

# A comparative study of homoeopathic treatment versus integrated approach of homoeopathy and yoga in the treatment of menstrual disorders in females with PCOS

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homoeopathy and yoga in the treatment of menstrual disorders in females with PCOS.

<p>Title of the study</p>          <p>MATERIALS AND METHODS – study design, sample size, methodology</p>	<p>A comparative study of homoeopathic treatment versus integrated approach of homoeopathy and yoga in the treatment of menstrual disorders in females with PCOS.</p>          <p>Study design: Interventional Study.</p>          <p>Sample size-Total number of participants is 84. The participants in the study will be categorised into two groups. 42 cases of PCOS will be treated with homoeopathic treatment and 42cases will be enrolled for homoeopathic treatment along with regular yoga therapy. The numbers of these cases are based on the availability and frequency of their visits to our OPD.</p>          <p>Sample size calculation</p> <p>Assuming that the effect size =0.5 at 98% C.I and 90% power, the required sample size is 84 cases, 42 in each group.</p> <p><u>Formula used</u></p> $n = \frac{2(Z_{\alpha}+Z_{\beta})^2 p(1-p)}{(p_1-p_2)}$ <p>Z α=1.96 at 95%C.I</p> <p>Z β=1.281at 90%power</p> $\frac{(p_1-p_2)}{p(1-p)} = \frac{0.5(\text{effect size})}{p(1-p)}$ $= \frac{2(1.96+1.281)^2}{(0.5)^2}$
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$$\frac{21.008}{(0.5)^2}$$

84cases

42+42 in each group

#### Methodology-

All these cases of PCOS will be diagnosed according to Rotterdam criteria(Ref- Focus Reproductive health Polycystic ovary syndrome AnupdateVolume 41, No.10, October 2012 Pages 752-756) and FerrimanGallwey scale for hirsutism (Ref-Ferriman DM, Gallwey JD. Clinical assessment of body hair growth in women. J ClinEndocrinol 1961;21:1440–1447).

The data will be collected in the enclosed case format. 42 subjects of PCOS will be treated with homoeopathic treatment and 42 subjects will be enrolled for homoeopathic treatment along with regular yoga therapy trained by a professional.

The subjects will be recruited to receive treatment randomly, based on sealed envelope method. Each subject will be followed up for 1 year to assess the outcome of the treatment .The follow-up of these cases will be assessed symptomatically and by clinical assessment. At the end of the treatment reduction in hirsutism will be assessed by Ferriman-Gallwey scale for hirsutism and hormonal assay will be done to find out reduction in hyperandrogenism . Each case will be evaluated before and after treatment as per the study protocol.

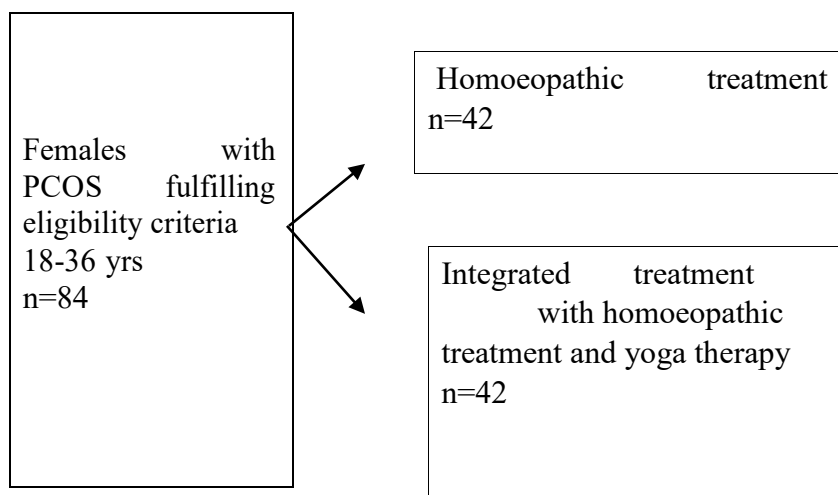


1. Inclusion criteria includes:

- Female aged 18-36 years
- Females diagnosed with PCOS according to Rotterdam criteria.
- Participants willing to adopt a healthy life style and regularly practice yoga (at least 30 minutes for

2. The Exclusion criteria includes:

- Diabetes mellitus, Cushing's disease, hyper-prolactinemia
- Untreated hypo or hyperthyroidism
- Adrenal hyperplasia and adrenal tumour
- Ovarian tumour hyperthecosis
- History of intake of drugs aldactone/metformin or history of oral contraceptive pills (OCP) use or if it interfere with carbohydrate metabolism 4 weeks prior to enrolment
- pregnancy, breast feeding cases with any systemic disease.



Population: Females aged between 18-36yrs, visiting the Homoeopathic OPD at Deralakatte, Kankanady and receiving treatment of menstrual irregularities.



Sampling technique: Simple random sampling.

Feasibility: The study is feasible in terms of availability of patients at our OPD settings

Duration of study: Total of 3 years. All 84 cases are expected to be registered in a span of 1 year 6 months. Registration will be followed by treatment of 1 year, with 6 months for analysis and reporting by the end of 3 years.

#### Types of Intervention

Patients fulfilling the eligibility criteria, among which 42 will be enrolled for homoeopathic treatment, 42 will be enrolled for homoeopathic treatment integrated with daily yogic practice. Medicine shall be given in Q, 6C, 30C, 200C or 1M potency as per the prescribing totality. The medicine will be repeated depending on the potency and complaints of the patient in accordance with the principles of homoeopathy. Yoga therapy includes daily yogic practice which include –

#### 1. Physical postures (Asanas - 1 min each):

- a. Surya Namaskara (Sun Salutation) for 10 min [5 rounds];
- b. Prone asanas:
  - Cobra Pose (Bhujangasana),
  - Locust Pose (Salabhasana),
  - Bow Pose (Dhanurasana)
- d. Standing asanas:
  - Triangle Pose (Trikonasana),
  - Twisted Angle Pose (Parsva -konasana),
  - Spread Leg Intense Stretch (Prasaritapadottanasana);
- e. Supine asanas –
  - Inverted Pose (ViparitaKarni),
  - Shoulder Stand (Sarvangasana),
  - Plough Pose (Halasana);
- f. Sitting asanas
  - Sitting forward Stretch (Paschimottanasana),
  - Fixed angle Pose (Baddha- konasana),

- |  |   |
|--|---|
|  | <ul style="list-style-type: none"><li>• Garland Pose (Malasana)</li></ul> |
|--|---|



	<p>2. Breathing Techniques (Pranayama – 2 min each):</p> <ul style="list-style-type: none"> <li>• Sectional Breathing (Vibhagiya- Pranayama),</li> <li>• Forceful Exhalation (Kapalabhati),</li> <li>• Right Nostril Breathing (Suryanuloma Viloma) 2 min,</li> <li>• Alternate nostril breathing (Nadishuddhi)</li> </ul> <p>3. Guided relaxation (Savasana) for 10 min</p> <p>4. OM Meditation (OM Dhyana) for 10 min</p> <p>5. Group Lecture: Lectures, in the form of cognitive restructuring based on the spiritual philosophy underlying yogic concepts, spiritual coping strategies</p> <p><u>Assessment of treatment outcome</u></p> <p>Assessment of regularity in menstrual cycle will be based on recording the LMP and duration of menstrual cycle on a monthly basis during the patients visit to the OPD.</p> <p>Assessing the reduction in hyperandrogenism- Based on physical examination according to Ferriman Gallwey scale, hormonal assay (LH,FSH,Prolactin,Testosterone )before and after treatment.</p>
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	<p>The collected data will be analyzed by frequency, percentage, mean, standard deviation, t test and chi-square test.</p> <p>Null Hypothesis: No significant difference in cases of PCOS treated with homoeopathic medicines compared to cases treated with integrated approach of homoeopathic treatment and yoga.</p> <p>Alternate Hypothesis: There may be a significant difference in cases of PCOS treated with homoeopathic medicines compared to cases treated with integrated approach of homoeopathic treatment and yoga.</p> <p>Biostatistician</p> <p>Mrs Sucharitha Suresh, MSc(Statistics), Assistant Professor, Department of Community Medicine, Fr Muller Medical College, Kankanady, Mangaluru 575002</p>
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# Informed Consent

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## CONSENT

Study title: A comparative study of homoeopathic treatment versus integrated approach of homoeopathy and yoga in the treatment of menstrual disorders in females with PCOS.

Subject Name: \_\_\_\_\_

Date of Birth/Age: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

(i)	I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions and have received satisfactory answers.	[      ]
(ii)	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected	[      ]
(iii)	I understand that the sponsor of the clinical trial, other working on the Sponsor's behalf, the ethics committee and the regulatory authorities will not need my permission to look at my health records, both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	[      ]
(iv)	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).	[      ]
(v)	I agree to take part in the above study.	[      ]

Please initial (subject) the boxes provided above.

	<p>All the above has been explained to me in the language I know and I understand. I have received a signed copy of the informed consent Form.</p> <p>_____ Date:</p> <p>Signature (or thumb impression) of the subject/legally acceptable representative</p> <p>_____</p> <p>Signatory's name</p> <p>_____ Date:</p> <p>Signature of person administering informed consent discussion</p> <p>_____ Name of person administering informed consent discussion</p> <p>_____</p> <p>Signature of impartial witness</p> <p>_____</p> <p>Name of impartial witness</p> <p>_____ Date:</p>
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