduction of −5.30 ± 2.9 kg ($p < 0.0001$).

Body Mass Index (BMI) (kg/m²): The Standard Group's mean BMI increased somewhat (+0.36 ± 1.0 kg/m2), which was in line with weight changes. On the other hand, the mean BMI of the Experimental Group decreased significantly by −2.05 ± 0.97 kg/m². The enhanced intervention had a superior effect on total body mass, as evidenced by the highly significant difference in BMI change between groups ($t(38) = 6.89$, $p < 0.0001$).

Waist Circumference (WC) (cm): The Standard Group showed a slight increase in WC (+0.4 ± 1.6 cm). Conversely, the Experimental Group demonstrated a significant reduction of −5.7 ± 2.2 cm. The difference in WC change between groups was highly significant ($p < 0.0001$).

Waist-to-Hip Ratio (WHR): The Standard Group showed a slight increase in WHR (+0.001 ± 0.02). A noteworthy decrease of -0.018 ± 0.01 was attained by the Experimental Group. Particularly noteworthy are the Experimental Group's highly significant decreases in waist circumference (WC) and waist-to-hip ratio (WHR), two indicators of central adiposity that are closely associated with insulin resistance and cardiovascular risk in PCOS.

Comparisons of these modifications between groups further demonstrated the improved intervention's superior effectiveness. Weight change ($t (38) = 6.52$, $p < 0.0001$) and BMI change ($t (38) = 6.89$, $p < 0.0001$) showed highly significant differences according to independent t-tests, suggesting that the Experimental group experienced significantly larger reductions than the Standard group. The groups also showed significant differences in WHR change ($p < 0.001$) and WC change ($p < 0.0001$). It is highly likely that the addition of functional foods (fenugreek seeds and black raisins) offered a

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significant, synergistic benefit beyond standard dietary modification alone. Pasquali and Gambineri (2002) also showed that even modest weight loss can result in significant improvements in ovulation and hormonal balance. They also described how obesity aggravates insulin resistance and hyperandrogenism in PCOS [3].

Parameter	Control Mean (Baseline → 3 mo)	Experimental Mean (Baseline → 3 mo)	p-value (between groups)
Weight (kg)	60.10 → 61.05 (+0.95 ± 3.1)	71.65 → 66.35 (−5.30 ± 2.9)	<0.0001
BMI (kg/m²)	22.16 → 22.52 (+0.36 ± 1.0)	27.56 → 25.51 (−2.05 ± 0.97)	<0.0001
WC (cm)	77.7 → 78.1 (+0.4 ± 1.6)	96.3 → 90.6 (−5.7 ± 2.2)	<0.0001
WHR	0.820 → 0.821 (+0.001 ± 0.02)	0.850 → 0.832 (−0.018 ± 0.01)	<0.001

Table 3: Effect of 3 months intervention on Anthropometric Parameters (Control vs. Experimental Group)

C. Clinical Symptom Outcomes

The intervention also yielded notable improvements in key clinical symptoms of PCOS, with the Experimental group consistently demonstrating superior outcomes.

1. **Menstrual Regularity:** PCOS's hallmark symptom, irregular menstruation, significantly improved in both groups, but the Experimental group's resolution was more thorough. The Standard group's prevalence of delayed menses dropped from 90% (18 participants) at baseline to 15% (3 participants) after the intervention. Delays in menstruation decreased from 85% (17 participants) to an astounding 0% (0 participants) in the experimental group. Both groups also saw improvements in excessive bleeding, with the Experimental group exhibiting a larger decrease (from 35% to 5%) than the Standard group (from 25% to 10%). Both groups saw a significant decrease in delayed menses, according to McNemar's test ($p < 0.001$). The benefits of fenugreek seed extract on reproductive symptoms were reported by Bashtian et al. (2013), and the improvements in ovarian morphology and menstrual regularity [9].

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2. **Hirsutism Scores:** The intervention showed a positive outcome on hirsutism also. By month three, the Experimental group's mean hirsutism score had significantly decreased from 7.4 at baseline to 4.2. The Standard group, on the other hand, demonstrated a slight decline, with mean scores falling from 7.2 to 6.0.

3. **Insulin Resistance (IR):** Insulin resistance (IR) also improved in both groups. From a baseline mean of 4.2 to 2.5 post intervention in the experimental group, while the standard group presented a decline from 4.1 at baseline to 3.5 after intervention. Experimental group's IR decreased more significantly (by 1.7 units) than the Standard group's (by 0.6 units) as shown in table 4. The results of this study strongly support lifestyle intervention as the main therapeutic strategy in the 2023 International Evidence-Based Guideline for the Assessment and Management of PCOS [11]. The observed reductions in inflammation and insulin resistance are consistent with the findings of Papavasiliou & Papakonstantinou (2017) [1]. Dubey et al. (2021) also observed the positive effect of fenugreek seeds on improved insulin resistance in PCOS patients [12].

A similar study by Jarrett and Lujan (2016) [5] demonstrated that hypocaloric diets can increase the frequency of ovulation in obese women with PCOS, highlighting the vital role that weight control plays in the treatment plan as a whole. The benefits of black raisins, like better glycemic control and the possibility of increased satiety, are in line with research by Williamson & Carughi (2010) [10], who found that raisins contain healthy polyphenols that can affect the glycemic index and reduce insulin response. Additionally, since inflammatory markers are frequently elevated in PCOS, indicating a history of low-grade chronic inflammation, the antioxidative qualities of these polyphenols are significant. This supports the suggestions made by Szczuko et al. (2021) [13] to include antioxidants in PCOS treatment.

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Symptoms mean (% of participants)	Control		Experimental	
	Before	After	Before	After
Delayed menses	18 (90)	3 (15)	17 (85)	0 (0)
Irregular menses	15 (75)	3 (15)	15 (75)	0 (0)
Excessive bleeding	15 (75)	2 (10)	7 (35)	1 (5)
Hirsutism score	7.2	6	7.4	4.2
Insulin resistance	4.1	3.5	4.2	2.5

Table 4: Clinical Symptom intra and inter comparison between two groups at baseline & 3 months post intervention

Conclusion

Comprehensive dietary intervention with functional foods serve as a powerful tool in reducing the symptoms of PCOS. In the present study, BMI, insulin sensitivity and menstrual regularity all showed significant improvements in both the Control Care and Experimental Care groups ($p < 0.05$). The Experimental group in which functional foods such as 10 g fenugreek seeds and 20 g black raisins were given, experienced a more profound resolution of clinical symptoms than the Standard group.

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