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Efficacy of a polyherbal formulation in PCOD: A prospective clinical trial

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Polycystic ovarian disease (PCOD) is one of the most common endocrine disorders affecting women of reproductive age worldwide, with a prevalence of 5–15% depending on diagnostic criteria. Its aetiology involves genetic and environmental factors. Clinically, PCOD presents with hyperandrogenism, oligomenorrhoea, anovulation, and polycystic ovarian morphology. Due to the limitations and side effects of conventional therapies, there is increasing interest in alternative and holistic approaches. This study aimed to evaluate the efficacy of a Unani polyherbal formulation in the clinical management of PCOD. A pre–post interventional clinical study was conducted on 30 women aged 18–35 years diagnosed with PCOD based on ESHRE/ASRM criteria. Patients with pelvic pathology, malignancy, uncontrolled diabetes, hypertension, thyroid disorders, or those using contraceptives were excluded. Participants received a formulation comprising Nankhawah, Badiyan, and Wajturki, administered orally twice daily for five days before the expected menstrual period and continued for five days, for three consecutive cycles. Outcome measures included ovarian volume, menstrual cycle duration, body weight, acanthosis nigricans (AN) score, modified Ferriman–Gallwey (mFG) score, and SF-12 quality of life. Statistically significant improvements were observed post-treatment ($p<0.001$). Ovarian volumes reduced, and menstrual cycle duration decreased markedly. AN and mFG scores showed significant reduction, indicating improvement in hyperandrogenism. SF-12 scores demonstrated enhanced quality of life. The Unani polyherbal formulation showed promising therapeutic efficacy in managing PCOD by regulating menstrual cycles, reducing hyperandrogenic features, and improving quality of life.

Keywords: *Acanthosis nigricans*, *Badiyan*, mFG score, *Nankhawah*, PCOD, Polyherbal formulation, Quality of life, *Wajturki*

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Polycystic ovarian disease (PCOD) is a complex endocrine and metabolic disorder affecting women of reproductive age, characterized by disturbances in hormonal regulation and clinical features predominantly related to hyperandrogenism, which may have both immediate and long-term health consequences[1]. According to the World Health Organization, it affects approximately 116 million women globally, accounting for about 3.4% of the female population[2]. The condition is commonly identified by the presence of hyperandrogenism, menstrual irregularities, and polycystic ovarian morphology, although the clinical presentation may vary considerably among individuals[3].

The pathophysiology of PCOD involves dysregulation of the hypothalamic–pituitary–ovarian axis. Increased luteinizing hormone (LH) secretion, often associated with pituitary dysfunction, interferes with normal follicular development and ovulation. Consequently, immature follicles persist within the ovaries and develop into cystic structures. Additionally, hyperinsulinemia plays a crucial role by stimulating androgen production, which contributes to features such as hirsutism and acne, while also impairing ovulation and potentially leading to infertility[4].

PCOD is frequently associated with a range of metabolic and systemic complications, including insulin resistance, diabetes mellitus, cardiovascular disorders, dyslipidemia, hypertension, psychological disturbances, and an increased risk of endometrial pathology[5]. Conventional management strategies include the use of combined oral contraceptives, anti-androgenic drugs, insulin-sensitizing agents, and ovulation-inducing medications. These therapeutic options encompass a variety of pharmacological agents such as pioglitazone, empagliflozin, sitagliptin, liraglutide, statins, and N-acetyl cysteine. However, these treatments may not always yield satisfactory outcomes and can be associated with adverse effects.

Considering the increasing prevalence and multifactorial nature of PCOD, there is a need to explore alternative therapeutic approaches that are both effective and safe. Identification of novel targets

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and drug repositioning strategies may help in improving treatment outcomes while reducing cost and time[6]. In this context, traditional systems of medicine, particularly Unani medicine, offer a holistic approach aimed at correcting underlying imbalances and improving overall health status.

According to the Unani system of medicine (USM), disease occurs due to an imbalance in the quality and quantity of the four humours (*akhlāṭ arbaʿa*), namely *dam* (blood), *ṣafrā* (yellow bile), *sawdā* (black bile), and *balgham* (phlegm). Although PCOD is not explicitly described in classical Unani texts, its clinical manifestations can be correlated with conditions such as *iḥtibās al-ṭamth* (amenorrhea), *uqr* (infertility), and obesity[7]. The development of ovarian cysts is attributed to derangement in temperament, particularly *suʾ-i-mizaj barid* (abnormal cold temperament) of the liver, leading to excess production and dominance of phlegmatic humour (*khilt-i-balgham*), which may contribute to cyst formation[8].

Unani therapeutics employs herbal drugs possessing properties such as anti-inflammatory, emmenagogue, demulcent, analgesic, and metabolic regulatory actions to restore humoral balance and regulate menstrual function[9]. Pharmacological studies have demonstrated that *Nankhwah*, *Badiyan*, and *Wajturki* exhibit multiple therapeutic activities, including estrogenic, anti-inflammatory, antioxidant, anti-diabetic, and hepatoprotective effects. Their bioactive constituents include thymol, glycosides, saponins, flavonoids, sterols, and essential oils, which may contribute to their overall efficacy[10-12].

Therefore, the present study was undertaken to evaluate the efficacy of a polyherbal formulation comprising *Nankhwah*, *Badiyan*, and *Wajturki* in reducing ovarian volume as assessed by ultrasonography and in improving associated clinical features in women with PCOD.

Materials and Methods

Trial design and setting

This prospective pre- and post-interventional study without a control group was carried out from June 2023 to June 2024 in the Department of Ilmul Qabalat wa Amraze Niswan, National Institute of Unani Medicine, Bengaluru.

Participants

The study included patients in the age group of 18 to 35 years. Patients fulfilling two of the three criteria of ESHRE/ASRM, namely oligomenorrhoea or amenorrhoea, hyperandrogenism (hirsutism/acne), and USG findings of PCOD, were included. Patients with obesity and acanthosis nigricans were also included.

Patients with pelvic pathology, malignancies, uncontrolled diabetes, hypertension, thyroid dysfunction, pregnancy, lactation, and those on contraceptives (IUCD, use or OCP use within last 3 months) were excluded.

Selection of the participants

To recruit trial participants, individuals underwent a thorough screening process that included complete medical history, general physical examination, and systemic examination. The trial enrolled participants who met the inclusion and exclusion criteria. The demographic profile of the participants, detailed disease history, and physical and systemic examinations were recorded in the Institutional Ethics Committee (IEC)-approved Case Report Form (CRF).

Intervention

The ingredients of the polyherbal formulation contained *Nankhwah* [*Trachyspermum ammi* L.] – 4 g, *Badiyan* [*Foeniculum vulgare* Mill.] – 4 g, and *Wajturki* [*Acorus calamus* L.] – 4 g. All drugs were purchased from the local raw drug market of Bengaluru and sent to the Central Ayurveda Research Institute for identification and authentication of *Trachyspermum ammi* L. (RRCBI-mus218), *Foeniculum vulgare* Mill. (RRCBI-mus145), and *Acorus calamus* L. (RRCBI-18890). The specimens were submitted to the Department of Ilmul Advia, NIUM, with voucher specimen number 142/IQ/RES/2023, and the preparation was carried out at the pharmacy of NIUM as per standard methods.

Method of preparation, route of administration, and dosage

Joshānda (decoction) was prepared as per standard procedure from *Nankhwah, Badiyan, and Wajturki* (4 g each) and administered in a dose of 6 g twice daily for 5 days before the expected date of menstruation and continued for the next 5 days irrespective of the occurrence of menstruation, for three cycles/months, orally.

Outcome Measures

Primary outcome

Change in ovarian volume as an objective parameter, assessed pre- and post-study.

Secondary outcome

Change in duration of cycle, body weight, Modified Ferriman–Gallwey score[13], Acanthosis

nigricans scale[14], and SF-12 survey[15], which were assessed at each follow-up, except SF-12, which was assessed pre- and post-study. Additionally, the socioeconomic status of the patients was assessed using Kuppuswamy's socioeconomic status scale 2022, while the patients' temperament was evaluated based on the parameters mentioned in classical Unani literature during enrolment.

Safety and adverse effect monitoring

To evaluate the safety of the drugs, clinical signs and symptoms were assessed at each follow-up, and laboratory investigations such as AST, ALT, S. alkaline phosphatase, B. urea, and S. creatinine were done at pre- and post-study follow-up. Additionally, UPT, TSH, FBS, and Hb% were done at the beginning of the trial for exclusion, and USG pelvis was done at baseline and at the end of the study for assessment of the efficacy of the intervention.

Sample size

It was calculated based on a previous study[16]. Assuming the following parameters: $Z\alpha = 1.96$, $Z\beta = 0.84$, SD = 4.43, Σ difference = 1.26, and by applying the formula $N = 2 (Z\alpha - Z\beta) \times SD^2 / (\Sigma \text{ difference})^2$, the total sample size calculated was 29.29 patients, which was approximated to 30 patients. Adding a dropout rate of 15%, the final sample size was estimated to be $35.26 \approx 36$ subjects.

Statistical analysis

Descriptive and inferential statistical analyses were carried out in the present study. Results on continuous measurements are presented as Mean ± SD (Min–Max), and results on categorical measurements are presented as number (%). Significance was assessed at a 5% level of significance. The Shapiro–Wilk test was used to check the normality of data. Paired t-test and Wilcoxon signed-rank test were used to calculate outcome measures. Statistical significance was defined as $p<0.05$.

The statistical software, namely SPSS 22.0 and R environment ver. 3.2.2, were used for the analysis of the data, and Microsoft Word and Excel were used to generate tables.

Ethical approval

The Institutional Ethics Committee approved the study protocol, after which the study was started. IEC number: NIUM/IEC/2021-22/009/ANQ/01, and registration with the Clinical Trials Registry of India was done with CTRI number CTRI/2023/06/054068 dated 19/06/2023. Patients fulfilling the inclusion criteria were given an information sheet containing details regarding the nature of the study. Patients were given sufficient time to go through the study details mentioned in the information sheet. They were given an opportunity to ask questions, and if they agreed to participate in the study, they were asked to provide their signature on the consent form. Compliance was ensured by regular phone calls to the patients. Patients were followed up for 3 cycles/months during the trial and for 1 month after the completion of the intervention. Adverse effects (if any) were recorded, specifying their characteristics (onset, severity, and duration) and possible relationship with drug administration during the entire study period.

Results

Participants flow

A total of 81 patients were screened and assessed for eligibility, of which 14 patients denied participation and 31 were excluded for not meeting the inclusion criteria. Finally, 36 patients were enrolled, out of which 6 patients discontinued the treatment during follow-up for various reasons (2 patients were diagnosed with typhoid, 1 with dengue, 2 did not respond, and 1 shifted to another state). At the end, 30 patients were assessed for subjective and objective parameters, and statistical analysis was performed on the 30 patients who completed the trial as per protocol (Fig. 1).

Demographic profile

The Mean ± SD of the age of the participants included in the study was 26.17±4.778, which indicates that the majority of patients were in their mid-twenties, consistent with the typical age range mentioned in both literatures. The maximum number

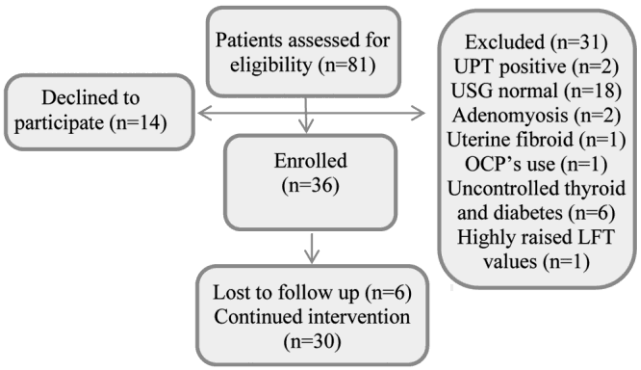

Fig. 1 — Participant flow diagram

of patients (12) had AOM at 13 years, 11 patients had AOM at 14 years, 6 patients had AOM at 11-12 years, and only 1 patient's AOM was at 15 years. The Mean ± SD of AOM was 13.13±1.008.

Out of the total participants, 56.7% were married and 43.3% were unmarried. Most of the patients included in the study belonged to the upper lower middle class (46.7%), followed by lower middle (26.7%), upper middle (16.7%), and lower class (10%), which was assessed using the Kuppuswamy SES scale. A total of 86.7% of the participants gave a negative family history, and only 13.3% had a positive family history of PCOD. Regarding occupation, 46.7% were housewives, 26.7% were working women, 16.7% were students, and 10% were unoccupied.

In terms of education, 66.7% had primary, secondary, or higher secondary schooling, 30% were graduates, and 3.3% were illiterate. About 43.33% of the study population had a waist circumference of 91-100 cm, followed by 36.33% having 101-120 cm, and 20% having WC between 70-90 cm, with a Mean ± SD of 97.83±9.98. Furthermore, 64.7% of the study participants were parous, and 35.29% were nulliparous and anxious to conceive. A total of 60% participants had *balghami mizaj* (phlegmatic temperament) and 40% had *damvi mizaj* (sanguine temperament), which strongly correlates with and supports the Unani literature (Table 1).

Changes in primary outcome measure

Ovarian volume on US

Right ovary – The Mean ± SD of the study participants before and after treatment was 12.52±2.77 and 9.85±2.59, respectively, with a p value < 0.001, which is considered highly significant.

Left ovary – The Mean ± SD of the study participants before and after treatment was 12.24±3.33 and 10.30±2.18, respectively, with a p value < 0.001, which is considered highly significant (Table 2).

Changes in secondary outcome measure

***Duration of cycle* (*DOC*)**

The Mean ± SD of DOC of the participants before treatment was 81.00±33.615. It showed a significant reduction throughout the trial, with a p value < 0.001 at all time points of the study, and the Mean ± SD at C1, C2, C3, and after treatment was 29.93±31.703, 35.60±37.643, 35.60±37.643, and 40.40±34.330, respectively (Table 2).

Body weight

The study participants had a mean body weight of 68.96±12.43 before treatment. There was no difference in Mean ± SD at any point of the study, and the P values were 0.478, 0.19, 0.153, and 0.181, which are not considered statistically significant (Table 2).

***Acanthosis nigricans* (*AN*)**

The Mean ± SD of the study participants before treatment was 1.63±1.37, and at C1, C2, C3, and after treatment it was 1.60±1.32, 1.43±1.22, 1.23±1.07, and

Table 1 — Demographic data of study participants

Demographic data	No. of patients (n=30)	(%)
	Age group	
18-20	4	13.3
21-30	19	63.3
31-40	7	23.3
	Mean ± SD=26.17±4.778	
	Age of menarche (AOM)	
11-12	6	20.0
13	12	40.0
14	11	36.7
15	1	3.3
	Mean ± SD=13.13±1.008	
	Marital status	
Married	17	56.7
Unmarried	13	43.3
	Socioeconomic status (SES)	
Lower	3	10.0
Lower middle	8	26.7
Upper lower	14	46.7
Upper middle	5	16.7
	Family history	
Absent	26	86.7
Present	4	13.3
	Occupation	
Housewife	14	46.7
Working	8	26.7
Student	5	16.7
Nil	3	10.0
	Education	
Graduate	9	30.0
Schooling	20	66.7
Illiterate	1	3.3
	Waist circumference	
70-90	6	20.0
91-100	13	43.33
101-120	11	36.33
	Mean ± SD=97.83±9.98	
	Parity (n=17)	
Parous	11	64.7
Nulliparous	6	35.29
	Mizaj (temperament)	
Balghami (phlegmatic)	18	60.0
Damvi (*sanguine*)	12	40.0

1.23±1.07, respectively. The maximum difference in mean was observed at the end of the intervention and 4 weeks after the end of the intervention. The p values were significant and highly significant at C2, C3, and after treatment, *i.e.*, 0.014, 0.001, and 0.001, respectively (Table 2).

Modified Ferriman–Gallwey score (mFG)

The study participants had a Mean ± SD value of 14.57±4.32 before treatment. At C1, C2, C3, and after treatment, the values were 14.57±4.32, 14.20±3.97, 13.90±3.75, and 13.80±3.72, respectively. The maximum difference in mean was noted 4 weeks after the end of the intervention. The p values were 1, 0.04, 0.04, and 0.002 at different points of the study, where the p values at C2, C3, and after treatment are considered statistically significant and highly significant, respectively (Table 2).

SF-12

The Mean ± SD of quality of life before treatment was 598.67±247.82. There was a significant improvement in the mean after treatment, *i.e.*, 857.33±207.22, with a highly significant p value < 0.001 (Table 2).

Safety profile

No significant differences in p value was observed in safety profile before and after treatment (Table 3).

Table 2 — Changes in parameters from baseline to the end of the trial

Ovarian volume*	Mean ± SD	P value
Right ovary		
BT	12.52±2.77	<0.001**
AT	9.85±2.59	
Left ovary		
BT	12.24±3.33	<0.001**
AT	10.30±2.18	
DOC^		
BT	81.00±33.615	
C1	29.93±31.703	<0.001**
C2	35.60±37.643	<0.001**
C3	35.60±37.643	<0.001**
AT	40.40±34.330	<0.001**
Body weight*		
BT	68.96±12.43	
C1	68.69±12.55	0.478
C2	68.44±12.26	0.19
C3	68.28±12.13	0.153
AT	68.24± 12.29	0.181
AN^		
BT	1.63±1.37	
C1	1.60±1.32	0.31
C2	1.43±1.22	0.014*
C3	1.23±1.07	0.001**
AT	1.23±1.07	0.001**
mFG^		
BT	14.57±4.32	
C1	14.57±4.32	1
C2	14.20±3.97	0.04*
C3	13.90±3.75	0.04*
AT	13.80±3.72	0.002**
SF-12*		
BT	598.67± 247.82	<0.001**
AT	857.33± 207.22	

* Test used: paired sample t test
^ Test used: Wilcoxon Signed Ranks Test.
BT-Before treatment, AT-After treatment, C-Cycle mFG-modified Ferriman-Gallway score, AN- Acanthosis nigricans
DOC- duration of cycle

Discussion

Interpretation of results and overall evidence

The mean age of participants in the present study was 26.17±4.778 years, which falls within the commonly affected reproductive age group and is consistent with observations reported by Vaidya *et al.*[17]. Similarly, the mean age of menarche (13.13±1.008 years) is comparable with findings of Kalpita *et al.*[18], indicating a similar baseline reproductive profile. The distribution of marital status, socioeconomic status, educational level, and occupational pattern and family history observed in this study also demonstrates trends comparable with earlier reports, including those of Zubair *et al.*[19] Bano *et al.*[20], Ranathunga *et al.*[21]. These similarities suggest that the study population is representative of the typical demographic characteristics of PCOD patients described in previous literature.

The predominance of *balghami mizaj* (phlegmatic temperament) (60%) among participants supports the Unani concept of humoral imbalance in the pathogenesis of PCOD, which is in agreement with classical Unani literature[22,23]. This concordance between clinical findings and traditional concepts strengthens the applicability of Unani principles in understanding and managing the disease.

Table 3 — Changes in safety parameters before and after trial

Test	BT (Mean ± SD)	AT (Mean ± SD)	P value
AST	21.03±5.47	20±8.4	0.2270
ALT	23.42±8.4	23±12.8	0.4399
ALK	97.02±17.91	101.06±25.20	0.2382
BU	20.59±12.43	19.3±4.01	0.2954
Sr. Creatinine	0.69±0.11	0.71±0.029	0.2910

Test used: Wilcoxon signed ranks test
AST-asparate aminotransferase, ALT-Alanine aminotransferase, ALP- Alkaline phosphatise, BU- Blood urea

The per-protocol analysis in the present study demonstrated a statistically significant reduction in the duration of the menstrual cycle. In addition, there was a marked improvement in objective parameters such as ovarian volume, acanthosis nigricans (AN) score, and Modified Ferriman–Gallwey (mFG) score, along with a significant enhancement in quality of life as assessed by the SF-12 survey. These findings indicate the overall effectiveness of the intervention in improving both clinical and subjective outcomes in patients with PCOD. However, no statistically significant change in body weight was observed throughout the study period. This may be attributed to the absence of dietary and lifestyle modifications, as the intervention was limited to pharmacological therapy alone.

The observed therapeutic effects may be explained by the pharmacological properties of the constituent drugs. The formulation contains bioactive compounds such as thymol, flavonoids, glycosides, saponins, and essential oils, which are known to exert multiple biological activities[10-12]. From a Unani perspective, the drugs possess properties such as *mulattif* (demulcent), *mufatteh sudda* (deobstruent), *mudirr-i-bawl-o-hayd* (emmenagogue and diuretic), and *muhallil* (anti-inflammatory), which help in resolving obstruction, improving circulation, and restoring normal physiological function. These combined actions may contribute to the regulation of menstrual cycles, reduction in ovarian volume, and alleviation of associated symptoms.

The estrogenic activity of the formulation may have contributed to the regulation of endometrial growth and shedding, thereby facilitating normalization of menstrual cycles. Furthermore, phytoestrogenic compounds may help in modulating hormonal imbalance by reducing androgen levels and improving estrogen–progesterone balance. These mechanisms may also explain the improvement observed in clinical features such as hirsutism and acanthosis nigricans.

In addition, the anti-inflammatory and antioxidant properties of the drugs may enhance vascular function and reduce systemic inflammation, which are known contributors to the pathophysiology of PCOD[24-26]. The anti-diabetic and insulin-sensitizing effects of the formulation may further improve metabolic disturbances, leading to better hormonal regulation and reduction in hyperandrogenic manifestations. These combined mechanisms may account for the overall clinical improvement observed in the present study.

The findings of the present study are consistent with earlier research on herbal and Unani interventions in PCOD. Begum W *et al*.[27], reported a significant reduction in the duration of menstrual cycle following treatment with *Majoon-i-Idrare haiz*, indicating a comparable effect on cycle regulation. Similarly, Zubair *et al.*[19]. observed improvement in acanthosis nigricans scores, suggesting beneficial effects on metabolic and insulin resistance parameters. Haidari *et al.*[28] demonstrated a significant reduction in mFG score following intervention, supporting the role of herbal therapies in managing hyperandrogenic features.

Improvement in quality of life observed in the present study is also in agreement with findings reported by Bano *et al*.[20], who noted significant enhancement following herbal therapy. Furthermore, the reduction in ovarian volume aligns with the results of Ishaq *et al*.[29], indicating that herbal interventions may have a beneficial effect on ovarian morphology. The similarity in outcomes across these studies may be attributed to shared pharmacological actions such as anti-inflammatory, antioxidant, insulin-sensitizing, and hormone-modulating effects of the interventions.

In the present study, improvement was observed in 60% of participants with respect to duration of cycle, 40% in mFG and AN scores, 63.3% in quality of life, and 96.7% in ovarian volume. These findings suggest that the polyherbal formulation has considerable therapeutic potential in the management of PCOD. The results are further supported by recent systematic reviews and evidence-based studies, which highlight the efficacy of herbal therapies in PCOD through mechanisms such as reduction of oxidative stress, improvement in insulin sensitivity, and modulation of hormonal imbalance[30,31].

Strengths and limitations of the study

The present study is first of its kind to evaluate the effect of *Nankhawah*, *Badiyan*, and *Waj Turki* administered in the form of *Joshanda* in patients of PCOD. The study employed multiple validated outcome measures including ovarian volume on ultrasonography, acanthosis nigricans (AN) scale, modified Ferriman–Gallwey (mFG) score, and SF-12 quality of life survey, which provided a comprehensive assessment of clinical and subjective improvement.

However, the study has certain limitations. It was a single-arm clinical study with a relatively small sample

size and short duration of intervention. Hormonal profile assessment was not carried out, as the primary focus was on clinical and symptomatic improvement, which should be considered in future research. Additionally, only one post-treatment follow-up was conducted, which limits the evaluation of long-term efficacy and sustainability of therapeutic effects.

Conclusion

The findings of the present study suggest that the Unani formulation comprising *Nankhawah*, *Badiyan*, and *Waj Turki* is effective in the management of PCOD and its associated symptoms. The intervention demonstrated significant reduction in ovarian volume on ultrasonography, regularization of menstrual cycle duration, improvement in quality of life, and reduction in associated clinical features such as acanthosis nigricans and hirsutism. These results are in accordance with the principles described in classical Unani literature regarding the management of disorders associated with *ghalba-e-balgham* (dominance of phlegm) and su-e-mizaj (abnormal temperament).

Nevertheless, further studies with larger sample size, randomized controlled design, longer duration of treatment, and extended follow-up periods are recommended. Future research should also include pre- and post-intervention hormonal profiling to better elucidate the exact mechanism of action of the formulation on endocrine and metabolic parameters in PCOD.

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Author Contributions

AN- primary researcher, WB: guide, GNW: secondary researcher.

Conflict of Interest

Authors declare that there is no conflict of interest.

Ethical Committee Number

NIUM/IEC/2021-22/009/ANQ/01

Trial Registration Number

CTRI/2023/06/054068

Informed Consent

Written informed consent was obtained from all the participants prior to their enrollment in the study. Participants were informed about the nature, objectives and procedures of the study and confidentiality of the patient information was strictly maintained.

Data Availability

The datasets generated and analysed during the current study are not publicly available due to ethical and confidentiality restrictions related to patient information.

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