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ROLE OF STRUCTURED YOGA PROTOCOL ON SUBJECTIVE WELLBEING OF FEMALES SUFFERING FROM PREMENSTRUAL SYNDROME – AN OPEN LABELLED SINGLE ARM CLINICAL STUDY

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ABSTRACT:

Background: "Premenstrual Syndrome" (PMS) is a psychosomatic condition of unknown cause; approximately 80-90% of people experience PMS symptoms. It is reducing the life satisfaction and mental peace of women. The primary treatment line in modern science is sedatives, SSRIs, anxiolytics, but they cause so many side effects. Therefore, we planned this research to investigate the potential benefits of yoga in alleviating PMS symptoms. **Methods:** We developed a 30-minute yoga protocol as part of a non-randomized single-group open-label clinical trial, with a sample size of 50. The intervention began after the second menstrual cycle, which followed the diagnosis of the condition based on observations from two menstrual cycles. 47 patients completed the trial, while 3 dropped out. The WHO QOL Scale was used for assessment. **Results:** Statistical data has shown a significant improvement in subjective well-being of females suffering from PMS. **Conclusion:** Yoga protocol is an effective, natural, non-pharmacological treatment for premenstrual syndrome, and it is very helpful in increasing the subjective well-being and mental peace of women.

KEYWORDS: working women, Psychology, mental peace, wellbeing

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1. INTRODUCTION

Premenstrual syndrome is the most common problem in the reproductive life of women. Symptoms start in the luteal phase and resolve after attaining menstruation. Approximately 80 to 90% of the women experience premenstrual symptoms. [1] PMS is a set of both psycho somatic symptoms like anxiety, depression, sadness, mood swings, breast tenderness, fatigue, headache, bloating, etc. 95% of girls had at least one PMS symptom. [2] The PMS affected women shows the signs and symptoms like weakness, irritation, worrying and fighting without any reason. Mood swings worsen the situations by resulting into quarrels. Sometimes women fail to do her ordinary day to day activities. [3]

The pathophysiology of PMS is still not fully understood and is still ambiguous, complex, and multifaceted. Progesterone is expected to influence opioids, catecholamine. It is also thought that this illness is caused by women's increased sensitivity to progesterone in the presence of an underlying serotonin deficit. Increased levels of prolactin or increased sensitivity to its effects, sensitivity to endogenous hormones, abnormal functioning of the HPA axis, nutritional deficiencies, fluid, electrolyte imbalance, all appears to be contributed PMS. [4]

The aim of this research is to discover a natural effective treatment for premenstrual syndrome because the line of treatment is the use sedatives, SSRIs, anxiolytics. [5] But these medications causes so many side effects such as vomiting, spotting, fatigue. [6] [7]

It is important to manage the PMS effectively without causing any side effects. Yoga is form of holistic medicine heals both mind and body, so it is the best method for prevention as well as management of both affective and somatic disorder. [8] Thus Yoga offers natural and effective therapy to reduce PMS symptoms. [9] [10]

Considering the above factors, the clinical research was planned to assess the effect of structured Yoga protocol in improving the subjective wellbeing of females suffering from PMS

Objective

To estimate the role of structured yoga protocol on subjective wellbeing of females suffering from PMS

2. MATERIALS AND METHODS

Hypothesis:

H_0: Structured Yoga protocol is not effective in improving the subjective wellbeing of females suffering from PMS

H_1: Structured Yoga protocol is effective in improving the subjective wellbeing of females suffering from PMS

Research Question:

- Whether structured Yoga protocol is effective in improving the subjective wellbeing of females suffering from PMS?

Ethical clearance was taken from Institutional Ethical Committee (IEC) and the number is **KLE/BMK/MRC/790/21**. CTRI Registration was done and the obtained number is **CTRI/2022/02/039932.** A patient information sheet was prepared to explain the study in detail to the patients before the enrolment. The consent form was prepared to take the consent of the patient. Diagnosed case of PMS within the age

group of 18years to 30 years were taken from OPD and IPD units KAHERs Shri BMK Ayurveda hospital Shahapur Belagavi after checking the criteria irrespective of occupation and socioeconomic status in 6th June 2022 to 20th February 2023

Consent was taken from the subjects, after enrolment subjects were observed for 2 menstrual cycles without any intervention for collection of prospective history as it is mentioned in diagnostic criteria. After 2nd menstrual cycle, 30 minutes structured yoga protocol was taught by the principal investigator during the 10th to 20th day of her menstrual cycle then the Patient was instructed to practice the same structured yoga protocol herself from 21st day to attainment of next menstrual cycle in the home. The same procedure was continued for 3 consecutive cycles. Expected Primary outcome was improvement in subjective wellbeing of females suffering from PMS

Inclusion criteria:

- Age: Patients between 18 to 30 years
- Subjects fulfilling the diagnostic criteria
- No any psychic and somatic disease history
- No any recent incidents like relative death and medical emergency
- Regular menstrual cycle
- Patients who are ready to involve in research

Exclusion Criteria:

- Age – below 18 and above 30 years
- Irregular menstrual cycle
- Recent history of surgery
- Lactating mother
- Known case of Hypothyroidism, Hyperthyroidism, PCOD
- Patients who are not ready to participate in research

Withdrawal Criteria:

Your involvement in the study may be terminated by the principal investigator for any of the following reasons at any time

- During the course of the study if the subject gets conceived (pregnancy)
- Any serious adverse events requiring major interventions.
- Any time during the study continuation of study drug could lead to harmful effect.
- Any untoward event where in investigator feels continuation of trail may jeopardise the health state of the patient

Study type: Interventional

Study design: open clinical trial

Masking: Open label

Control: No

Groups: single group

Sample size: 50

Sample size calculation

$n = \left(\frac{Z.\sigma}{d}\right)^2$

Z = 1.96 (95% confidence was taken)

d = precision

d = (Standard error of mean) X (Z)

Standard error of mean = $\frac{\sigma}{\sqrt{n}} = \frac{1.715}{\sqrt{36}} = 0.28$

n = sample size of previous research.

σ = standard deviation of previous research.

Precision =d = 0.28 X 1.96

d = 0.5

Sample size = $\left(\frac{(1.96)(1.715)}{0.5}\right)^2$

$= (6.7228)^2$

= 45.196

Hence with the above formula the sample size estimated is 45.196 ~ 45 But in the current study the sample size used is 50 considering all dropouts which is more than the estimated value of 95% confidence level.

Table1- Trial details

Group	Intervention	Duration	Follow up
Single group	Yoga protocol	3 Menstrual cycles	For every cycle

Group &Intervention details

Table2 Structured yoga protocol

Loosening exercises (each exercise 2 cycles)		Duration
Eye exercise	Up and down movement of eye Right and left movement of eye Diagonal movement of eye Rotation (Clockwise& Anti-clockwise)	7 minutes
Head and neck	Up and down, Right and left Rotation (clockwise& anti clock-wise) movement of head and neck	
Shoulder exercise	Forward rotation of shoulder Backward rotation of shoulder	
Elbow joint exercise	Flexion of elbow joint Extension of elbow joint	
Wrist joint exercise-	Flexion of wrist joint Extension of wrist joint Rotation of wrist joint	
Waist exercise	Forward bending Backward bending Rotation	
Knee joint exercise	Rotation (clock wise and anti- clock wise)	
Ankle joint exercise	Plantar flexion of ankle joint Dorsiflexion of ankle joint	

Table 2 a: Yoga Protocol

Form of yoga	**Asanas**	**Duration**
Standing	Padahastasana	2 rounds (1min)
	Adhomukhashwanasana	2 rounds (1min)
Sitting	Paschimottasana	2 rounds (1min)
	Baddhakonasana	2 rounds (1min)
Prone	Bhujangasana	2 rounds (1min)
	Dhanurasana	2 rounds (1min)
Supine	Sethubhandasana	2 rounds (1min)
	Shavasana	4 min

Pranayama	Nadishuddi pranayama	10 rounds (3 min)
	Bhramari pranayama	10 rounds (4 min)
Omkara chanting		5 rounds (2 min)
Dhyana		3min

There was no any deviation from study protocol and we executed the same protocol how we planned, throughout the study

Diagnosis

"ACOG Diagnostic Criteria: (American College of Obstetricians and gynaecologists' guidelines for women's health). [11] [12]

Premenstrual syndrome will be diagnosed

- If the patient reports at least one of the affective and somatic symptoms 5 days before menses in 3 previous menstrual cycles
- Symptoms must be relieved within 4 days of the onset of menses, without recurrence until at least 13th day of the cycle.
- The symptoms must occur reproducibly during two cycles of prospective recording.
- The patient must exhibit identifiable dysfunction in social, academic, or work performance.

Affective symptoms - Angry outbursts, Anxiety, Confusion, Depression, Irritability, Social withdrawal

Somatic symptoms- Abdominal bloating, Breast tenderness or swelling, Head ache, Joint or muscle pain, swelling of extremities, weight gain"

- **Study Site:** KAHERs Shri BM Kankanawadi Ayurveda Hospital and Medical Research centre Shahapur Belagavi
- **Study Period:** 18 months

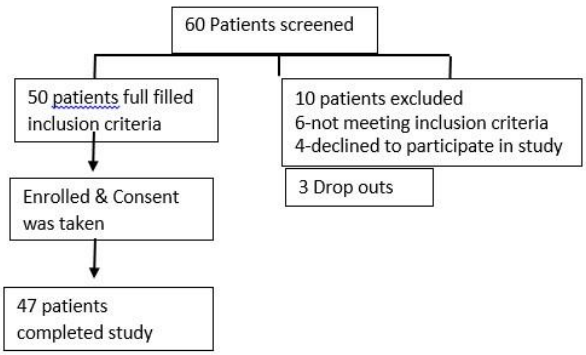

Fig 1. CONSORT Flow chart

Assessment criteria Assessment was done for every cycle with the help of "WHOQOL –BREF" questionnaire. [13]

Primary outcome – Structured yoga protocol is effective in improving subjective wellbeing of females suffering from PMS

Statistical method

- Wilcoxon matched pair test used for statistical analysis.
- As we have single group there were no additional analysis and there was no any issue of missing data.

3. RESULTS

Table 3: Comparison of different treatment time points with Q1 domain of QOL scores

Follow up Days	Mean	SD	Median	IQR	% of change	Z-value	P-value
0th day	2.2	0.7	2.0	0.0			

After 3rd menstrual cycle	2.6	0.9	2.0	0.5	14.29	2.8031	0.0051*
0th day	2.2	0.7	2.0	0.0			
After 4th menstrual cycle	4.0	0.7	4.0	0.0	80.00	5.9154	0.0001*
0th day	2.2	0.7	2.0	0.0			
After 5th menstrual cycle	4.4	0.7	4.0	0.5	96.19	5.9313	0.0001*

*p<0.05 indicates significant

The P value for Q1 of QOLis 0.0051, 0.0001, and 0.0001 after 3rd 4th and 5th menstrual cycle respectively

Thus it can be finalized that there is a considerable enhancement in Q1 of QOL after 3rd 4th and 5th menstrual cycle 96.19% improvement was seen in Q1 of QOL

Table 4: Comparison of different treatment time points with Q2 domain of QOL scores

Follow up Days	Mean	SD	Median	IQR	%of change	Z-value	P-value
0th day	2.3	0.7	2.0	0.0			
After 3rd menstrual cycle	2.6	0.9	2.0	0.8	12.15	2.3664	0.0180*
0th day	2.3	0.7	2.0	0.0			
After 4th menstrual cycle	4.1	0.6	4.0	0.0	78.50	5.9154	0.00001*
0th day	2.3	0.7	2.0	0.0			
After 5th menstrual cycle	4.4	0.7	5.0	0.5	95.33	5.9260	0.0001*

*p<0.05 indicates significant

The P value for Q2 domain of QOL is 0.0180, 0.00001 and 0.0001 after 3rd, 4th, and 5th menstrual cycle respectively. Thus, it can be concluded that there is a considerable enhancement in the Q2 domain of QOL after the 3rd, 4th and 5th menstrual cycle and also 95.33% improvement was seen in Q2 domain of QOL after 5th menstrual cycle.

Table 5: Comparison of different treatment time points with physical health of QOL scores

Follow up Days	Mean	SD	Median	IQR	%of change	Z-value	P-value
0th day	22.7	2.5	22.0	1.5			
After 3rd menstrual cycle	23.7	2.4	24.0	2.0	4.79	3.6147	0.0003*
0th day	22.7	2.5	22.0	1.5			
After 4th menstrual cycle	26.7	1.8	27.0	1.0	18.03	5.7194	0.0001*
0th day	22.7	2.5	22.0	1.5			
After 5th menstrual cycle	28.0	1.7	29.0	1.0	23.38	5.8413	0.0001*

*p<0.05 indicates significant

The P value for physical health of QOLis 0.0003, 0.0001, and 0.0001 after 3rd 4th and 5th menstrual cycle respectively. Thus it can be finalized that there is a considerable enhancement in physical health of QOL after 3rd 4th and 5th menstrual cycle 23.38% improvement was seen in physical health of QOL

Table 6: Comparison of different treatment time points with psychological health of QOL scores

Follow up Days	Mean	SD	Median	IQR	%of change	Z-value	P-value
0th day	17.8	1.9	18.0	1.3			
After 3rd menstrual cycle	18.3	2.1	18.0	1.8	2.75	2.6348	0.0084*
0th day	17.8	1.9	18.0	1.3			
After 4th menstrual cycle	20.6	1.6	21.0	1.5	16.03	5.6834	0.0001*
0th day	17.8	1.9	18.0	1.3			
After 5th menstrual cycle	21.2	1.3	22.0	0.5	19.14	5.7959	0.0001*

*p<0.05 indicates significant

The P value for psychological health of QOLis 0.0084, 0.0001, and 0.0001 after 3rd 4th and 5th menstrual cycle respectively. Thus it can be finalized that there is a considerable enhancement in psychological health of QOLafter 3rd 4th and 5th menstrual cycle, 19.14% improvement was seen in psychological health of QOL

Table 7: Comparison of different treatment time points with social relationship of QOL scores

Follow up Days	Mean	SD	Median	IQR	%of change	Z-value	P-value
0th day	11.1	2.6	12.0	2.8			
After 3rd menstrual cycle	11.3	2.5	12.0	2.3	1.73	2.3664	0.0180*
0th day	11.1	2.6	12.0	2.8			
After 4th menstrual cycle	12.5	2.4	13.0	2.5	12.67	5.3028	0.0001*
0th day	11.1	2.6	12.0	2.8			
After 5th menstrual cycle	12.8	2.5	15.0	2.5	15.55	5.4424	0.0001*

*p<0.05 indicates significant

The P value for social relationship of QOLis 0.0180, 0.0001, and 0.0001 after 3rd 4th and 5th menstrual cycle respectively. Thus it can be finalized that there is a considerable enhancement in social relationship of QOL after 3rd 4th and 5th menstrual cycle, 15.55% improvement was seen in social relationship of QOL

Table 8: Comparison of different treatment time points with environmental health of QOL scores

Follow up Days	Mean	SD	Median	IQR	%of change	Z-value	P-value
0th day	37.8	2.3	39.0	2.0			
After 3rd menstrual cycle	38.1	2.2	39.0	1.5	0.90	2.1004	0.0357*
0th day	37.8	2.3	39.0	2.0			
After 4th menstrual cycle	39.7	1.1	40.0	0.0	5.07	4.6690	0.0001*
0th day	37.8	2.3	39.0	2.0			
After 5th menstrual cycle	39.9	0.6	40.0	0.0	5.52	4.6248	0.0001*

*p<0.05 indicates significant

The P value for environmental health of QOL is 0.0357, 0.0001, and 0.0001 after 3rd 4th and 5th menstrual cycle respectively. Thus it can be finalized that there is a considerable enhancement in environmental health of QOL after 3rd 4th and 5th menstrual cycle, 5.52% improvement was seen in environmental health of QOL

Table 9: Comparison of different treatment time points with to total QOL scores

Follow up Days	Mean	SD	Median	IQR	%of change	Z-value	P-value
0th day	89.3	5.5	89.0	3.3			
After 3rd menstrual cycle	91.4	5.6	92.0	3.8	2.36	3.5466	0.0004*
0th day	89.3	5.5	89.0	3.3			
After 4th menstrual cycle	99.6	4.5	100.0	3.3	11.48	5.9683	0.0001*
0th day	89.3	5.5	89.0	3.3			
After 5th menstrual cycle	101.8	4.1	101.0	3.0	14.01	5.9052	0.0001*

*p<0.05 indicates significant

The p value of total QOL domain is 0.0004, 0.0001, and 0.0001 after 3rd 4th and 5th menstrual cycle respectively. Thus, it can be concluded that there is a considerable enhancement in the total QOL domain. 14.01% improvement was seen in total QOL score.

4. DISCUSSION ON OBSERVATIONS

Age: In the present study, age of the maximum patients was ranging between26 year to 30 year (65.96%), we found the similar results as in earlier studies a significant prevalence in the reproductive age group.

Religion: in the current study maximum subjects were Hindu (95.74%)

Education: in the present study most of the subjects were graduates (65.96%) and post graduates (21.28%)

Occupation: we can observe that majority of the subjects were working women and students this could be due to PMS mainly affects daily routines, the quality and quantity of their work, relationship with friends and coworkers so working women are seriously concerned about PMS.

Marriage: Study showed married and unmarried were almost equal i.e. 24 (51.06%) and 23 (48.94%) respectively. This shows that the prevalence of PMS is not influenced by marital status.

Family history: Among the patients, only 17.04 % patients had a history of PMS in the family. This proves that having a family history does not cause PMS.

H/O of occupational stress: In the present study57.45 % of patients reported being stressed out because of their occupation. This suggests that women who are under stress are more likely to develop PMS.

Family planning method: in this study among 48.94% married, 25.53% were using oral pills. By this we can say there is a relation b/w oral pills and PMS symptom

DISCUSSION ON "WHO QOL –Bref" SCALE

The "WHO QOL Bref" scale contains total 26 questions among them 2 are related to general health & 24 items are related to physical, mental, social and environmental health. 24 items divided into 4 domains physical domain has 7 questions,

social relationship domain contains 3 questions, psychological and environmental domain has 6 & 8 questions respectively. [14] Many studies have proved the reliability and other benefits of this scale in assessing QOL of the individual. So we have selected this scale in our study to assess the QOL.

WHO defines "QOL as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns". [15] While assessing QOL we see the person's physical, mental, social and environmental health. If individual's all these dimensions are good he will be having good quality of life.

Physical domain mainly covers pain, daily energy, and capacity of work. *Asana* help in improving endurance, power, static and dynamic stability muscle strength and flexibility and maintains homeostatic control of the body, by which person's physical performance improves. Intense stretching and muscle training during yoga poses also increase the number of mitochondria, and boost the oxidative capacity of skeletal muscles. These actions might have improved the physical domain scores of QOL.

By *pranayama* and *omkar* chanting oxygen supply increases in the body relaxes the whole-body leads to reduction in the sympathetic activity and increased parasympathetic activity, thereby feels the sense of wellbeing. [16]

We can tell that QOL is in between expectations and experiences, because individual's opinions about their life changes based on their good and bad experiences. If in life everything is fine all their expectations are fulfilling, they will be happy and satisfied with their life but if they experience bad things then their opinion differs. [17] It tells that the nature of accepting the present situation is decreasing in people. In Ayurveda we can compare this to the concept of *satva, pravarasatva*people easily accept the current situation and solve the problems without difficulty and they will be positive about their life in all situations where as *avara sattva* people are opposite to them. *Madyama sattva* people change their opinion based on the others advice. So, in quality of life also we assess the opinion about satisfaction, enjoyment in their life.

Asana, pranayama, omkar, dyana helps to control the mind, and has action on guna's of the person. It increases *sattva guna* in person by reducing laziness, depression, ignorance, excessive sleep by changing the behaviour of the person. Regular practice of yoga and *pranayama* helps to develop self-discipline, self–consciousness, determination, and mastery over the emotions and also promotes traits like friendliness, compassion, and greater self-control, as well as a sense of calm and wellbeing. [18] It also results in significant changes in perspective on life, increased self-awareness, and more energy to live it fully and with genuine enjoyment.

Due to changes in these things progresses the social health i.e behaviour towards relations, friends, co-workers, family members' changes and their opinion about environmental health also changes. The attitude towards life changes spontaneously as sense of control and determination improves so that by yoga we can improve the subjective wellbeing of the individual.

After intervention patient didn't develop any contradictory complaints.

In addition to the above-mentioned explanation and previously indicated findings, this study also found that the women's quality of life had significantly improved. Total score assessment of "WHO QOL" showed 14.01% increased improvement and mean difference was from 89.3 to 101.8. Physical domain showed 23.38% improvement, and mean changes was from 22.7 to 28.0. Psychological domain showed 19.14% and mean difference was 17.8 to 21.2. Environmental health domain and social health domains showed5.52% & 15.55% respectively.

Generalizability: The findings suggest that yoga is a beneficial and adaptable intervention for improving PMS symptoms and enhancing overall wellbeing. Its structured yet flexible nature allows for easy integration into the daily routines of women across various age groups and cultural backgrounds. The positive outcomes observed indicate strong potential for wider application. As a non-invasive and holistic practice, yoga can be confidently recommended as a supportive strategy for managing PMS. Future research across diverse populations will further reinforce its broad applicability.

Limitation of the study: There was difficulty in convincing subjects for daily practice of yoga. Study may have been strong if blinding or RCT study design was used. Study would have been stronger if comparative group had been there.

5. CONCLUSION: The results of this research indicate that continuous practice of yoga for 3 months daily significantly improves the subjective wellbeing of females suffering from premenstrual syndrome (PMS) and also helps in reduction of symptoms like anxiety, anger, irritation, headache, abdominal pain, cramps. And also, subjects had told that regular practice of yoga improved their working capacity and patience in their daily routine. Regular practice of yoga is associated with reductions in physical discomfort, emotional instability, and stress, leading to enhanced overall well-being. These results support the incorporation of yoga as a complementary, non-pharmacological intervention for managing PMS symptoms and improving life quality in affected individuals. Further studies with control group can be added. Randomized control clinical trials can be planned.

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Data collection and literature search: Dr. SR

Writing – original draft: Dr. SR

Reviewing & editing: Dr. SR, Dr. GH

Approval of final manuscript: All authors

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