

Original Article

A Randomized Trial of a Structured Lifestyle Intervention for Improving Fertility Outcomes in Women with Polycystic Ovary Syndrome Undergoing Ovulation Induction

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ABSTRACT

Background: Polycystic ovary syndrome is a leading cause of anovulatory infertility and is frequently associated with obesity, insulin resistance, menstrual dysfunction, and reduced response to fertility treatment. Structured lifestyle intervention may improve reproductive outcomes by targeting modifiable metabolic drivers of ovulatory dysfunction. **Objective:** To evaluate whether a structured lifestyle intervention added to standard ovulation induction improves ovulation, clinical pregnancy, live birth, and metabolic outcomes among women with PCOS-related infertility. **Methods:** A parallel-group randomized controlled trial was conducted in tertiary infertility clinics in Central Punjab, Pakistan, between August 2025 and February 2026. Eighty women aged 18–35 years with PCOS-related infertility and BMI 25–40 kg/m² were randomized to structured lifestyle intervention plus standard ovulation induction (n=40) or standard care alone (n=40). The 16-week intervention included individualized dietary counseling and supervised physical activity. **Results:** Complete outcome data were available for 73 participants. Compared with controls, the intervention group showed higher ovulation (83.8% vs 58.3%, p=0.016), clinical pregnancy (48.6% vs 25.0%, p=0.036), and live birth rates (40.5% vs 19.4%, p=0.047). Greater reductions were observed in BMI, waist circumference, and HOMA-IR, and menstrual regularity was more frequent in the intervention group. **Conclusion:** Structured lifestyle intervention added to ovulation induction improved fertility and metabolic outcomes in women with PCOS-related infertility. **Keywords:** Body Mass Index; Diet Therapy; Female Infertility; Ovulation Induction; Polycystic Ovary Syndrome; Pregnancy; Randomized Controlled Trial

INTRODUCTION

Polycystic ovary syndrome is one of the most common endocrine disorders affecting women of reproductive age and represents a major cause of anovulatory infertility worldwide (1). The condition is characterized by varying combinations of ovulatory dysfunction, clinical or biochemical hyperandrogenism, and polycystic ovarian morphology, and it frequently coexists with central adiposity, insulin resistance, dyslipidemia, and chronic low-grade metabolic dysfunction (2). These abnormalities are clinically important because reproductive impairment in PCOS is not limited to failure of ovulation alone; excess adiposity and compensatory hyperinsulinemia may intensify ovarian androgen production, disturb follicular maturation, impair endometrial receptivity, and reduce the likelihood of conception even when pharmacological ovulation induction is used (3).

Ovulation induction with agents such as letrozole or clomiphene citrate remains a central component of infertility management in women with PCOS; however, ovulatory response does not always translate into clinical pregnancy or live birth (4). This discrepancy suggests that treatment success is influenced by broader metabolic and lifestyle-related factors that affect ovarian function, implantation potential, and pregnancy maintenance. Obesity and insulin resistance are particularly relevant in this context because they are modifiable contributors to anovulation, menstrual irregularity, reduced treatment responsiveness, and adverse reproductive outcomes. Therefore, interventions that improve weight, body composition, physical activity, and insulin sensitivity may enhance the reproductive effectiveness of ovulation induction rather than functioning only as general health advice (5).

Lifestyle modification has consequently become an important component of PCOS management. Dietary optimization, reduced energy intake, low-glycemic dietary patterns, and regular physical activity have been associated with improvements in body weight, waist circumference, insulin sensitivity, androgen excess, and menstrual cyclicity (6). Even modest weight reduction may restore ovulatory function in some women and may improve the endocrine milieu required for successful conception (7). Nevertheless, previous evidence has often emphasized intermediate outcomes such as weight loss, menstrual regularity, hormonal markers, or metabolic indices, while fewer studies have evaluated clinically meaningful fertility endpoints, particularly clinical pregnancy and live birth, among women actively undergoing ovulation induction (8).

The available literature also remains heterogeneous because lifestyle interventions differ substantially in intensity, duration, supervision, adherence monitoring, dietary composition, exercise prescription, and participant characteristics (9). Routine verbal advice may be insufficient to produce sustained behavioral change, whereas structured programs delivered with professional counseling, activity supervision, adherence tracking, and regular follow-up may provide a more effective adjunct to fertility treatment. This distinction is clinically important because infertility treatment in PCOS often involves repeated visits, emotional burden, and financial cost; identifying a low-risk, non-pharmacological strategy that improves both reproductive and metabolic outcomes would support a more integrated and patient-centered approach to care (10).

The present randomized controlled trial was therefore designed according to a PICO framework in which the population comprised overweight or obese women aged 18–35 years with PCOS-related infertility undergoing ovulation induction; the intervention was a structured lifestyle program incorporating individualized dietary counseling and supervised physical activity; the comparison was standard ovulation induction with routine care alone; and the outcomes were ovulation, clinical pregnancy, live birth, anthropometric improvement, menstrual regularity, and insulin resistance. The study tested the hypothesis that adding a structured lifestyle intervention to standard ovulation induction would improve fertility outcomes and metabolic parameters more effectively than standard care alone in women with PCOS-related infertility.

MATERIALS AND METHODS

A parallel-group randomized controlled trial was conducted in tertiary infertility clinics in Central Punjab, Pakistan, between August 2025 and February 2026 to evaluate the effect of a structured lifestyle intervention on reproductive and metabolic outcomes among women with polycystic ovary syndrome undergoing ovulation induction. The study was designed to compare structured dietary and physical activity support plus standard ovulation induction with standard ovulation induction and routine care alone. The total study duration was seven months, including recruitment, baseline assessment, randomization, delivery of the intervention, and outcome follow-up, while the active lifestyle intervention was implemented over 16 weeks.

Eligible participants were women aged 18–35 years with infertility of at least 12 months' duration, diagnosed with PCOS according to the Rotterdam criteria, scheduled for ovulation induction, and having

a body mass index between 25 and 40 kg/m². Participants were required to have at least one patent fallopian tube documented during prior infertility evaluation. Women were excluded if they had diabetes mellitus requiring pharmacological treatment, thyroid dysfunction, hyperprolactinemia, severe endometriosis, confirmed male-factor infertility, previous bariatric surgery, current pregnancy, current use of weight-loss medication, or any medical condition limiting safe participation in moderate-intensity physical activity. These eligibility criteria were applied to reduce confounding from endocrine, anatomical, male-factor, and medical conditions that could independently affect ovulation, conception, or adherence to physical activity.

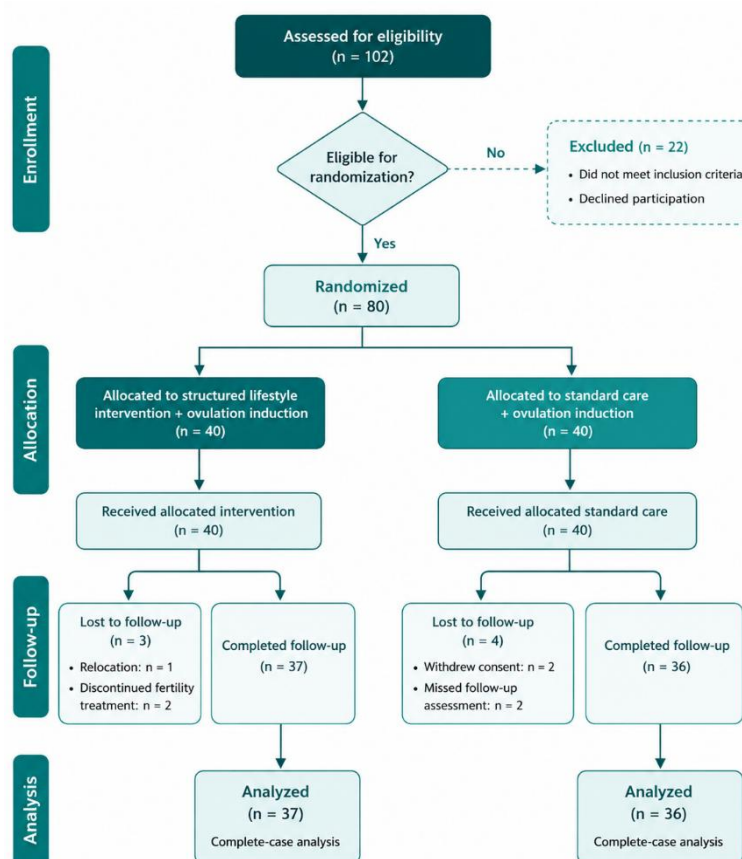


Figure 1 CONSORT Flowchart

Women attending participating infertility clinics were screened for eligibility during routine fertility assessment. Those fulfilling the selection criteria were informed about the study objectives, intervention requirements, follow-up schedule, potential benefits, and expected time commitment. Written informed consent was obtained before enrollment. Baseline assessment included demographic information, infertility duration, type of infertility, anthropometric measurements, menstrual history, PCOS-related clinical profile, and metabolic assessment. Body mass index was calculated from measured weight and height, waist circumference was measured using a standardized technique, and insulin resistance was assessed using the Homeostatic Model Assessment for Insulin Resistance. Baseline reproductive and metabolic measurements were recorded before randomization to ensure comparability between groups.

The sample size was based on detecting a clinically meaningful difference in ovulation and clinical pregnancy outcomes between the intervention and control groups, using 80% power and a two-sided alpha level of 0.05. A minimum of 72 participants was required, and the target sample was increased to 80 to compensate for anticipated attrition during intervention and follow-up. After baseline assessment, participants were randomly assigned in a 1:1 ratio to the structured lifestyle intervention group or the control group. Randomization was performed using a computer-generated block randomization sequence prepared by an independent researcher who was not involved in recruitment, intervention

delivery, or outcome assessment. Allocation concealment was maintained using sequentially numbered, sealed, opaque envelopes opened only after completion of baseline assessment. Participant blinding was not feasible because of the behavioral nature of the intervention; however, clinicians responsible for reproductive outcome assessment and the statistician conducting data analysis were blinded to group allocation.

Participants in both groups received standard ovulation induction with letrozole according to institutional fertility protocols. The structured lifestyle intervention group additionally received individualized dietary counseling and supervised physical activity for 16 weeks. Dietary counseling was delivered every two weeks by a registered nutritionist and focused on a calorie-controlled, low-glycemic-index dietary pattern intended to achieve gradual weight reduction of 5–10% where clinically feasible. Counseling emphasized portion control, reduced intake of refined carbohydrates and sugar-sweetened beverages, increased consumption of vegetables, lean protein sources, whole grains, and unsaturated fats, and alignment of dietary recommendations with local food availability and cultural eating patterns. Participants maintained dietary logs that were reviewed during follow-up visits to reinforce adherence and identify barriers.

The physical activity component included at least 150 minutes per week of moderate-intensity aerobic exercise combined with two supervised resistance-training sessions per week. Aerobic activity consisted of brisk walking or equivalent moderate-intensity activity, while resistance sessions included major muscle group exercises adapted to participant capacity and safety. Exercise adherence was monitored through attendance records, participant activity logs, and scheduled telephone reminders. Participants in the control group received standard fertility care and general verbal advice regarding healthy eating and physical activity but did not receive structured dietary counseling, supervised exercise sessions, activity monitoring, or scheduled behavioral coaching.

The primary outcomes were ovulation rate and clinical pregnancy rate. Ovulation was assessed using mid-luteal serum progesterone measurement and transvaginal ultrasonography according to institutional fertility monitoring protocols. Clinical pregnancy was defined as ultrasonographic visualization of a gestational sac. Secondary outcomes included live birth rate, change in body mass index, change in waist circumference, change in HOMA-IR, and menstrual regularity after the intervention period. Anthropometric and metabolic measurements were recorded at baseline and at completion of the 16-week intervention, while pregnancy and live birth outcomes were tracked during the study follow-up period. Menstrual regularity was assessed from participant-reported cycle pattern during follow-up and categorized according to return of regular cycles.

Bias was addressed through random allocation, allocation concealment, blinded outcome assessment, blinded statistical analysis, standardized measurement procedures, and predefined eligibility criteria. Potential confounding was minimized by excluding participants with major endocrine, anatomical, male-factor, or medical causes of infertility other than PCOS-related ovulatory dysfunction. Adherence-related bias was addressed through structured attendance monitoring, dietary diaries, activity logs, and telephone reminders in the intervention group. Data integrity was supported by standardized data collection forms, double-checking of entered values against source records, and consistent timing of baseline and post-intervention measurements.

Data were analyzed using a complete-case approach for participants with available post-intervention outcome data, with randomized denominators and attrition reported transparently. Continuous variables were summarized as mean \pm standard deviation, while categorical variables were summarized as frequencies and percentages. Normality of continuous variables was assessed using the Shapiro–Wilk test. Between-group comparisons for continuous variables were performed using independent-samples t-tests, and within-group pre–post changes were evaluated using paired-samples t-tests. Categorical outcomes, including ovulation, clinical pregnancy, live birth, and menstrual regularity, were compared between groups using chi-square or Fisher's exact tests as appropriate. Repeated-measures analysis of

variance was applied to evaluate time, group, and time-by-group interaction effects for body mass index, waist circumference, and HOMA-IR. Associations between changes in metabolic parameters and reproductive outcomes were examined using correlation analysis, with interpretation guided by the scale and distribution of variables. Statistical significance was set at $p < 0.05$.

RESULTS

A total of 102 women with PCOS-related infertility were assessed for eligibility between August 2025 and October 2025. Of these, 22 were excluded because they either did not meet the eligibility criteria or declined participation. Eighty participants were randomized equally into the structured lifestyle intervention group ($n=40$) and control group ($n=40$). During follow-up, three participants in the intervention group and four participants in the control group were lost to follow-up, resulting in complete outcome data for 73 participants: 37 in the intervention group and 36 in the control group.

Table 1. Baseline Demographic and Clinical Characteristics of Randomized Participants

Variable	Total Sample (N=80)	Intervention (n=40)	Control (n=40)	Risk Difference	95% CI	p-value
Age (years), mean \pm SD	28.6 \pm 4.2	28.4 \pm 4.0	28.8 \pm 4.3	-0.4	-2.25 to 1.45	0.681
BMI (kg/m ²), mean \pm SD	31.5 \pm 3.8	31.7 \pm 3.9	31.3 \pm 3.7	0.4	-1.29 to 2.09	0.642
Duration of infertility (years), mean \pm SD	3.4 \pm 1.5	3.5 \pm 1.4	3.3 \pm 1.6	0.2	-0.47 to 0.87	0.573
Waist circumference (cm), mean \pm SD	98.2 \pm 8.5	98.7 \pm 8.1	97.8 \pm 8.9	0.9	-2.89 to 4.69	0.648
HOMA-IR, mean \pm SD	3.8 \pm 1.1	3.9 \pm 1.0	3.7 \pm 1.2	0.2	-0.29 to 0.69	0.417
Primary infertility, n (%)	58 (72.5)	30 (75.0)	28 (70.0)	5.0%	-14.6 to 24.6	0.617

Baseline demographic, anthropometric, metabolic, and infertility-related characteristics were comparable between groups. Mean age was 28.4 ± 4.0 years in the intervention group and 28.8 ± 4.3 years in the control group, with no statistically significant difference between groups (mean difference -0.4 years, 95% CI -2.25 to 1.45; $p=0.681$). Baseline BMI was also similar between groups (31.7 ± 3.9 vs 31.3 ± 3.7 kg/m²; $p=0.642$), as were waist circumference, HOMA-IR, duration of infertility, and frequency of primary infertility. These findings indicated adequate baseline comparability before the intervention.

Table 2. Primary Reproductive Outcomes After Intervention

Outcome	Intervention (n=37)	Control (n=36)	Absolute Risk Difference	Relative Risk Odds Ratio	95% CI for Risk Difference	p-value	
Ovulation, n (%)	31 (83.8)	21 (58.3)	25.5%	1.44	3.69	5.4 to 45.5	0.016
Clinical pregnancy, n (%)	18 (48.6)	9 (25.0)	23.6%	1.95	2.84	2.2 to 45.1	0.036
Live birth, n (%)	15 (40.5)	7 (19.4)	21.1%	2.08	2.82	0.7 to 41.5	0.047

Participants receiving the structured lifestyle intervention demonstrated significantly better reproductive outcomes than those receiving standard care alone. Ovulation occurred in 31 of 37 participants in the intervention group compared with 21 of 36 participants in the control group, corresponding to an absolute improvement of 25.5 percentage points and a 44% higher probability of ovulation in the intervention group (RR=1.44; OR=3.69; $p=0.016$). Clinical pregnancy was achieved by 18 participants in the intervention group and 9 in the control group, producing an absolute risk difference of 23.6 percentage points and nearly double the probability of clinical pregnancy among women receiving the structured intervention (RR=1.95; OR=2.84; $p=0.036$). Live birth was reported in 15 women in the intervention group compared with 7 in the control group, representing an absolute improvement of 21.1 percentage points and a relative probability approximately two times higher in the intervention arm (RR=2.08; OR=2.82; $p=0.047$).

Table 3. Within-Group Pre-Post Changes in Anthropometric and Metabolic Outcomes

Variable	Intervention Baseline	Intervention Post	Mean Change	p-value	Control Baseline	Control Post	Mean Change	p-value
BMI (kg/m ²), mean \pm SD	31.7 \pm 3.9	29.8 \pm 3.5	-1.9	<0.001	31.3 \pm 3.7	30.9 \pm 3.6	-0.4	0.091
Waist circumference (cm), mean \pm SD	98.7 \pm 8.1	92.9 \pm 7.4	-5.8	<0.001	97.8 \pm 8.9	96.5 \pm 8.5	-1.3	0.108
HOMA-IR, mean \pm SD	3.9 \pm 1.0	2.8 \pm 0.8	-1.1	<0.001	3.7 \pm 1.2	3.5 \pm 1.1	-0.2	0.123

Within-group analysis showed marked improvement in anthropometric and metabolic parameters among participants receiving the structured lifestyle program. BMI decreased from 31.7 ± 3.9 to 29.8 ± 3.5 kg/m² in the intervention group, reflecting a mean reduction of 1.9 kg/m² ($p < 0.001$), whereas the

control group showed a smaller and statistically non-significant reduction of 0.4 kg/m² (p=0.091). Waist circumference decreased by 5.8 cm in the intervention group compared with 1.3 cm in the control group, while HOMA-IR decreased by 1.1 units in the intervention group compared with 0.2 units in the control group. These findings indicated that structured dietary counseling and supervised physical activity produced clinically meaningful metabolic improvement beyond routine care.

Table 4. Between-Group Comparison of Secondary Outcomes and Effect Sizes

Outcome	Intervention (n=37)	Control (n=36)	Difference	95% CI	Effect Size	p-value
BMI reduction (kg/m²), mean ± SD	1.9 ± 0.8	0.4 ± 0.6	1.5	1.17 to 1.83	2.12	<0.001
Waist circumference reduction (cm), mean ± SD	5.8 ± 2.9	1.3 ± 2.1	4.5	3.32 to 5.68	1.77	<0.001
HOMA-IR reduction, mean ± SD	1.1 ± 0.6	0.2 ± 0.4	0.9	0.66 to 1.14	1.76	<0.001
Regular menstrual cycles, n (%)	28 (75.7)	16 (44.4)	31.2%	9.9 to 52.6	RR=1.70; OR=3.89	0.006

Between-group comparisons confirmed that improvements in secondary outcomes were significantly greater in the intervention group. Mean BMI reduction exceeded the control group by 1.5 kg/m² (95% CI 1.17 to 1.83; Cohen’s d=2.12; p<0.001), indicating a large treatment effect. Waist circumference reduction was 4.5 cm greater in the intervention group than in the control group (95% CI 3.32 to 5.68; Cohen’s d=1.77; p<0.001), while HOMA-IR reduction was 0.9 units greater (95% CI 0.66 to 1.14; Cohen’s d=1.76; p<0.001). Menstrual regularity was also significantly higher in the intervention group, with 28 of 37 participants reporting regular cycles compared with 16 of 36 controls. This corresponded to an absolute improvement of 31.2 percentage points, a 70% higher probability of regular cycles, and nearly fourfold higher odds of menstrual regularity in the intervention arm (RR=1.70; OR=3.89; p=0.006).

Table 5. Repeated-Measures ANOVA for Anthropometric and Metabolic Outcomes

Outcome	Time Effect F-value	Time Effect p-value	Group Effect F-value	Group Effect p-value	Time × Group Interaction F-value	Interaction p-value
BMI	42.7	<0.001	8.4	0.005	18.6	<0.001
Waist circumference	38.5	<0.001	7.8	0.007	16.9	<0.001
HOMA-IR	31.9	<0.001	6.9	0.011	14.7	<0.001

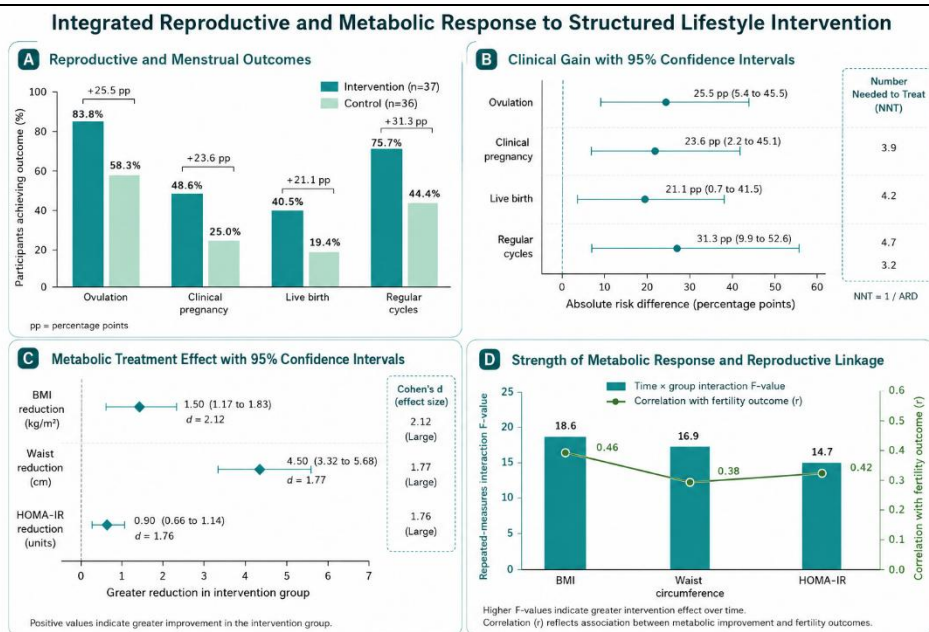


Figure 2 Integrated reproductive and metabolic response to structured lifestyle intervention in women with PCOS undergoing ovulation induction

The structured lifestyle intervention produced consistent clinical gains across reproductive and metabolic endpoints, with absolute improvements of 25.5 percentage points for ovulation, 23.6 percentage points for clinical pregnancy, 21.1 percentage points for live birth, and 31.3 percentage points for menstrual regularity. The derived number needed to treat was approximately 3.9 for ovulation, 4.2 for clinical pregnancy, 4.7 for live birth, and 3.2 for menstrual regularity, indicating clinically

meaningful benefit. Metabolic response was also substantial, with greater reductions in BMI, waist circumference, and HOMA-IR in the intervention group, supported by large standardized effect sizes. Significant time-by-group interactions for BMI, waist circumference, and HOMA-IR further indicate that the observed metabolic improvements were attributable to the structured intervention rather than routine care alone.

Repeated-measures ANOVA demonstrated significant time effects for BMI, waist circumference, and HOMA-IR, confirming that these parameters changed over the study period. Significant group effects were also observed for all three variables, indicating measurable differences between treatment groups. Most importantly, the time \times group interaction was significant for BMI ($F=18.6$, $p<0.001$), waist circumference ($F=16.9$, $p<0.001$), and HOMA-IR ($F=14.7$, $p<0.001$), demonstrating that the magnitude of improvement over time was significantly greater among participants receiving the structured lifestyle intervention. Correlation analysis further supported the relationship between metabolic improvement and reproductive outcomes. Reduction in BMI was positively associated with ovulation achievement ($r=0.46$, $p<0.001$) and clinical pregnancy ($r=0.38$, $p=0.002$). Reduction in HOMA-IR was also associated with ovulation status ($r=0.42$, $p<0.001$). These associations suggested that improvements in body weight and insulin resistance were clinically linked with better reproductive response during ovulation induction.

DISCUSSION

The present randomized controlled trial demonstrated that adding a structured lifestyle intervention to standard ovulation induction was associated with significantly better reproductive and metabolic outcomes among overweight and obese women with PCOS-related infertility. Compared with standard care alone, the intervention group achieved higher ovulation, clinical pregnancy, and live birth rates, with absolute improvements of 25.5, 23.6, and 21.1 percentage points, respectively. These findings are clinically important because live birth, rather than ovulation alone, represents the most meaningful endpoint in fertility treatment. The approximate number needed to treat was 3.9 for ovulation, 4.2 for clinical pregnancy, and 4.7 for live birth, suggesting that structured lifestyle support may provide a practical and clinically relevant adjunct to pharmacological ovulation induction in this population (11).

The improvement in ovulation observed in the intervention group is biologically plausible because obesity, central adiposity, and insulin resistance are closely linked with hyperinsulinemia, increased ovarian androgen production, impaired follicular maturation, and anovulation in PCOS. In the present study, participants receiving structured dietary counseling and supervised physical activity showed greater reductions in BMI, waist circumference, and HOMA-IR than controls, indicating that the intervention improved key metabolic drivers of reproductive dysfunction. The significant association between BMI reduction and ovulation, as well as between HOMA-IR reduction and ovulation, supports the interpretation that metabolic improvement contributed to enhanced ovarian responsiveness during ovulation induction (12).

The higher clinical pregnancy and live birth rates in the intervention group suggest that lifestyle modification may improve fertility outcomes through mechanisms extending beyond restoration of ovulation. Improved insulin sensitivity, reduction in central adiposity, lower inflammatory burden, improved endocrine balance, and better endometrial receptivity may collectively enhance conception and pregnancy maintenance. Although the present trial was not designed to isolate these mechanisms individually, the concurrent improvement in metabolic and reproductive endpoints strengthens the clinical argument for integrating structured lifestyle programs into fertility care for women with PCOS who are overweight or obese (13).

These findings are consistent with previous reports indicating that lifestyle modification can improve reproductive function, menstrual cyclicity, and metabolic health in women with PCOS. However, many earlier studies focused primarily on surrogate outcomes such as weight loss, menstrual regularity, or

biochemical parameters rather than clinically meaningful fertility endpoints. The present study adds value by reporting ovulation, clinical pregnancy, and live birth outcomes alongside anthropometric and insulin-resistance measures. This combined reporting is important because it demonstrates that lifestyle intervention may not only improve intermediate metabolic indicators but may also translate into outcomes that are directly relevant to patients seeking fertility treatment (14).

The magnitude of metabolic improvement observed in the intervention group was substantial. BMI reduction was 1.5 kg/m² greater than in the control group, waist circumference reduction was 4.5 cm greater, and HOMA-IR reduction was 0.9 units greater. These changes were supported by large standardized effect sizes and significant time-by-group interactions, suggesting that the observed improvements were attributable to the structured intervention rather than routine care or natural variation over time. The improvement in menstrual regularity was also clinically meaningful, with regular cycles reported by 75.7% of women in the intervention group compared with 44.4% in the control group (15).

A key implication of this study is that general lifestyle advice may be insufficient for women with PCOS undergoing fertility treatment. The intervention in this trial included individualized dietary counseling, supervised physical activity, adherence logs, and scheduled follow-up, which likely contributed to sustained behavioral engagement. This distinction may explain why structured interventions often produce stronger outcomes than routine counseling alone. In fertility practice, integrating nutritionists, physiotherapists, exercise professionals, and reproductive clinicians may therefore improve both treatment effectiveness and long-term metabolic health among women with PCOS (16).

The study has several strengths. The randomized controlled design reduced selection bias, while allocation concealment and blinded outcome assessment strengthened internal validity. The inclusion of live birth as an outcome improved the clinical relevance of the findings. The intervention addressed both diet and physical activity, reflecting a practical multidisciplinary model that can be adapted to routine infertility care. The study also evaluated both reproductive and metabolic outcomes, allowing a more integrated interpretation of treatment response (17).

Certain limitations should be acknowledged. First, the trial was conducted in tertiary infertility clinics within Central Punjab, which may limit generalizability to women from different geographic, ethnic, socioeconomic, or healthcare settings. Second, participant blinding was not feasible because of the behavioral nature of the intervention, creating potential performance-related influences. Third, although outcome assessors and statisticians were blinded, adherence to dietary and activity components partly relied on self-reported logs, which may be affected by reporting bias. Fourth, the final analysis was based on participants with complete follow-up data rather than a fully imputed intention-to-treat dataset, and this should be considered when interpreting the precision of the estimates. Fifth, the intervention period was limited to 16 weeks, so the long-term sustainability of lifestyle changes and reproductive benefits beyond the study period could not be assessed (18).

Future multicenter trials with larger sample sizes, longer follow-up, and prespecified intention-to-treat sensitivity analyses are needed to confirm these findings. Additional research should evaluate whether the effectiveness of structured lifestyle intervention differs by BMI category, insulin-resistance severity, PCOS phenotype, baseline androgen status, or type of ovulation induction agent. Future studies should also examine adherence strategies, cost-effectiveness, patient acceptability, and maintenance of lifestyle change after completion of supervised support. These areas are important for translating structured lifestyle intervention from research settings into routine fertility services (19).

Overall, the findings indicate that a structured lifestyle intervention incorporating individualized dietary counseling and supervised physical activity improved ovulation, clinical pregnancy, live birth, menstrual regularity, BMI, waist circumference, and insulin resistance among women with PCOS undergoing ovulation induction. The clinical value of the intervention lies in its dual reproductive and metabolic

benefit, supporting its integration as a core component of fertility management rather than as optional general advice (20).

CONCLUSION

The addition of a structured lifestyle intervention to standard ovulation induction improved reproductive and metabolic outcomes among overweight and obese women with PCOS-related infertility. Women receiving individualized dietary counseling and supervised physical activity achieved higher ovulation, clinical pregnancy, and live birth rates than those receiving standard care alone, alongside greater reductions in BMI, waist circumference, and HOMA-IR. These findings support the integration of structured, monitored lifestyle programs into fertility management for women with PCOS, particularly where metabolic dysfunction may reduce treatment responsiveness. Larger multicenter trials with longer follow-up and full intention-to-treat sensitivity analyses are warranted to confirm durability, generalizability, and implementation feasibility.

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