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Research Protocol

Obstetrics and Gynaecology Section

Effect of Callisthenic Exercises vs Yoga on Health Related Quality of Life, Lipid Profile, Anthropometric Measurements and ultrasonography Findings in Polycystic Ovarian Syndrome: A Research Protocol

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ABSTRACT

Introduction: Polycystic Ovarian Syndrome (PCOS) is an endocrine disorder, and individuals with this condition are at a risk of developing complications like metabolic syndromes throughout their lifetime. Not much is known about studies reporting the combined effects of calisthenic exercise with either aerobic exercise or progressive resistive exercises that have shown positive outcomes in PCOS.

Need for the study: Extensive literature search has revealed gaps in reporting the individualised effects of calisthenic exercise in PCOS and its comparative effects with yoga. The present research article presents a study protocol comparing calisthenic exercises and yoga protocols prescribed for women with PCOS.

Aim of the study: To evaluate and compare the effects of calisthenic exercises and yoga in women with PCOS.

Materials and Methods: This research protocol is planned to conduct a randomised clinical trial in Belagavi, Karnataka, India, and will employ a randomised, open-label, parallel-armed, double-blinded clinical experimental design. The duration of the study will be near bout four years, from June 2022 to August 2026. A total of 102 females with PCOS, aged between 18 and 35, will be randomly allocated to either a yoga group (N=51) or a calisthenic exercise group (N=51). For a period of 1½ months (i.e., six weeks), group therapy sessions will be held five times a week. Ultrasonography scans, which will assess ovarian cyst count and size, ovarian volume, and total lipid profile, will be conducted twice (pre- and post-intervention). The PCOS Questionnaire (PCOSQ-26) will be utilised to assess health-related quality of life, as well as anthropometric measurements such as waist-hip ratio and Body Mass Index (BMI). These measurements will be assessed prior to the intervention, six weeks following the intervention, and at the 12-week follow-up. Inferential as well as statistical methods will be used to analyse the gathered data. A test for normal distribution will be conducted, depending on whether parametric tests (Z test and/or ANOVA) or non-parametric tests (Mann-Whitney U test or Wilcoxon signed-rank test) will be performed. A probability value of less than 0.05 will be considered statistically significant.

Keywords: Body mass index, Diet, Exercise, Polycystic ovarian syndrome, Physical activity

INTRODUCTION

In 1935, Irving Stein and Michael Leventhal coined the term PCOS also known as “Stein-Leventhal Syndrome,” to refer to the trio of “Amenorrhea,” “Obesity,” and “Hirsutism” [1]. In 2017, estimates of PCOS prevalence worldwide ranged from 5.5% to 12.6% [2], while estimates for India in 2018 varied from 8.2% to 22.50% [3]. PCOS is an endocrine disorder that primarily affects females between the ages of 17 and 45 who are fertile. It is heterogeneous in nature and is characterised by Hirsutism, irregular menstruation, chronic anovulation, hyperandrogenism, and central obesity. Additionally, it can cause acne and metabolic abnormalities such as insulin resistance, hyperinsulinemia, dyslipidemia, and adiposity [4]. PCOS has a negative impact on mental health, which may manifest as depression [5], social isolation and anxiety related to sexual dysfunction, which is eight times more common compared to women without the condition [6]. All these physical and psychological factors ultimately lead to infertility [4].

Standard care for PCOS includes lifestyle modifications such as diet and physical exercises like aerobics, resistance training, aquatic therapy, Pilates, High-Intensity Interval Training (HIIT), yoga, and acupuncture, which have been proven to be effective in managing PCOS [7].

Calisthenics exercises, performed according to basic principles, involve rhythmic movements to enhance body strength and flexibility, providing health benefits with minimal risk of injury [8]. This form of exercise is gaining popularity in recent years due to its nature where no equipment is required, and exercises are performed using one’s body weight. Studies reporting the combined effects of calisthenic exercise with either aerobic exercise or progressive resistive exercises have shown positive outcomes in PCOS [9,10]. However, the individual effects of a calisthenic exercise program in PCOS remain understudied. Furthermore, these combinations of exercises have been studied in PCOS women with higher BMI but not in those with normal BMI.

Yoga therapy is an emerging complementary and alternative medicine that has been proven effective in women with PCOS [11]. Since the nature of calisthenics and yoga training is different, it was hypothesised that their effects would be distinct. Extensive literature search has revealed gaps in reporting the individualised effects of calisthenic exercise in PCOS and its comparative effects with yoga. Additionally, the residual effects at a 3-month follow-up are not well understood. Hence, the present study is being conducted to determine and compare the effects of calisthenic exercises and yoga in females with PCOS.

Objectives

To determine and compare the effects of calisthenic exercises and yoga on ultrasonography findings in terms of ovarian cyst count and

size, lipid profile, anthropometric measurements, and health-related quality of life in women with PCOS.

Study Hypothesis

Alternate hypothesis (Ha): There will be a significant difference in the effects of calisthenic exercises and yoga on ultrasonography findings in terms of ovarian cyst count and size, ovarian volume, lipid profile, anthropometric measurements, and health-related quality of life in PCOS.

Null hypothesis (H0): There will be no significant difference in the effects of calisthenic exercises and yoga on ultrasonography morphology in terms of ovarian cyst count and size, ovarian volume, lipid profile, anthropometric measurements, and health-related quality of life in PCOS.

Review of Literature

Lifestyle modifications, such as diet and physical activity including aerobic exercises, progressive resistance exercises, aquatic exercises, pilates, HIIT yoga, and acupuncture, have been proven to be effective in managing PCOS [7]. A systematic review and meta-analysis published in 2020 on exercise interventions in PCOS suggests that moderate to vigorous intensity exercise may have the greatest impact on cardiorespiratory fitness, body composition, and insulin resistance, with a minimum of 120 minutes of exercise per week to yield favourable health outcomes [12].

Calisthenics first appeared in ancient Greece. The Greek words “kallos” for beauty and “thenos” for strength are the origin of the word “calisthenics” [13]. Calisthenics exercises are a type of exercise consisting of a variety of simple, often rhythmic movements intended to increase body strength and flexibility [8]. Studies in the literature describe the beneficial effects of calisthenics exercises on body composition, flexibility, aerobic capacity, leg strength, blood pressure, resting pulse, total cholesterol, triglycerides, systolic and diastolic blood pressure, decrease in BMI, and improvement in bone mineral density [8,13,14].

Yoga has been practiced since before the Vedic era. It is a form of mind-body medicine that unites the physical, mental and spiritual aspects and promotes overall wellness [15]. Yoga is advantageous for enhancing the body’s biochemical processes and lowering metabolic risk factors [16]. Yoga facilitates blood flow and oxygen delivery to cells and reproductive tissues, builds muscle strength and flexibility, lowers cortisol and testosterone levels, balances sex hormones, and regularises menstruation [16,17].

MATERIALS AND METHODS

A randomised controlled trial will be conducted in KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi, Obstetrics & Gynaecology Physiotherapy Outpatient Department (OPD). The duration of the study will be 4 years from June 2022 to August 2026. Recruitment of the participants will be conducted over a period of upto 30 months. Participants in this trial will be randomly assigned to one of two groups, with each group consisting of 51 participants, in an open-label, parallel-armed, double-blinded trial. Participants will be invited through advertisements and screening camps.

The research reference number KAHER/EC/22-23/ has been accepted by KLE University’s ethics board for the study involving individuals. The study is registered under CTRI number CTRI/2023/02/049579, registered in January 2023. Informed written consent will be obtained from each participant in the prescribed format prior to the performance of study-related procedures (e.g., physical examination, laboratory screening, or any other investigational procedure). Participants will receive full information about the study, including a description of any foreseeable risks and discomforts. They will also be informed of their right to opt out of the study at any time without providing any reasons.

Inclusion criteria: The participants will be women diagnosed with PCOS according to the 2003 Rotterdam criteria [18], aged between 18 and 35 years, including both nulliparous and multiparous women, who are willing to adhere to the treatment plan recommendations for the duration of the trial.

Exclusion criteria: Based on ACSM guidelines, participants with exercise contraindications will be excluded [19]. Participants with associated co-morbid conditions such as diabetes mellitus, hypertension, endocrine disorders, cardiovascular disorders, cancer, tumours, etc., as well as pregnant women, those with physical disabilities, women on any medical management for PCOS or infertility treatment, and those currently on any form of exercise protocol, will be excluded from the study.

Sample size Estimation: The necessary sample size was determined using the results of a prior study that considered PCOSQ and BMI [10].

Sample Size at 95% Confidence Interval & 95% of Power

$n=(Z_{1-\alpha/2}+Z_{1-\beta})^2 (SD_1^2+SD_2^2)/(\bar{x}_1-\bar{x}_2)^2$

$Z_{1-\alpha/2}=1.96$ $SD_1=4.65$ $\bar{x}_1=21.50$

$Z_{1-\beta}=1.64$ $SD_2=3.54$ $\bar{x}_2=24.46$

$n=51$

Required sample size: Hence, the required sample size was calculated as 50.52 x 2=101.46

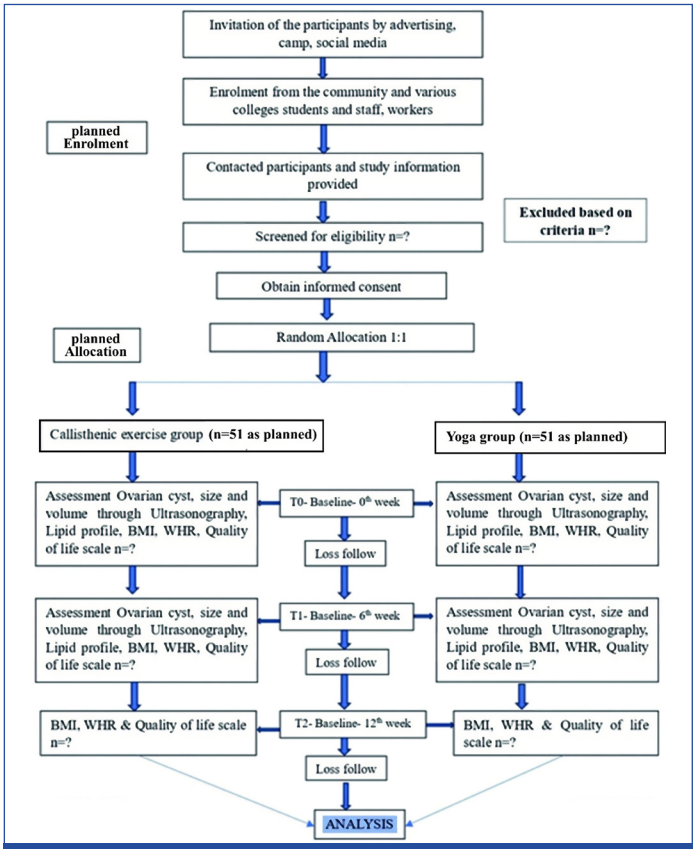
Total sample size is 51+51=102

Recruitment: Attraction strategies will include flyers, advertisements, and screening events held at community centers and universities. Qualified participants will be provided with a comprehensive explanation of the study upon evaluation.

Randomisation: Group treatment will be conducted with participants randomly assigned to either yoga or calisthenics groups, with ten to twelve people in each group, depending on the location where they live. The groups will be assigned through block randomisation in a 1:1 ratio.

Blinding: Double-blinding will be used during the trial. Participants and the investigator will be blinded to the research groups.

The study protocol is reported in accordance with the SPIRIT reporting criteria for protocol studies [20]. Statements from CONSORT-2010: Guidelines for Feasibility Trials and Extension to Pilot Studies have been cited in order to enhance trial reporting [Table/Fig-1].



[Table/Fig-1]: CONSORT flow diagram (SPIRIT guidelines) for Research Protocol.

After being divided into two groups at random, participants will be invited in groups at a designated time and day. They will be instructed about the equipment needed for the workouts, such as mats, shoes, clothes, etc. The warming-up and cooling-down phases of each intervention are scheduled first. The yoga and calisthenic exercise sessions will take place in a spacious recreation area.

Callisthenic Exercise

There will be a licensed physiotherapist leading the sessions. A total of 51 participants will receive supervised group therapy, with each group session consisting of 8-12 people. According to ACSM guidelines for exercise [19], intensity will be prescribed and maintained between 60-70% of the maximum heart rate (HR Max= 220- age). Participants will perform five sessions of calisthenic exercises per week for six weeks. Each session will include a 5-minute warm-up, a 45-minute calisthenic exercise session, and a 10-minute cool-down, totaling 60 minutes per session. The exercise protocol is registered with the Copyrights Office of the Government of India with registration number L-138873/2023.

Yoga Group

Sessions will be led by a licensed yoga instructor. An orientation workshop session will be conducted for study participants before commencing the intervention, where they will be explained in detail about the study protocol. Supervised group therapy will be provided, with each group consisting of 8-12 participants. Over a period of six weeks, a total of five intervention sessions will be conducted each week. The yoga program will consist of a 60-minute session, including warm-up, yoga poses, pranayama, and cool-down.

Diet Program

The diet plan will be prepared by a licensed nutritionist. Study participants will receive a printed diet plan to follow for a period of six weeks. Participants in both groups will be provided with a diet modification chart that includes high-protein and low-carbohydrate foods, with calorie intake restricted to 1200-1500 calories per day.

Relevant concomitant care: Until the trial is over, participants will be instructed to abstain from all drugs, other types of exercise, and weight-loss regimens.

Adherence to interventions: Every two weeks, the daily exercise attendance log book and diet will be examined and maintained throughout the study.

Criteria for Dropouts

- Participants not complying with 70-75% attendance,
- Missing more than 10 sessions
- Participants who are not able to carry out the exercise due to a personal or medical condition.
- Any medical emergency or worsening of pre-existing concurrent medical conditions that the subject encounters during the study period.

Criteria for protocol modifications/discontinuation: The protocol will be amended or modified only in the event of an unfavourable occurrence or a practical obstacle encountered during the trial's conduct. If any changes occur, the Research Ethical Committee will be informed of the modifications and the request for permission.

Data Collecting Procedures

A licensed physiotherapist who is blinded to the group assignment will conduct the outcome assessments. Age, co-morbidities, age at menarche, menstrual cycle information, and other demographics will be recorded [Table/Fig-2].

	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		Close-out
TIMEPOINT**	$-t_1$	0	t_0/(Pre-intervention) Baseline	t_1/(post-intervention) week 6	t_2/ Week 12
Planned enrolment					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
Planned interventions					
[Callisthenic exercise]			X	X	X
[Yoga]			X	X	X
Planned assessments					
[History taking and PCOSQ-26 scale]	X		X	X	X
[Body mass index]	X		X	X	X
[Waist hip ratio]	X		X	X	X
[Ultrasonography]			X	X	
[Lipid Profile]			X	X	

[Table/Fig-2]: Schematic diagram of schedule of enrolment, interventions, and assessments (participant timeline).

Outcomes

1. **Ultrasonography Scan [21]:** A gynaecologist will perform ultrasonography using either a trans-vaginal probe or a trans-abdominal probe scanning method. Measurements of the number and size of ovarian cysts, as well as their volume, will be collected before the intervention (T0) and six weeks after (T1).
2. **Lipid profile:** The lipid profile will be measured at pre-intervention (T0) and in the sixth week post-intervention (T2), including triglycerides, HDL, and LDL levels.
3. **Anthropometric Measurements:**
   a. **Body Mass Index (BMI) [22]:** BMI is calculated by dividing a participant's weight in kilograms (or pounds) by the square of their height in meters (or feet). BMI will be measured pre-intervention (T0), at six weeks post-intervention (T1), and during the 12-week follow-up (T2).
   b. **Waist Hip Ratio [23]:** With participants standing, the circumference of the waist will be measured using a non-stretch fibre tape in centimetres. To ensure accuracy, the measurement will be taken one centimetre above the umbilicus during full expiration. The nearest 1 centimetre will be used for rounding decimals. Measurements of waist circumference will be taken before the intervention (T0), six weeks after the intervention (T1), and again after the 12-week mark (T2).
4. **Polycystic Ovarian Syndrome Questionnaire (PCOSQ-26) [24]:** This is a common, trustworthy, and legitimate tool for assessing the health-related quality of life (HRQOL) of women with PCOS. The questionnaire consists of 26 items categorised into emotions (8 items), body hair (5 items), weight (5 items), problems with infertility (4 items), and problems with menstruation (4 items). It will be evaluated six weeks following the intervention (T1), before the intervention (T0), and during the 12-week follow-up (T2).

Safety monitoring: The expected adverse events will include fatigue, sprains, joint pain, breathlessness, etc. In the event of an unfavourable incident, the participant will be eliminated after consulting the Ethical Review Committee. The individual will be transferred for further investigation and oversight.

Administration of data: To ensure anonymisation, the information will be recorded and entered into an Excel file. The lead investigator will be the only individual with access to these records, which will be securely stored. The statistician will remain blinded by assigning the intervention groups A and B. Without participant coding or de-identification, data cannot be accessed by anyone.

Confidentiality: The confidentiality and privacy of the study participants' personal information will be maintained. Scientific articles and presentations containing a codified version of the group data will be made available. The information will be digitally secured and password-protected. In the unlikely event that participants' photos are published, the authors will take measures to protect their identities and ensure their names are not disclosed.

PLANNED STATISTICAL METHODS

Statistical methods: SPSS software version 29.0 (SPSS, Inc., Chicago, IL, USA) will be used for the statistical analysis. For the collected data, both descriptive and inferential statistical analyses will be applied. Standard deviation and mean will be used to present quantitative variables. A test for normality distribution will be conducted to determine whether non-parametric tests (the Mann-Whitney U test or the Wilcoxon signed-rank test) or parametric tests (the Z test and/or ANOVA) should be performed. The intention-to-treat concept will be used in the primary impact analysis. Statistical significance will be determined by a probability value of less than 0.05.

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