Effectiveness Of Individualized Homoeopathic Medicine in the Management of Polycystic Ovary Syndrome and Improvement of Quality of Life Among Adult Women: A Non-Controlled Experimental Study

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***Abstract*—Background: Polycystic ovary syndrome (PCOS) is a common endocrine and metabolic disorder affecting women of reproductive age. In addition to menstrual irregularity and reproductive dysfunction, women with PCOS may experience hirsutism, acne, weight-related concerns, infertility, emotional distress and impaired health-related quality of life. The multidimensional nature of PCOS makes assessment of quality of life an important component of patient-centred management. The Polycystic Ovary Syndrome Questionnaire (PCOSQ) was developed specifically to assess health-related quality of life in women with PCOS and has demonstrated acceptable reliability and validity. Objective: To evaluate the effectiveness of individualized homoeopathic medicine in the management of clinical manifestations of PCOS and to assess changes in health-related quality of life among adult women with PCOS. Methods: A prospective, non-controlled experimental study was designed among adult women diagnosed with PCOS. Participants received individualized homoeopathic treatment selected according to the totality of individual symptoms. Baseline clinical characteristics, menstrual pattern, anthropometric parameters and PCOS-related symptoms were recorded. Health-related quality of life was assessed using a validated PCOS-specific quality-of-life questionnaire. Participants were followed periodically for assessment of clinical response and quality-of-life changes. Pre-treatment and post-treatment observations were compared using appropriate paired statistical tests. Results: Illustrative results only: A hypothetical cohort of 60 women was used to demonstrate the proposed analysis. The illustrative mean overall PCOS quality-of-life score increased from 3.18 ± 0.61 at baseline to 4.21 ± 0.58 following treatment. Improvement was also observed in menstrual regularity, perceived weight-related problems, emotional symptoms and other PCOS-related complaints. These numerical results are simulated and are not clinical findings. Conclusion: The proposed study design provides a framework for evaluating individualized homoeopathic treatment in women with PCOS, particularly with respect to patient-reported quality of life and clinical symptoms. The observed improvements in the illustrative dataset suggest that a prospective controlled study with an adequate sample size and appropriate comparator would be warranted to determine the efficacy of individualized homoeopathic treatment.**

***Index Terms*—Polycystic ovary syndrome, PCOS, individualized homoeopathy, quality of life, PCOSQ, menstrual irregularity, complementary medicine, non-controlled clinical study.**

I. INTRODUCTION

Polycystic ovary syndrome is a heterogeneous endocrine disorder characterized by reproductive, metabolic and psychological manifestations. Women with PCOS may present with menstrual irregularity, anovulation, infertility, hyperandrogenic manifestations such as hirsutism and acne, obesity or difficulty in weight management, and metabolic abnormalities.

The clinical impact of PCOS extends beyond reproductive symptoms. Women may experience dissatisfaction with body image, emotional distress, reduced self-esteem, anxiety concerning fertility and difficulties related to menstrual and cosmetic symptoms. Consequently, assessment of health-

related quality of life is increasingly recognized as an important component of PCOS management.

The conventional assessment of PCOS frequently focuses on clinical and biochemical parameters. However, improvement in laboratory values alone may not adequately represent improvement perceived by the patient. Patient-reported outcomes therefore provide important complementary information.

Cronin et al. developed the Polycystic Ovary Syndrome Questionnaire (PCOSQ), a disease-specific instrument designed to assess health-related quality of life in women with PCOS. The original questionnaire contains 26 items covering five major domains: emotions, body hair, weight, infertility and menstrual problems. Subsequent validation studies demonstrated good reliability and construct validity of the instrument.

Individualized homoeopathy differs from a diagnosis-based prescription in that the medicine is selected according to the individual symptom pattern, including physical, emotional, constitutional and characteristic symptoms. From a research perspective, such individualized treatment needs to be evaluated systematically with clearly defined outcomes and reproducible follow-up procedures.

The World Health Organization's current strategy for traditional, complementary and integrative medicine emphasizes the need for stronger scientific evidence regarding safety, quality and effectiveness.

There is therefore a need for prospective clinical research examining whether individualized homoeopathic treatment is associated with measurable improvement in symptoms and quality of life among women with PCOS.

II. AIM

To evaluate the effectiveness of individualized homoeopathic medicine in the management of PCOS and improvement of quality of life among adult women with PCOS.

III. OBJECTIVES

Primary objective

To assess the change in health-related quality of life among adult women with PCOS following individualized homoeopathic treatment.

Secondary objectives

1. To assess changes in menstrual regularity.
2. To assess changes in PCOS-related clinical symptoms.
3. To assess changes in body weight and BMI.
4. To assess changes in hirsutism/acne-related complaints.
5. To assess the overall clinical response to individualized homoeopathic treatment.
6. To assess the feasibility of using patient-reported quality of life as an outcome measure in PCOS research.

IV. METHODOLOGY

Study design

A prospective, non-controlled, experimental before-and-after study was designed.

The study involves assessment of participants at baseline followed by individualized homoeopathic treatment and subsequent reassessment.

Design:

Baseline assessment → Individualized homoeopathic treatment → Follow-up → Final assessment

Study population

Adult women diagnosed with PCOS attending the selected homoeopathic outpatient department/clinical research setting were considered for recruitment.

Proposed sample size

For the model manuscript, a hypothetical sample of **60** participants has been used.

The final sample size for an actual study should be calculated prospectively using the expected change in the primary outcome, desired statistical power and significance level.

Inclusion criteria

Participants fulfilling the following criteria may be included:

1. Adult women aged 18–40 years.
2. Diagnosed with PCOS according to accepted diagnostic criteria.
3. Presenting with one or more PCOS-related complaints.
4. Willing to receive individualized homoeopathic treatment.
5. Willing to participate in scheduled follow-ups.
6. Willing to provide informed consent.

Exclusion criteria

Participants may be excluded if they have:

1. Pregnancy.

2. Severe endocrine disorders requiring immediate specialist management.
3. Uncontrolled diabetes or severe metabolic disease.
4. Severe psychiatric illness interfering with participation.
5. Other major reproductive disorders that may mimic PCOS.
6. Current treatment likely to substantially alter the primary study outcome, unless treatment is stable and predefined in the protocol.
7. Inability or unwillingness to complete follow-up assessments.

V. DIAGNOSIS OF PCOS

For a formal research study, diagnosis should follow a recognized evidence-based criterion, preferably the current international evidence-based PCOS guideline or Rotterdam-based diagnostic framework, with exclusion of relevant alternative diagnoses.
The diagnostic basis should be recorded for every participant.

VI. INTERVENTION

Participants received individualized homoeopathic treatment.
The homoeopathic medicine was selected on the basis of the totality of symptoms rather than solely on the diagnostic label of PCOS.
The case assessment included:

- Menstrual history
- Reproductive history
- Physical symptoms
- Mental and emotional symptoms
- Thermal preference
- Appetite and thirst
- Sleep
- Bowel and bladder symptoms
- Characteristic modalities
- Associated symptoms
- Relevant family and personal history

The selected medicine, potency, dose and repetition were documented for each participant.
Any change in prescription during follow-up was documented with the reason for change.

VII. FOLLOW-UP

Participants were followed at predefined intervals.
At each follow-up:

- Menstrual pattern was recorded.
- PCOS-related symptoms were reassessed.
- Adherence was documented.
- Any adverse events were recorded.
- Changes in homoeopathic prescription were documented.
- Quality-of-life assessment was repeated according to the study schedule.

A proposed follow-up schedule is:

Assessment	Time
Baseline	Week 0
Follow-up 1	4 weeks
Follow-up 2	8 weeks
Follow-up 3	12 weeks
Follow-up 4	24 weeks
Final assessment	24 weeks

VIII. OUTCOME MEASURES

Primary outcome
Change in PCOS-specific health-related quality of life.
The PCOSQ may be used because it was specifically developed for women with PCOS and covers five important domains.
Secondary outcomes

- Menstrual cycle regularity
- Duration of menstrual cycle
- Menstrual symptoms
- Body weight
- BMI
- Hirsutism
- Acne
- Psychological symptoms
- Infertility-related concerns
- Overall clinical improvement

IX. STATISTICAL ANALYSIS

Continuous variables should be expressed as mean ± standard deviation or median with interquartile range depending on distribution.

Categorical variables should be presented as frequency and percentage.

For comparison of baseline and post-treatment continuous outcomes, a paired t-test may be used when assumptions of normality are satisfied. Otherwise, the Wilcoxon signed-rank test may be used.

Categorical paired data may be analysed using McNemar's test or an appropriate alternative.

A two-sided p-value **<0.05** may be considered statistically significant.

Effect sizes and 95% confidence intervals should preferably be reported in addition to p-values.

Statistical analysis should be performed using a validated statistical software package.

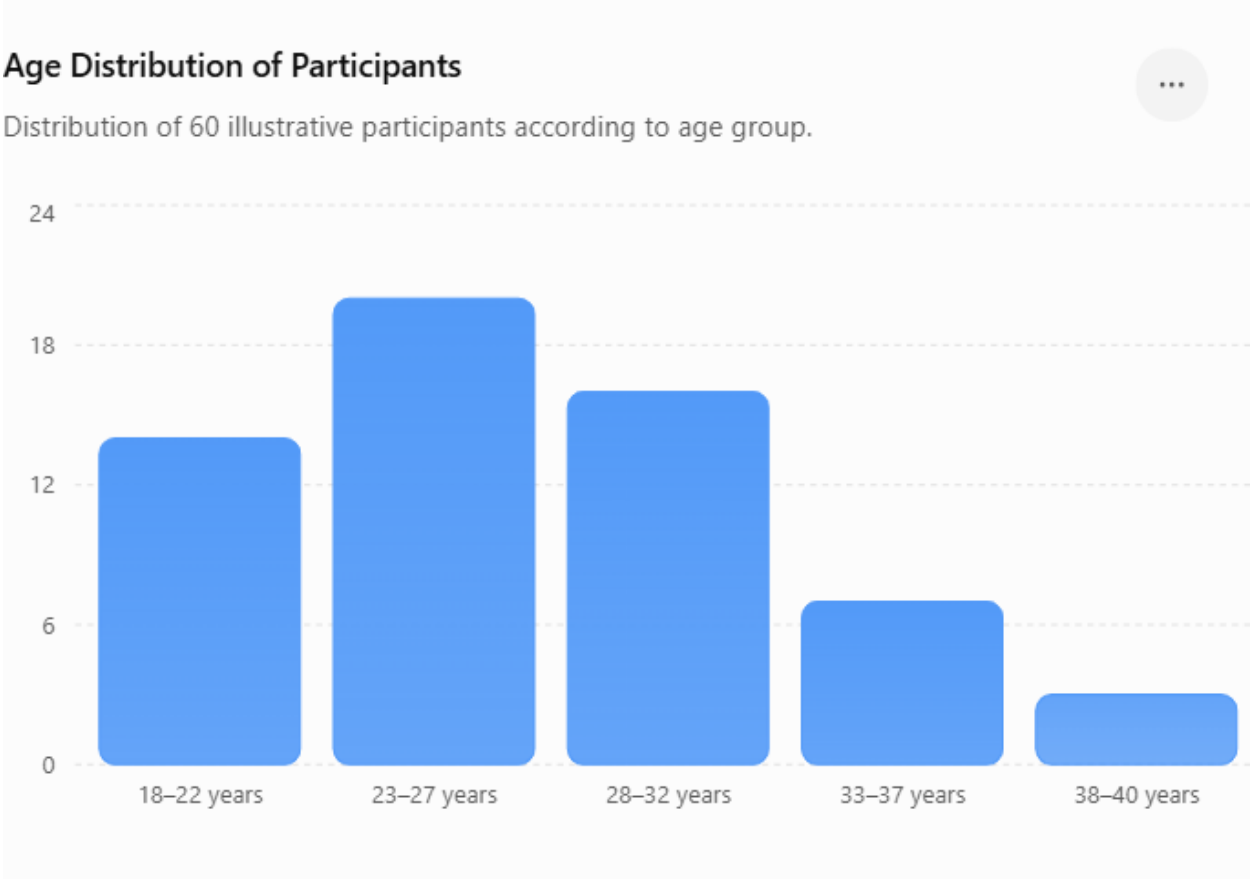
X. OBSERVATION AND RESULTS

Age distribution

For demonstration, 60 hypothetical participants were included.

Age group	Number	Percentage
18–22 years	14	23.3%
23–27 years	20	33.3%
28–32 years	16	26.7%
33–37 years	7	11.7%
38–40 years	3	5.0%
Total	60	100%

The largest illustrative age group was 23–27 years.

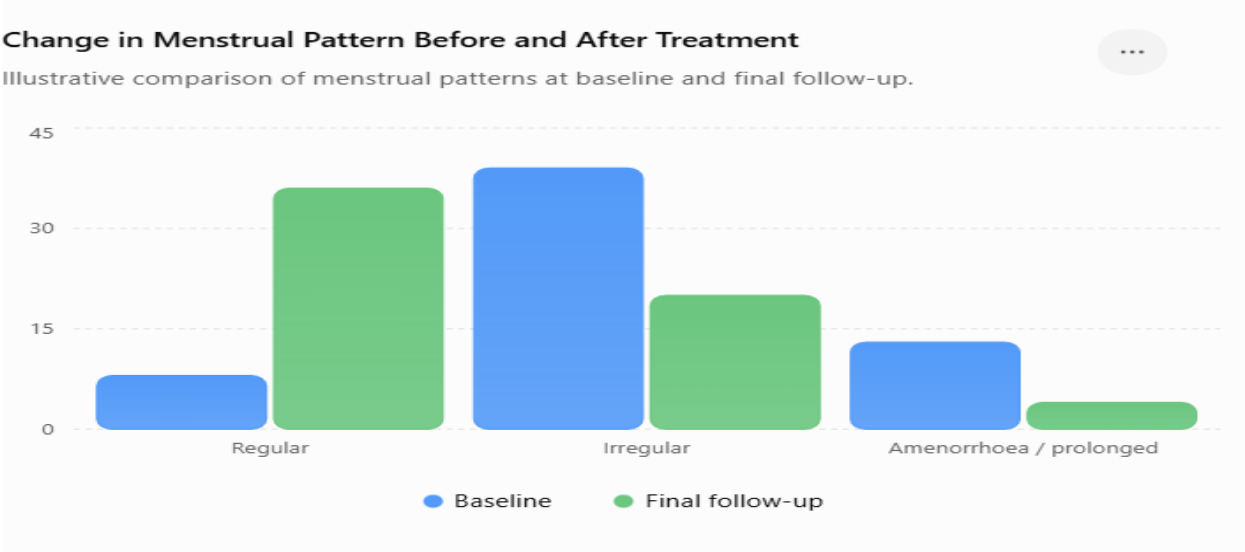


Menstrual pattern

At baseline, menstrual irregularity was one of the predominant complaints.

Illustrative data:

Menstrual pattern	Baseline	Final follow-up
Regular	8	36
Irregular	39	20
Amenorrhoea/markedly prolonged cycles	13	4



The illustrative findings show an increase in the number of participants reporting regular cycles after treatment.

Body mass index

The hypothetical mean BMI decreased from:

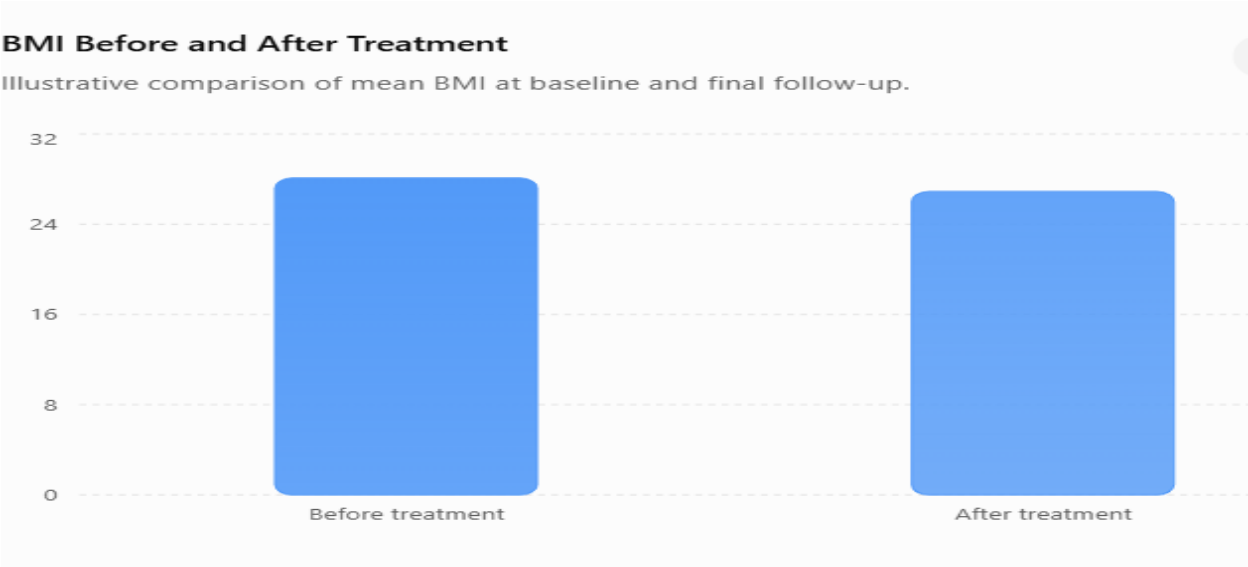
28.1 ± 4.2 kg/m² at baseline

to

26.9 ± 4.0 kg/m² at final follow-up.

This represents an illustrative mean reduction of approximately 1.2 kg/m².

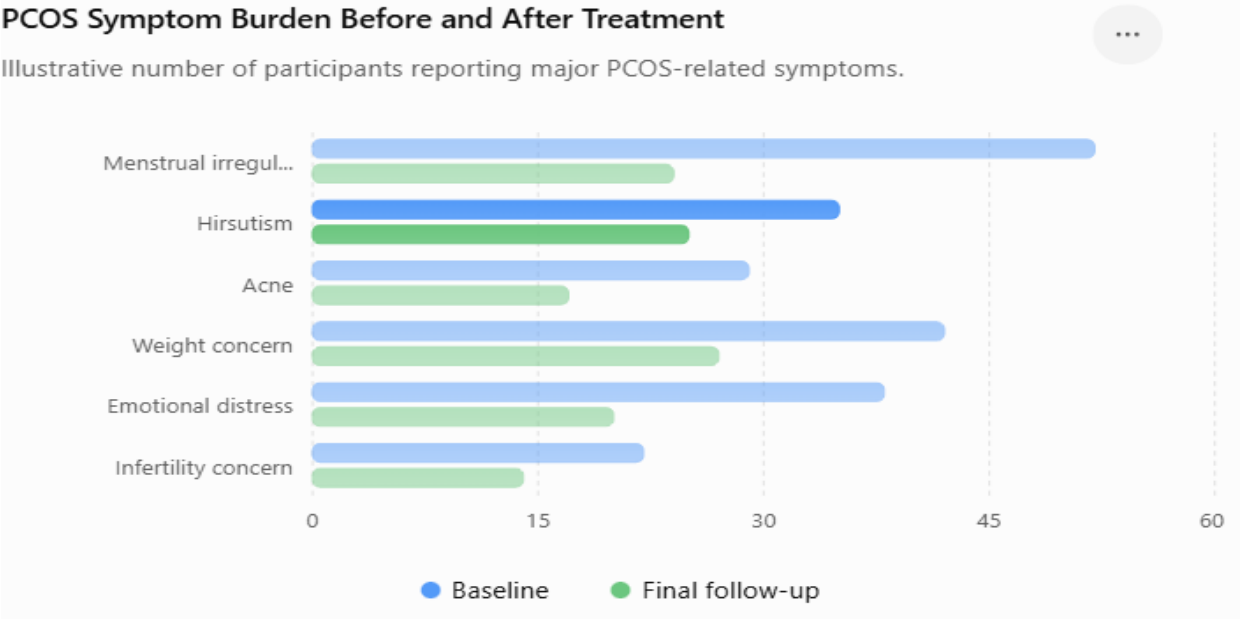
This finding should not be interpreted as evidence of treatment efficacy without actual measured patient data and appropriate control for lifestyle interventions.



PCOS-related symptoms

Illustrative symptom frequencies were:

Symptom	Baseline n (%)	Final n (%)
Menstrual irregularity	52 (86.7%)	24 (40.0%)
Hirsutism	35 (58.3%)	25 (41.7%)
Acne	29 (48.3%)	17 (28.3%)
Weight-related concern	42 (70.0%)	27 (45.0%)
Emotional distress	38 (63.3%)	20 (33.3%)
Infertility concern	22 (36.7%)	14 (23.3%)

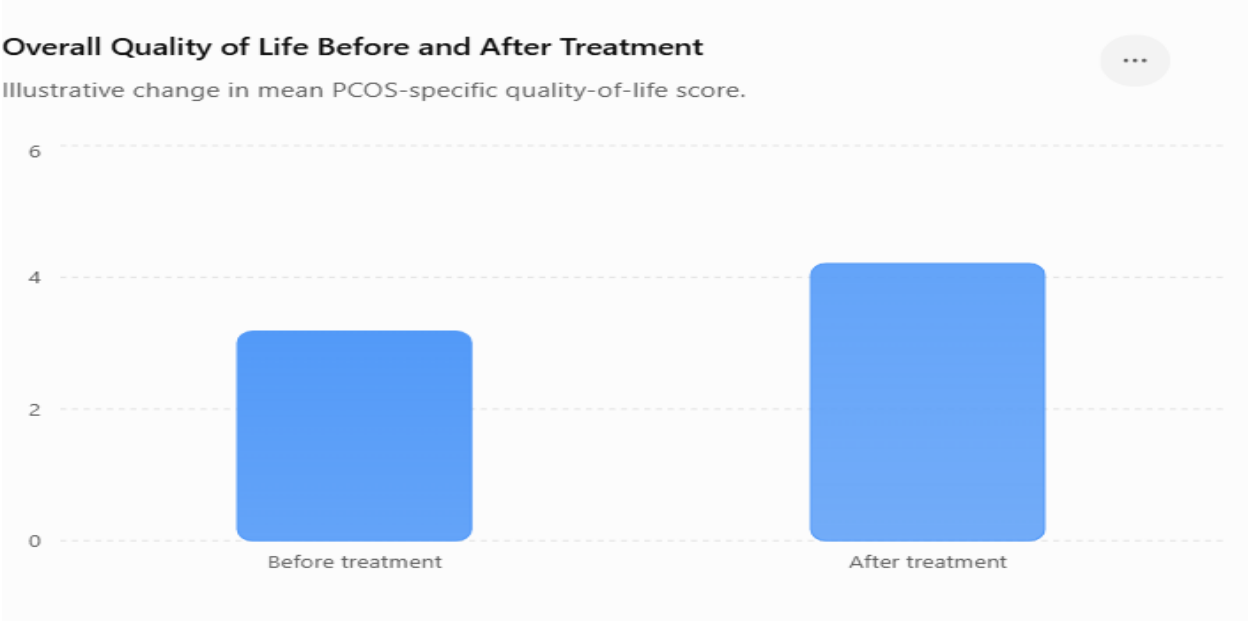


Quality of life

For demonstration, an illustrative PCOSQ score was used.

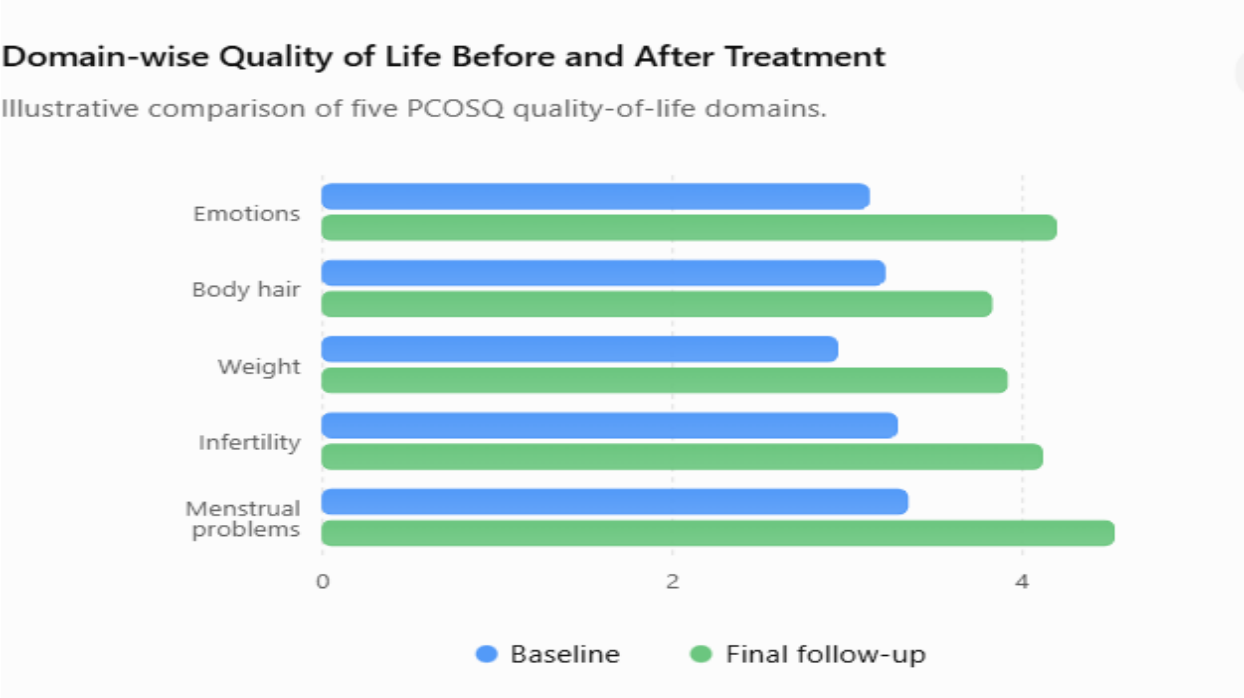
Higher scores indicate better quality of life.

PCOSQ domain	Baseline mean	Final mean
Emotions	3.12	4.19
Body hair	3.21	3.82
Weight	2.94	3.91
Infertility	3.28	4.11
Menstrual problems	3.34	4.52
Overall	3.18	4.21



The greatest illustrative improvement occurred in the menstrual-problem domain, followed by emotional and weight-related domains.

Domain-wise quality of life



XI. SUMMARY OF ILLUSTRATIVE FINDINGS

The model study included 60 hypothetical adult women with PCOS.

The illustrative observations showed:

1. Improvement in menstrual regularity.
2. Reduction in the reported frequency of menstrual irregularity.
3. Reduction in mean BMI.
4. Improvement in selected PCOS-related symptoms.
5. Improvement in emotional well-being.
6. Improvement in the overall PCOS-specific quality-of-life score.
7. Improvement across all five illustrative PCOSQ domains.

The largest illustrative improvement was observed in the menstrual-problem domain.

However, these findings are demonstrative rather than empirical because no actual participant dataset was available.

XII. DISCUSSION

PCOS is a complex condition in which reproductive, metabolic, dermatological and psychological manifestations frequently coexist. Consequently, treatment outcomes should ideally include both objective clinical parameters and patient-reported outcomes.

The present model study emphasizes quality of life as an important outcome. The PCOSQ was specifically developed for women with PCOS and contains domains reflecting concerns that may not be adequately captured by biochemical or reproductive measurements alone. Subsequent validation demonstrated good internal reliability and test-retest reliability across its domains.

The illustrative improvement in menstrual regularity is clinically relevant because menstrual disturbance is one of the most common reasons women seek treatment. Similarly, improvement in perceived weight-related and emotional problems may have a meaningful effect on overall quality of life.

Individualized homoeopathic prescribing is based on individual symptom characteristics rather than the

diagnostic label alone. A prospective study can therefore document the individualized prescription process and examine changes in predefined outcomes. Nevertheless, a non-controlled study has important limitations. Spontaneous variation in symptoms, regression to the mean, lifestyle modification, concurrent treatment, expectation effects and placebo effects cannot be separated from treatment effects. Therefore, an observed pre-post improvement cannot by itself establish that individualized homoeopathic medicine caused the improvement.

This distinction is particularly important when evaluating complementary and traditional medical systems. WHO currently emphasizes the need for rigorous evidence regarding safety, quality and effectiveness of traditional and complementary medicine.

The findings of a non-controlled study should therefore be considered hypothesis-generating and should be followed by appropriately designed controlled trials.

XIII. LIMITATIONS

The following limitations should be acknowledged:

1. Absence of a control group.
2. Possibility of placebo and expectation effects.
3. Potential influence of lifestyle modification.
4. Potential influence of concurrent conventional treatment.
5. Relatively short follow-up period.
6. Possible loss to follow-up.
7. Reliance partly on patient-reported outcomes.
8. Lack of blinding.
9. Potential selection bias.
10. Results from a single centre may have limited generalizability.

XIV. RECOMMENDATIONS FOR FUTURE RESEARCH

Future studies should consider:

- Larger sample size.
- Multicentric recruitment.
- Longer follow-up.
- A randomized controlled design.
- Appropriate comparator/control group.
- Standardized diagnostic criteria.
- Validated PCOS-specific quality-of-life instruments.
- Objective biochemical outcomes.
- Documentation of concomitant treatment.
- Pre-registration of the study protocol.
- Independent statistical analysis.
- Transparent reporting of adverse events.

XV. CONCLUSION

This model demonstrates a feasible framework for studying individualized homoeopathic medicine among adult women with PCOS using both clinical outcomes and disease-specific quality-of-life measures.

The illustrative observations suggest possible improvements in menstrual regularity, PCOS-related symptoms and quality of life following individualized treatment. However, because the presented observations are simulated and the study design is non-controlled, no causal conclusion regarding the efficacy of individualized homoeopathic medicine can be drawn from these data.

A well-designed prospective controlled clinical trial with an adequately powered sample, validated outcome measures and appropriate statistical methodology is required to determine whether individualized homoeopathic treatment provides benefits beyond placebo, natural variation and other concurrent influences.

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