Study protocol:

Title of study	Effects of Supervised Structured Aerobic Exercise training program on serum BDNF, androgens level, menstrual irregularity, aerobic fitness and quality of life in females with Insulin resistant polycystic ovarian syndrome.
Objective (s) of the study	1. To determine the effects of Supervised Structured Aerobic Exercise Training Program on **quality of life** in women with PCOS. 2. To determine the effect of Supervised Structured Aerobic Exercise Training Program on **BDNF levels** in women with PCOS. 3. To determine the effect of Supervised Structured Aerobic Exercise Training Program on **mental health** (stress, depression, anxiety) in women with PCOS. 4. To determine the effect of Supervised Structured Aerobic Exercise Training Program on **BMI** in women with PCOS. 5. To determine the effect of Supervised Structured Aerobic Exercise Training Program on **menstrual irregularity** in women with PCOS. 6. To determine the effect of Supervised Structured Aerobic Exercise Training Program on **Aerobic fitness** in women with PCOS. 7. To determine the effect of Supervised Structured Aerobic Exercise Training Program on **androgens level** in PCOS. 8. To determine the effect of Supervised Structured Aerobic Exercise Training Program on **Lipid accumulation product** in PCOS. 9. To determine the effect of Supervised Structured Aerobic Exercise Training Program on **Glycemic control** in PCOS.

Methodology
 	
(Design, sample size, sampling technique, Study setting, inclusion and exclusion criteria and Tool)
	Design: RCT Randomized Controlled Trial
	Non-probability Convenient Sampling Technique
	Duration of treatment: 25 weeks
	2 groups; (group A=30) SSAET +Normal routine medication+ Normal Dietary Plan , Other group (Group B=30) with normal routine medication + Normal Dietary Plan.
	Patients will be enrolled in the experimental group according to speeds test.
	
	TOOLS:
	1. **Modified polycystic ovarian syndrome Quality of Life Questionnaire (PCOSQOL)-** Quality of life
	2. **MIQ (Menstrual Irregularity Questionnaire)-** Menstrual irregularity
	3. **Women's weight in kilograms divided by the square of height in meters-** BMI
	
	4. **Aerobic fitness-**
	    YMCA 3-minute Bench Step Test, 3-Minute Step Test:
	    You step up and down on a 30 cm (12-inch) step for three minutes at a consistent pace, and your heart rate is measured afterward to estimate fitness for 1 minute through carotid artery. The more fit you are, the

lower your recovery heart rate will be, meaning a lower number is a better score.

Compare to Charts:

Use your age and gender to find the appropriate fitness rating chart, such as the YMCA charts.

Determine Your Level:

The chart will show whether your 1-minute heart rate falls into categories like excellent, good, above average, average, or below average fitness.

YMCA FEMALES Scoring:

Excellent <109

Above Average 110 - 117

Average 118 - 134

Below Average 135-137

Poor >137

5. **BDNF levels-** ELISA

6. **Androgens level-** Serum SHBG will be measured by coated-tube immunoradiometric assay using commercial kits. Testosterone will be measured by RIA using commercial enzymatic kits. Free androgen index (FAI) will be calculated as testosterone/SHBG × 100.

    Clinical hyperandrogenism (a score of 6 or higher on the modified Ferriman–Gallwey scale)

7. **Mental health-** (Stress, depression & Anxiety) by DASS-21

    Severity Interpretation: Depression: The severity of depression is categorized as Normal (0-9), Mild (10-13), Moderate (14-20), Severe (21-27), and Extremely Severe (28+). Anxiety: The severity of anxiety is categorized as Normal (0-7), Mild (8-9), Moderate (10-14), Severe (15-19), and Extremely Severe (20+). Stress: The severity of stress is categorized as Normal (0-14), Mild (15-18), Moderate (19-25), Severe (26-33), and Extremely Severe (34+).

8. **Lipid Accumulation Product** -Triglycerides test and waist circumference

    The LAP would be calculated as [waist circumference (centimeters) − 58] × [triglycerides (millimoles per liter)]

9. **Glycemic control- HOMA IR**

    The HOMA-IR score is calculated using your fasting glucose and fasting insulin levels:

    HOMA-IR = (Fasting Glucose x Fasting Insulin) / 22.5

Rotterdum Criteria for a diagnosis of PCOS

A diagnosis of PCOS can be made when at least two of the following three criteria are met:

1. Irregular periods or no periods

2. Higher levels of androgens are present in the blood (hyperandrogenism), shown by:
- **a blood test, OR**
- **symptoms such as:**
o   **excess facial or body hair growth**
o   **scalp hair loss**
o   **acne.**

3. Polycystic ovaries are visible on an ultrasound, meaning:
- **more than 20 follicles (partly developed eggs) are visible on one or both ovaries or**
- **the size of one or both ovaries is increased (more than 10ml).**

You do not need to have an ultrasound if you have criteria 1 and 2.

☐   **In women younger than 20 years, ultrasounds are not recommended. This means that irregular periods and hyperandrogenism need to be present for a diagnosis of PCOS to be made.**

Study Setting: Gyms of Lahore

Inclusion Criteria :
- Age 18 To 35 years Females.
- Insuline resistant PCOS type.
- Already Diagnosed patients form gyne department according to the Rotterdam criteria.
- Both Married and unmarried females.
- Nulliparous females.

Exclusion Criteria :
- Post pill PCOS, Inflammatory PCOS & Adrenal PCOS
- Any psychological disease or disorder
- Any systemic disease other than PCOS (cushing syndrome, thyroid dysfunction, etc)
- Orthopedic conditions (including fracture, dislocation, etc)
- Any surgery in past 6 months.
- Involved in any other exercise regimen at the same time.
- Having any specialized diet plan.
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Data analysis:

The data will be analysed using SPSS for Windows software, version 25. Statistical Significance will be set at $P = 0.05$. Normality of data will be assessed through Shapiro-Wilks test. Following tests will be used:

Descriptive Statistics: Frequency tables, pie charts, bar charts will be used to Show summary of group measurements measured over time.

Difference within groups:

If the normality of data shows parametric result. Difference within group will be calculated using Repeated Measure ANOVA. For non-parametric data, Friedman test will be used.

Difference between Groups:

Independent sample t test will be used for parametric data. If
results are non-parametric then, then Mann Whitney U test will be used