

ORA- Clinical Research



Efficacy of Yoga and Pranayama in the Management of Premenstrual Syndrome (PMS) in Working Women – An open labeled single arm clinical trial

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ABSTRACT:

Background: Premenstrual Syndrome (PMS) is a physiological problem experienced by 90% of the woman during their menstrual cycle. It affects their routine activities, work productivity, and also causes disturbance in their relationships, due to depression, anxiety, anger issues. To establish a non-pharmacological treatment, we have planned this research. **Methods:** Research is been planned with open label single arm study design, with consecutive sampling technique. Research was conducted in working women aged 18-30 years suffering from premenstrual syndrome, a structured *yoga* protocol was prepared as intervention. Consent was taken; sample size was 47 based on inclusion and exclusion criteria working women were enrolled in the study. 2-month observation followed by intervention for 3 months was insisted. Every month follow up was there, 47 subjects completed the study out of 50. Premenstrual Symptom Screening Tool (PSST) was used as assessment tool. Wilcoxon signed rank test was used to analyse the data. **Result:** Statistical data has shown significant ($P < 0.05$) reduction in PMS symptoms in the working women suffering from PMS. After 5th menstrual cycle from 55% to 79 % improvement was there in different symptoms. **Conclusion** *Yoga* is an effective tool in the management of both physical and psychological symptoms of Premenstrual Syndrome.

KEYWORDS: Menstrual cycle, Premenstrual Syndrome, PSST, Single arm trial, *Yoga*

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1. INTRODUCTION

Premenstrual syndrome is a psycho-somatic disorder of unknown etiology. Often it affects women of all age. Horney first described premenstrual syndrome as "premenstrual tension" in her 1930s study. In 1960s Dalton used the term "premenstrual syndrome" until later 1980s psychiatrists did not find the relationship between hormonal variations during menses and mental health of the women. During luteal phase women feel disruption of work, misunderstandings with colleagues, family members, reduced work quality and quantity. [1]

PMS causes reduced productivity, school and work absenteeism, and lower quality of life. It causes both physical and psychological issues to the women. [2] 32748 participated in a study among them 13.8% were missing work during their menses and 3.4% missed work monthly. Average 23.2 days of lost days were less productive. 20.1% women mentioned periods are the main cause for their illness and absenteeism during the work. [2]

The treatment options in contemporary science are antidepressants, SSRIs (selective serotonin reuptake inhibitors), SNRIs (Selective noradrenaline reuptake inhibitors). These medications have so many side effects on body. The objective of the study was to establish a non-pharmacological natural treatment to manage premenstrual syndrome. PMS symptoms can be treated by activating the parasympathetic nervous system as it is responsible for rest and digest action. This action can calm down the bodily action, by that anger, irritation, anxiety, mood-swings most of the symptoms of PMS can be managed.

Pranayama helps in proper channelization of energy in the body. Yoga means union of mind and body. Yoga helps in increasing the sattva of the person. It helps us in changing the perspective of person towards positivity, as PMS is mood related disorder easily, we can tackle the symptoms through Yoga. Yoga helps in regulation of autonomic nervous system;

it improves mood of the person by balancing hormonal levels in the body. Hormones are having their effect on mood of the person so by maintain normal hormonal levels we can manage the psychological symptoms of conditions. Yoga heals a person as whole mind and body so yoga helps us in reducing PMS symptoms. [3] Aim of research was to see the effect of yoga only in PMS affected working women so open labelled single arm trial is planned. By observing the above factors, a study is planned to see the non-pharmacological effect in management of Premenstrual syndrome

Objectives

To assess the effect of yoga protocol on Premenstrual syndrome through PSST score on 3rd, 4th and 5th menstrual cycle after starting the intervention in PMS patients

Hypothesis

H0- Structured yoga protocol is not effective in reduction of PSST score of 3rd, 4th and 5th menstrual cycle after intervention PMS patients

H1- Structured yoga protocol is effective in reduction of PSST score of 3rd, 4th and 5th menstrual cycle after intervention in PMS patients

2. MATERIALS AND METHODS

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 mainly *Swasthavritta* OPD and also from other OPD & IPD wards like *Ashwatta*, *Udumbara*, *Chandraprabha*, *Indraprastha* of Ayurveda hospital of KAHERs Shri B.M Kankanawadi Ayurveda Hospital and research centre Belagavi after checking the criteria irrespective of occupation and socioeconomic status from 6th June 2022 to 20th January 2024 Consent was taken

from the subjects. Non probability sampling method i.e. consecutive sampling method was used for sampling. Total 60 patients were screened among them 50 subjects selected according to inclusion criteria 10 subjects were excluded.

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 reduction in PSST SCORE.

Sample size calculation

$$n = \left(\frac{Z_{1-\alpha/2} + Z_{1-\beta}}{\Delta/\sigma_d} \right)^2$$

$$Z_{1-\alpha/2} = 1.96 \text{ (95\% confidence was taken)}$$

$$Z_{1-\beta} = 0.84$$

Expected mean - 1.715 taken from previous research

$$\sigma_d = 4.2$$

$$n = (1.96 + 0.84 / 1.715 * 4.2)^2$$

$$n = (2.8 * 4.2 / 1.715)^2$$

$$n = (11.76 / 1.715)^2$$

$$n = (6.85)^2$$

$$n = 46.92$$

Hence with the above formula the sample size estimated is 46.92, 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.

Intervention details

Structured yoga protocol

Yoga protocol is prepared and then it was sent to 5 experts for validation. We have incorporated experts' opinions and rephrased the protocol.

Loosening exercise – 7 min

Standing *asana* – *padahasthasana* & *Adhomukh shwanasana* (2 rounds – 1 min)

Sitting *asana* – *Paschimottasana* & *Badda konasana* (2 rounds – 1 min)

Prone *asana* – *Bhujangasana* & *Dhanurasana* (2 rounds – 1 min)

Supine *asana* – *Sethubandhasana* (2 rounds – 1 min) & *Shavasana* (4min)

Pranayama – *Nadishudhi pranayama* & *Bhramari pranayama* (10 rounds – 4min)

Omkar chanting – (5 rounds- 2min)

Dhyana – 3min

This protocol was demonstrated by Principal investigator who was pursuing MD in *Swasthavritta* and *Yoga* subject, from 10th to 20th day of her menstrual cycle. Protocol is demonstrated sometimes in group and sometimes as individual based on their cycle. afterwards subject was asked to practice same protocol in the home. A diary has been given to document the daily *yoga* practice and asked them to send geo tagged photos daily to track the adherence to intervention and we have collected the photos from subjects to maintain the adherence to intervention. 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) [4], [5]

Premenstrual syndrome was diagnosed by the following criteria

- 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”

Table no. 1: Inclusion & Exclusion criteria

Inclusion criteria	Exclusion Criteria
Age: Patients between 18 to 30 years	Age – below 18 and above 30 years
Subjects fulfilling the diagnostic criteria	Irregular menstrual cycle
No any psychic and somatic disease history	Recent history of surgery
No any recent incidents like relative death and medical emergency	Lactating mother
Regular menstrual cycle	Known case of Hypothyroidism, Hyperthyroidism, PCOS
Patients who are ready to involve in research	Patients who are not ready to participate in

- **Study Site:** KAHERS Shri B.M Kankanawadi Ayurveda Hospital and research centre Belagavi
- **Study Period:** 18 months

It was an open labeled study, as there was no randomization we have taken the help of well-trained during follow up scoring calculation to avoid bias, for subjects also strictly advised to adhere to intervention and we have checked their diary and geo tagged photos. Among 3 drop outs one drop-out is due to pregnancy during the research time line, one more drop-out is due to not interested in following the research rules, and last drop out was due to transfer of job to another place. Data was analysed at 3rd, 4th and 5th menstrual

cycle after intervention. There were no any adverse effects during the trial, we asked the subjects to perform asana with very cautiously.

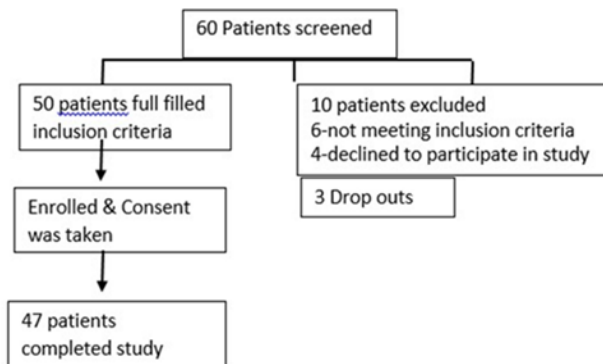


Fig 1 Flow chart

Assessment criteria Assessment was done for every cycle with the help of “Premenstrual Symptom Screening Tool”. [6, 7].

Primary outcome – Structured *yoga* protocol is effective in reduction of PSST score of 3rd 4th and 5th menstrual cycle after intervention in PMS patients

Statistical method

- Wilcoxon matched pair test used for statistical analysis. SPSS software version 20 (Statistical package for social science, IBM, Armonk, New York, USA) was used to analyse the data.

As we have single group there were no additional analysis and there was no any issue of missing data. To reduce the bias structured scoring scale is used and outcome assessor partially blinded. In this study individual participant was the unit of analysis.

3. RESULT

Table 2 : Demographic data

Age wise distribution of the subjects		
Age groups	No of patients	% of patients
21-25yrs	16	34.04
26-30yrs	31	65.96
Education wise distribution of the subjects		

Education	No of patients	% of patients
PUC	6	12.77
Degree	31	65.96
PG	10	21.28
Occupation wise distribution of the subjects		
Occupation	No of patients	% of patients
Student	16	34.04
House wife	13	27.66
Lecturer	6	12.77
Engineer	7	14.89
Others	5	10.64
Marital status wise distribution of the subjects		
Marital status	No of Subjects	% of Subjects
Married	23	48.94
Unmarried	24	51.06
Total	47	100.00
Family history wise distribution of the subjects		
Family history	No of Subjects	% of Subjects
No	39	82.98
Yes	8	17.02
H/O of occupational stress distribution of the subjects		
H/O Occupational	No of Subjects	% of Subjects
No	20	42.55
Yes	27	57.45

Table 3: Statistical Baseline clinical characteristics data

Symptoms	Mean	SD
Anger/Irritability	2.6	0.5
Anxiety/Tension	2.5	0.5
Tearful/increased sensitivity to rejection	2.0	0.7
Depressed mood or hopelessness	2.0	0.5
Decreased interest in work activities	1.7	0.6
Decreased interest in home activities	1.6	0.6
Decreased interest in social activities	1.4	0.7
Difficulty in concentrating	1.7	0.5
Fatigue / lack of energy	2.7	0.5
Over eating/ food carving	0.8	0.7
Insomnia	1.0	0.8

Hypersomnia	0.4	0.6
Feeling overwhelmed/out of control	1.2	0.6
Breast tenderness/ head ache/ joint/ musclepain/ bloating and weight gain	2.9	0.3
school/work efficiency/productivity	1.4	0.7
relationship with friends/ classmates/ coworkers	1.5	0.6
relationship with your family	1.4	0.6
social life activities	0.9	0.7
home responsibilities	0.9	0.7

*At baseline every symptom history noted, subjects mentioned varying degrees of symptoms

Analysis of data after intervention

First 2 menstrual cycles were only observed for the confirmation of the PMS. After 2nd menstrual cycle intervention started and after 3rd menstrual cycle the data was analysed. As shown in [table 4](#) except decreased interest in home activities, decreased interest in social activities, fatigue / lack of energy, insomnia, hypersomnia, and feeling overwhelmed/out of control, school/work efficiency/productivity symptoms all other symptoms showed significant (P< 0.05) reduction. As shown in [table 5](#) significant improvement was there. After 5th menstrual cycle we can witness a good result in [table 6](#).

Table 4: showing the results of intervention after 3rd menstrual cycle

Symptoms	Me an	SD	% of Change	P - value
Anger/Irritability	2.5	0.5	4.03	0.0431*
Anxiety/Tension	2.3	0.6	7.63	0.0077*
Tearful/increased sensitivity to rejection	1.9	0.6	7.29	0.0180*
Depressed mood or hopelessness	1.9	0.5	7.29	0.0180*
Decreased interest in work activities	1.6	0.7	6.33	0.0431*
Decreased interest in home activities	1.5	0.6	5.41	0.0679
Decreased interest in social activities	1.4	0.7	2.99	0.1797

Difficulty in concentrating	1.5	0.5	8.86	0.1797
Fatigue / lack of energy	2.4	0.7	12.40	0.0004*
Over eating/ food carving	0.8	0.7	2.63	
Insomnia	0.9	0.8	4.35	0.1797
Hypersomnia	0.3	0.6	11.76	0.1797
Feeling overwhelmed/out of control	1.2	0.6	3.51	0.1797
breast tenderness/head ache/joint/muscle pain/bloating and	2.6	0.5	10.37	0.0010*

weight gain				
school/work efficiency/productivity	1.3	0.7	4.62	0.1088
relationship with friends/ classmates/ coworkers	1.4	0.6	7.25	0.0431*
relationship with your family	1.3	0.6	10.61	0.0180*
social life activities	0.8	0.7	9.76	0.0679
home responsibilities	0.9	0.6	6.98	0.1088

Table 5: Results of intervention after 4th menstrual cycle

Symptoms	Mean	SD	% of Change	P - value
Anger/Irritability	1.6	0.5	37.90	0.0001*
Anxiety/Tension	1.5	0.5	40.68	0.0001*
Tearful/increased sensitivity to rejection	1.2	0.6	40.63	0.0001*
Depressed mood or hopelessness	1.1	0.4	43.75	0.0001*
Decreased interest in work activities	1.0	0.4	40.51	0.0001*
Decreased interest in home activities	1.0	0.4	36.49	0.0001*
Decreased interest in social activities	0.9	0.4	35.82	0.0001*
Difficulty in concentrating	1.0	0.3	39.24	0.0001*
Fatigue / lack of energy	1.6	0.5	40.31	0.0001*
Over eating/ food carving	0.6	0.5	31.58	0.0022*
Insomnia	0.5	0.5	52.17	0.0001*
Hypersomnia	0.2	0.4	35.29	0.0277*
Feeling overwhelmed/out of control	0.8	0.5	36.84	0.0001*
breast tenderness/head ache/joint/musclepain/bloating and weight gain	1.8	0.4	37.04	0.0001*
school/work efficiency/productivity	0.8	0.6	43.08	0.0001*
relationship with friends/ classmates/ coworkers	0.8	0.5	46.38	0.0001*
relationship with your family	0.7	0.5	46.97	0.0001*
social life activities	0.4	0.5	56.10	0.0001*
home responsibilities	0.4	0.5	53.49	0.0001*

*After 4th menstrual cycle almost all the symptoms showed significant reduction in the symptoms (P<0.05). % of reduction in symptoms also showed maximum improvement.

Table 6: Results of intervention after 5th menstrual cycle

Symptoms	Mean	SD	% of Change	P - value
Anger/Irritability	1.2	0.4	54.03	0.0001*
Anxiety/Tension	1.1	0.4	55.93	0.0001*
Tearful/increased sensitivity to rejection	0.9	0.5	58.33	0.0001*
Depressed mood or hopelessness	0.9	0.3	56.25	0.0001*

Decreased interest in work activities	0.7	0.5	58.23	0.0001*
Decreased interest in home activities	0.6	0.5	62.16	0.0001*
Decreased interest in social activities	0.6	0.5	61.19	0.0001*
Difficulty in concentrating	0.6	0.5	64.56	0.0001*
Fatigue / lack of energy	1.0	0.4	62.79	0.0001*
Over eating/ food carving	0.4	0.5	55.26	0.0001*
Insomnia	0.4	0.5	60.87	0.0001*
Hypersomnia	0.1	0.4	58.82	0.0051*
Feeling overwhelmed/out of control	0.4	0.5	63.16	0.0001*
breast tenderness/head ache/joint/muscle pain/bloating and weight gain	1.3	0.5	55.56	0.0001*
school/work efficiency/productivity	0.4	0.5	72.31	0.0001*
relationship with friends/ classmates/ coworkers	0.4	0.5	75.36	0.0001*
relationship with your family	0.4	0.5	74.24	0.0001*
social life activities	0.2	0.4	78.05	0.0001*
home responsibilities	0.2	0.4	79.07	0.0001*

*After 5th menstrual cycle all the symptoms showed significant reduction in the symptoms (P<0.05). % of reduction in symptoms also showed maximum improvement than 4th menstrual changes.

Table 7: Improvement in different cycles after intervention

Symptoms	% of Change after 3 rd menstrual cycle	% of Change after 4 th menstrual cycle	% of Change after 5 th menstrual cycle
Anger/Irritability	4.03	37.90	54.03
Anxiety/Tension	7.63	40.68	55.93
Tearful/increased sensitivity to rejection	7.29	40.63	58.33
Depressed mood or hopelessness	7.29	43.75	56.25
Decreased interest in work activities	6.33	40.51	58.23
Decreased interest in home activities	5.41	36.49	62.16
Decreased interest in social activities	2.99	35.82	61.19
Difficulty in concentrating	8.86	39.24	64.56
Fatigue / lack of energy	12.40	40.31	62.79
Over eating/ food carving	2.63	31.58	55.26
Insomnia	4.35	52.17	60.87
Hypersomnia	11.76	35.29	58.82
Feeling overwhelmed/out of control	3.51	36.84	63.16
breast tenderness/head ache/joint/muscle pain/bloating and weight gain	10.37	37.04	55.56
school/work efficiency/productivity	4.62	43.08	72.31
relationship with friends/ classmates/ co-workers	7.25	46.38	75.36
relationship with your family	10.61	46.97	74.24

social life activities	9.76	56.10	78.05
home responsibilities	6.98	53.49	79.07

*Data is showing % of Changes in the symptoms as result of intervention after 3rd, 4th 5th menstrual cycles

During studies we have not witnessed any negative findings, as we included simple and easy to perform asanas all patients performed *asana* and *pranayama* properly under our supervision. There was no any pre assumed pathways to intervention, so we don't have any pre assumed results. Along with reduction in symptoms, Patients quality of life was improved due to *yoga* intervention. Throughout the study patients were doing good there were no any adverse effects.

4. DISCUSSION

Premenstrual symptom screening tool, is a simple, authenticated questionnaire to identify and diagnose women, who are suffering from Premenstrual Syndrome or Premenstrual Dysphoric Disorder. It consists of 19 items, that shows how symptoms interfere with relationships and daily activities i.e., with this questionnaire we can assess the severity of mood changes in the PMS patients with respect to their routine household works, community activities, disturbance in their behaviour, sleep, attentiveness, studies, diet habits etc.

The severity of symptoms is assessed with 4 gradings i.e., none, mild, moderate and severe and they are rated as 0, 1, 2 and 3. It is considered as an instrument that includes all premenstrual symptoms that helps to measure the impairment in the luteal phase of the menstrual cycle, so this scale selected as assessment tool. The PSST scale has 0.93 (Cronbach α , for somatic symptoms, 0.94 for psychological symptoms, 0.93 for lack of work efficiency and 0.95 for abdominal symptoms. [8]

PMS symptoms become apparent during the luteal phase of menstrual cycle during which the follicle adapts into corpus luteum and releases progesterone for making the uterus wall thicker and helps in preparing the uterus for implantation of

fertilized egg. In luteal phase pitta *dosha* will be predominant along with *vata dosha* which may lead to the symptoms like anger, irritability, anxiety, tension, excessive hunger, sleep disturbances altered behaviour with friends, co-workers etc.

Research reveals that relaxation training based on *yoga* and *pranayama* has the effect of normalizing the function of the autonomic nervous system. Numerous studies have proved the efficacy of *yoga* and *pranayama* on mood related disorders. [9] As PMS is a psycho-neuro endocrine disorder in which both psychic and somatic symptoms are there. Thus, *Yoga* offers a non-pharmacological natural and effective treatment to alleviate PMS symptoms and serves as alternative to medications. [10], [11]

Yoga acts on autonomic nervous system and decreases the sympathetic activity and increases the parasympathetic activity. [12] Sympathetic activity is associated with the fight-or-flight response, while parasympathetic activity is linked to the rest and digest reaction.

During parasympathetic activity body feels relaxation, reduced heart rate, relaxed muscles, releases appropriate hormones and also amplify theta and delta brain waves. These benefit of may help in both physical psychological relaxation, reduction in aggressiveness, angry, anxiety, stress, sleeplessness. [13]

The *asana* namely *dhanuurasana*, *paschimottasana*, *baddakonasana*, *padahasthasana*, helps in relaxation of back, abdominal muscles. These *asanas* are having effect on reproductive organs. Whereas *Vajrasana* aids in the relaxation of pelvic floor muscles. [14] While doing *asana*, the placement of the limbs and the contraction and relaxation of the muscles stimulate the pressure receptors under the skin. As a result, the vagus nerve becomes more active and the

amount of cortisol decreases, [15] by this both psychological and somatic symptoms might have reduced.

Reduction in symptoms like irritation, anxiety, anger and could be due to the reason i.e practice of asanas secretes melatonin in the body, significant increase in plasma melatonin level is responsible for overall sense of well-being. [16] According to studies, practicing asana releases significant amounts of endorphins, which diminish PMS somatic symptoms by binding to both pre- and post-synaptic nerve terminals in the peripheral nervous system (PNS) by producing analgesic effects

Regular *yoga* practice produces alpha brain waves, which are directly linked to a state of calm, creativity, mood elevation, and relaxation. It is proved that *yogasana* and meditation practice increases the serotonin in the body which is having a direct role in behavioral changes [17] this might be the reason to reduction of symptoms like altered behavior with friends, co-workers and family members.

Studies have shown that practicing *Bhramari pranayama* regularly lowers anxiety, irritability, and stress levels by acting on the neurological system to boost parasympathetic activity and aid in the release of endorphins and serotonin, [18] this action might have improved the psychological symptoms like anxiety, mood swings, irritability, tearfulness. Researches have proved that *yoga* reduces inflammation, helps in inflammatory pathologies also. [19]

One research proved that *Yoga* practice results in spiritual transcendence, personal development, increased social connection, and coping methods to handle relationship losses and challenges these benefits might have reduced the behavioral and communication related symptoms.

Generalizability: This research is planned mainly for working women, calculated sample size was 47 we have enrolled 50 and 3 dropouts were there. In this research follow-up was done properly and intervention was for 3 months. After analysis of data result was significant. The results of this study

can be generalized to adult working women. in this study *yoga* gave a significant result so we can generally tell *yoga* helps in prevention of mood related conditions.

Limitation of the study: Study may have been strong if blinding or RCT study design was used. Study would have been stronger if comparative group or control group had been there and also it would have been better any biochemical investigations included. One more thing is Self-reported scale used for assessment it might have caused some biases. Main barrier during study was convincing subjects for daily practice of *yoga*, some patients were not taking their PMS symptoms seriously.

Scope of study: In future RCT studies can be conducted on the same topic. As a part of ergonomics various studies can be taken with this protocol in workplace for prevention and improvement of health.

5. CONCLUSION

PMS is having both affective and somatic symptoms, *yoga* helps in treating both physical and psychological symptoms. Therefore, in this study we have got good result. Results of this research explain regular practice of *yoga* can reduce both physical and psychological symptoms without any medications. Further other researches can be planned with different study design.

Abbreviations

PMS -Premenstrual Syndrome

SSRIs- Selective Serotonin Reuptake Inhibitors

PSST - Premenstrual Symptom Screening Tool

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