CHAPTER III

METHODOLOGY

The study was designed to determine the effectiveness of Cognitive Behavioral Nursing Strategies on premenstrual syndrome among adolescent girls at selected schools in Thiruvallur district, Tamilnadu, India. This chapter deals with the research design, setting of the study, population, sample, sample size, sampling technique, sample selection criteria, development, description, administration and scoring procedure of the tools, content validity and reliability of the tools, pilot study, data collection procedure and statistical analysis used for the study.

3.1 Research Design

This quantitative research used a pretest posttest control group design with school as the unit of randomization. The study had two arms a study group and a control group. Schools were matched by type (government and private) and randomized to the study or control arm. The schematic representation is as follows:

Table 4: Schematic representation of research design

<table>
<thead>
<tr>
<th>Group</th>
<th>Pretest</th>
<th>Interventions</th>
<th>Posttest</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>I</td>
</tr>
<tr>
<td>Study</td>
<td>O1</td>
<td>*X</td>
<td>O2</td>
</tr>
<tr>
<td>Control</td>
<td>O1</td>
<td>*</td>
<td>O2</td>
</tr>
</tbody>
</table>

R - School were randomly selected
O1 - Pretest assessment
X - Cognitive Behavioral Nursing Strategies - In two phases. Phase I - ITLS and
YRT demonstration by researcher for 3 days and providing booklet on “Easy way to feel good” Phase II- Practice of YRT by adolescent girls under researcher guidance for 40 consecutive school days

* - Routine Measures

O2 - Assessment of knowledge on the 16th day

Assessment of premenstrual distress, anxiety and depression on the 38th day

O3 - Assessment of knowledge on the 38th day

Assessment of premenstrual distress, anxiety and depression on the 68th day

3.1.1. Manipulation

Cognitive Behavioral Nursing Strategies were implemented by the researcher to the adolescent girls of the study group in two phases. During phase I ITLS on menstrual health, hygiene, lifestyle modification for PMS and demonstration of yoga relaxation techniques were implemented. Teaching was imparted by the researcher, through lecture, discussion and demonstration with various visual aids like flash cards, charts, pamphlet, information booklet and black board as a group sessions for 120 minutes, in three teaching session for 40 minutes. A total of 8 groups with 20 adolescent girls in each group were grouped for teaching session. The content outline for the ITLS was as follows (1) review structure and functions of female reproductive organs (2) Physiology of menstruation (3) Myths and misconceptions about menstruation (4) Definition of PMS (5) Causes of PMS (6) Symptoms of PMS (7) Life style measures for managing PMS (8) Self help measures to manage stress, to provide self care during menstruation and to deal with menstrual cramps (9) Demonstration of Yoga Relaxation Technique. At the end of ITLS the “Easy way to feel good” information booklet on menstrual hygiene, PMS, its management and steps
of yoga relaxation technique was given to the adolescent girls for their further reference and practice.

During phase II Yoga relaxation technique was once again demonstrated by the researcher for an hour. From 8th day to 60th day for 40 consecutive school days adolescent girls were instructed to practice every day for 30 minutes under the researcher’s supervision. Adolescent girls were advised to practice regularly even after study period to have long term effect.

3.1.2 Control Group

The control group adolescent girls requested to continue with their normal school activities and researcher completed the assessments at the same time intervals as that of the study group. The control group adolescent girls received same intervention after the completion of the study.

3.1.3 Recruitment

The researcher attended the headmistress’ meet conducted by chief education officer of Thiruvallur District of the urban sub-region in Chennai, to take permission to contact their ninth and eleventh standard students for a research study on adolescent girls’ health. Nine schools agreed to participate. For schools that showed interest, a short discussion between the headmistress and the researcher was held to provide further explanation of the study rationale, procedures and random allocation of schools. This initial contact also allowed the researcher to find out whether their students had been previously exposed to ITLS or yoga instructions. None of these schools had previously been exposed to ITLS or yoga instruction.

3.1.4 Randomization

Schools were matched in to two pairs according to their types i.e. government and private schools and randomized to the study or control arm. Out of
nine schools (five government schools and four private schools) agreed to participate. Four schools were selected randomly from the nine schools, by simple lottery method. Randomization of schools was accomplished by writing the names of the five government schools on separate pieces of paper, the researcher requested one of the headmistresses to pick two pieces of paper. This same procedure was followed for private schools.

After random selection of two government and two private schools for the study, the researcher prepared papers with intervention group or control group written upon them and requested one of the rural school headmistress to pick a piece of paper that determined either assignment to study or control group. The same procedure was followed for private schools. After assigning schools to either study group or control group, all 9th and 11th standard adolescent girls were invited to participate in the study. Out of 1196 students, 1181 students indicated interest in participating in the study. A detailed summary of the proposed study was explained to the adolescent girls after obtaining consent. A complete survey was done among 9th and 11th standard students to identify adolescent girls who fulfilled the inclusion criteria and then preliminary assessment was done to assess premenstrual distress and depression.

After the first preliminary retrospective assessment, adolescent girls were requested to maintain premenstrual daily symptoms diary for prospective record of symptoms. The researcher described the daily symptom diary and taught how to record symptoms in the daily record. Adolescent girls were instructed to record the symptoms for one menstrual cycle in the evening. Once in a week the researcher reminded the adolescent girls about keeping the daily symptom diary. Forty days after the first visit, the same adolescent girls were asked to complete a baseline assessment.
using the completed daily symptom dairy. Thus, the baseline assessment included the data of two consecutive menstrual cycles.

These retrospective and prospective cross sectional data were used to identity adolescent girls with mild, moderate, or strong premenstrual distress and mild or borderline depression. Based on this preliminary assessment the adolescent girls who had (1) severe premenstrual distress as measured by Moos Menstrual Distress Questionnaire or no premenstrual distress for consecutive two menstrual cycle (2) moderate depression, severe depression, very severe depression or no depression as measured by the Beck Depression inventory were excluded from the study. After this preliminary assessment with help of a random number generator 40, 9th and 11th standards adolescent girls were selected from each school.

3.2 Setting of the Study

The study was conducted in selected schools at Thiruvallur district. There are a total of 16 girl’s higher secondary schools in Thiruvallur district, out of which, nine schools gave permission to conduct the study. Out of these nine schools, two government schools, and two private schools were selected randomly for either the study or the control group. Participants were recruited from four schools at the sub urban regions of Thiruvallur district, (Matriculation board school and Public state board school). Thiruvallur District is in Tamil Nadu State in India. It is 14 km distance from its State Main City Chennai.

3.3 Population

The target population for the study included the adolescent girls in the age group of 14 to 18 years and studying ninth or eleventh standard. Adolescent girls in the age group of 14-18 years were included in the study because it was thought that they would benefit from the information related to PMS as they would be entering
adulthood in the near future and they would represent the literate young adolescent population of India.

The accessible population for the study included the adolescent girls who had been having mild, moderate or strong premenstrual distress and mild or borderline depression and studying in ninth or eleventh standard in selected schools at Thiruvallur district. 10th and 12th standard adolescent girls were excluded to avoid the interference of symptoms of depression due to educational stress of appearing for board examination.

3.4 Sample

The sample consisted of adolescent girls with PMS and those who fulfilled the inclusion criteria during the period of study at selected schools in Thiruvallur district.

3.5 Sample Size

Sample size was calculated using the formula

\[ n = \frac{2(Z_a + Z_{1-\beta})^2 \sigma^2}{\Delta^2} \]

Sample size was determined using power analysis and effect size. This study involves comparison of two means. A total of 142 subjects were needed to achieve a significance of 0.05 and a power of 0.8 for a 40% reduction in the total PMS score (Susan Shott, 1990). To get a comfortable sample size, considering the possibility of drop outs, the researcher decided to enroll 10% of excess sample for the study. Hence the sample constituted of 156 subjects per arm. Rounding up to the nearest whole number, the estimated sample size was 320. Three hundred and twenty eligible adolescent girls consented to participate in the research for a period of six months during the two years of data collection period, out of which 160 were randomly
assigned to the intervention group and 160 were assigned to the control group. The details are furnished in Appendix-F.

3.6 Sample Selection Criteria

3.6.1 Inclusion Criteria

Adolescent girls who:

- were in the age group of 14-18 years
- had mild, moderate, or strong premenstrual distress as measured by the Moos Menstrual Distress Questionnaire
- had mild or borderline depression as measured by the Beck Depression Inventory
- had been having regular menstrual cycles around 28-35 days for the past 6 months
- were willing to participate in the study with the parents’ consent

3.6.2 Exclusion Criteria

Adolescent girls who:

- were already practising yoga
- were unable to participate in the study due to health deviations
- were diagnosed to have PMS and on treatment
- had state/other board exams in that year
- were physically challenged
- had severe premenstrual distress, moderate, severe and extreme depression

3.7 Sampling Technique

All the schools available in one district were approached and those who agreed to participate were selected using simple random sampling (Lottery Method). Then adolescent girls with PMS and those who fulfilled the inclusion criteria were selected using a random number generator.
ASSESED FOR ELIGIBILITY – 16 SCHOOLS

- Excluded two schools - already practicing yoga
- Refused to participate – 5 schools

- Randomized nine schools
- Schools were matched in to a pair according to the type that is government (5) and private schools (4)

School Allocation

- Allocated to intervention group
- One government and one private school

- Allocated to control group
- One government and one private school

Assessed for eligibility (survey) 643 adolescent girls

Excluded
- Not attained menarche 50
- No PMD -117
- No depression – 218
- Moderate (75) + severe (12) depression

Individual Enrollment

Randomized 264 adolescent girls with PMS
Adolescent girls were matched in to a pair according to the class (IX & XI) standard

Allocated 160 adolescent girls

- Lost to follow up 2 long leave
- Discontinued intervention
  - Hospitalized for fever 3
  - Sprain 2
  - NSS (Sports) activity (3)

Analysis

- Analyzed 150
- Analyzed 160

Figure 3: Flow chart of participant’s recruitment
3.8 Development and Description of the Tool

Extensive review of literature, discussion and views of experts enhanced the development of the tool; the tool consists of six parts.

3.8.1 Part I: Background Variable Tool

A background variable tool was developed by the researcher to collect data on, demographic variables, personal data and gynecological related study variables (Appendix-D1). It consists of three sections

**Section A:** Demographic variables includes details such as age, educational status of mother, educational status of father, occupation of the mother, occupation of the father, total family income (annual) and type of family.

**Section B:** Personal data of the adolescent girls include; height, weight (BMI), class performance, class attendance and exercise habit.

**Section C:** Gynaecological related study variables include age at menarche, total number of days of bleeding, pain during menstruation, regularity of menstrual cycle, heaviness of periods, PMS awareness and PMS duration.

Scoring and Interpretation

No score was allotted. The data were used for descriptive analysis. The body mass index was calculated using formula: BMI=weight in kg /height in meter square and classified according to WHO.

Administration

The background variable questions were answered by adolescent girls during survey and post test I. The height, weight were measured by the researcher and details on the class performance, class attendance were collected from the class teacher.
3.8.2 Part II: Menstrual Distress Questionnaire (MDQ)

This standardized form was constructed by Rudolf. H. Moos (1969) (Appendix-D2). The MDQ was used to analyze the behavioral and affective responses of adolescent girls, the items of MDQ were associated with premenstrual, menstrual and post menstrual phases. The questionnaire contains description of symptoms classified into eight categories (total 47 items) such as, Pain (6), concentration (9), behavioral change (5), autonomic reaction (4), water retention (4), negative effect (8), arousal (5), and control (6), each of which was scored relating to three different phases of a menstrual cycle. Thus the questionnaire provided score based on 47 variables related to PMS.

The MDQ form comprised of three separate self reporting columns to measure common symptoms and feelings associated with premenstrual, menstrual and post menstrual phases. It allows participants to describe their experience and rate the intensity of their experience as follows:

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No experience of symptom</td>
</tr>
<tr>
<td>1</td>
<td>Present, mild</td>
</tr>
<tr>
<td>2</td>
<td>Present, moderate</td>
</tr>
<tr>
<td>3</td>
<td>Present, strong</td>
</tr>
<tr>
<td>4</td>
<td>Present, severe</td>
</tr>
</tbody>
</table>

Scoring and Interpretation

Each item had five options categorized on a 0-4 rating scale with scores as mentioned above. The total score was 188. The level of premenstrual distress was ranged as follows:

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No experience of symptoms</td>
</tr>
<tr>
<td>1 - 47</td>
<td>Mild</td>
</tr>
</tbody>
</table>
84 - 94   - Moderate
95 - 144  - Strong
145 - 188 - Severe

Administration

The MDQ was answered by adolescent girls during survey, pretest, posttest I and posttest II. Subjects were asked to report the presence or absence of these symptoms, based on their previous month’s menstrual cycle experiences as well as with the help of daily symptom diary.

3.8.3 Part III: State Trait Anxiety Inventory– STAI

This standardized form was constructed by Charles D. Spiel Berger (1991) (Appendix-D3). The STAI is a widely used standardized scale for measuring the state and trait form of anxiety. The scale comprises of two separate self report scales for measuring State Anxiety (S-Anxiety) and Trait Anxiety (T-Anxiety). Tamil version of the STAI was used in this study (Appendix D8).

State Anxiety

The S-Anxiety was evaluated with the State Trait Anxiety Inventory – STAI Form Y-1. This self reporting instrument consists of 20 short statements. It allows participants to evaluate how they felt during luteal phase and rate the intensity of their feeling of anxiety on a 4 point rating scale with the following four ratings.


Scoring and Interpretation

The scale has both positive and negative statements. The positive statements were 3, 4, 6, 7, 9, 12, 13, 14, 17 & 18 the options were scored as 1, 2, 3 & 4. The negative statements were 1, 2, 5, 8, 10, 11, 15, 16, 19 & 20, therefore reverse scoring
was used. Total S-Anxiety scores ranged from 20 to 80. The summed up scores indicated the S-.Anxiety. The higher the scores the more State Anxiety.

**Trait Anxiety:**

Using the form Y-2 of STAI the trait anxiety was measured. In the T-Anxiety scale, subjects reported on how they generally felt, by rating themselves on the 4 point frequency scale.


**Scoring and Interpretation**

The scale had both positive and negative statements. The positive statements were 22, 24, 25, 28, 29, 31, 32, 35, 37, 38 & 40 the options were scored as 1, 2, 3 & 4. The negative statements were 21, 23, 26, 27, 30, 33, 34, 36 & 39 therefore reverse scoring was used. Total Trait anxiety scores ranged from 20-80. The summed up scores indicated the T-.Anxiety. The higher score indicates higher level of anxiety.

**Administration**

STAI scale was utilized with the permission of Mind Garden (purchased). The adolescent girls answered the STAI questions during the pretest, posttest I and posttest II. There was no fixed time limit to complete the inventory.

**3.8.4 Part IV: Beck Depression Inventory (BDI)**

The Beck Depression Inventory created by Dr. Aaron T. Beck, is a 21-question multiple-choice self rated inventory with each item rated with a set of four possible answer choices of increasing intensity (Appendix-D4). When the test is scored, a value of 0 to 3 is assigned for each answer and then the total score is compared to a key to determine the severity of the depression. It can be easily administered for adolescents above 14 years as the reading level of the measure is only at sixth grade level and can be completed in about 10 minutes. BDI was chosen
over BDI-II because of its free availability for the primary-care users in India. BDI contains variables such as sadness, pessimism, sense of failure, dissatisfaction, guilt, sense of punishment, self dislike, self accusations, self harm, crying spells, irritability, social withdrawal, indecisiveness, self image change, work difficulty, sleep disturbance, fatigability, anorexia, weight loss, somatic pre occupation. The Tamil version of the BDI was used in this study (Appendix D8). In this study 20 questions were only utilized and 21st question that focused on loss of libido was removed as it was not related to students of Indian culture. The score interpretation is as follows;

Scoring and Interpretation

The total score was 60. The level of depression was grouped as follows

1 – 10 - Normal
11 – 16 - Mild mood disturbance
17 – 20 - Borderline depression
21 – 30 - Moderate depression
31 – 40 - Severe depression
Over 40 – Extreme

Scoring merely consists of adding the numerical values encircled by the adolescent girls for the 20 items. If an adolescent girl circles more than one number for the same item, only the highest score is used. Adolescent girl’s scores ranging from 11 to 16 that is mild and 17 to 20 that is borderline depression only were considered for the study.

Administration

The BDI questions were answered by adolescent girls during the survey, posttest I and posttest II. Subjects were asked to report the presence or absence of these symptoms,
based on their past two month’s experiences during luteal phase as well as with the help of daily symptom dairy.

3.8.5 Part V: Premenstrual Syndrome Knowledge Questionnaire (PMSKQ)

The Premenstrual Syndrome Knowledge Questionnaire (PMSKQ) was developed for this study by the researcher to measure the adolescent knowledge regarding PMS and related self care strategies (Appendix-D5). Formulation of the items was based on the objectives of each of the ITLS sessions. It consists of self administered structured questionnaire and has 20 multiple choice questions, with four options, of which one is the correct option.

Scoring and Interpretation

Each correct answer was scored as one and the wrong answer as zero. Total score was 20. The score was interpreted as follows:

- Adequate knowledge: 76 to 100%
- Moderately adequate knowledge: 50 to 75%
- Inadequate knowledge: < 50%

Administration

The premenstrual syndrome knowledge questions were answered by adolescent girls during the pretest, posttest I and posttest II. Post test I knowledge was assessed 16 days after pretest. Post test II knowledge was assessed 38 days after pretest.

3.8.6 Part VI: Yoga relaxation technique performance check list

Yoga relaxation technique performance check list was developed for this study by the researcher to measure the practice level. It was applied only to study group adolescent girls. The scale has pre performance preparation and the steps of yoga relaxation technique such as (Appendix-D6) asanas, pranayamas, and yoga relaxation. A total of eight techniques scores includes as follows.
Pre performance with score of 6
Step 1 – Vajrasana with score of 4
Step 2 - Bhujangasana with score of 6
Step 3 - Matsyasana with score of 3
Step 4 - Surya Anuloma Viloma with score of 5
Step 5 - Candro Anuloma vilomawith score of 5
Step 6 - Nadi Suddhi Pranayama with score of 5
Step 7 - Bhramari Pranayama with score of 3
Step 8 - Yoga Nidhra with score of 13

Scoring and Interpretation
Total Score range from 1 to 50. A score of one was given for correct performance and zero was given for wrong performance, the level of practice was grouped as follows:

<table>
<thead>
<tr>
<th>Practice Level</th>
<th>Score Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Satisfactory practice</td>
<td>76 to 100%</td>
</tr>
<tr>
<td>Moderately satisfactory practice</td>
<td>51 to 75%</td>
</tr>
<tr>
<td>Poor Practice</td>
<td>&lt; 50</td>
</tr>
</tbody>
</table>

Administration
The yoga relaxation technique performance check list was administered by the researcher during the 38th day and 68th day post intervention period and it was applied only to the study group.

3.8.7 Daily symptom dairy
Maintenance of premenstrual daily symptom diary was practised for prospective record of symptoms (Appendix-D7). This consists of the horizontal columns from the first day to 30th day of the month and vertical columns of 45 symptoms commonly expressed by adolescent girls with PMS. The diary was
prepared by the researcher based on the Moos Menstrual Distress Questionnaire. Adolescent girls were requested to record their symptoms at the end of the day, during evenings as mild, moderate, severe, if no symptoms were there the space for that day was left blank and they were also instructed to mark the first menstrual day in red pen. The researcher described the daily symptom diary and taught them how to record symptoms in the daily record. Weekly, the researcher reminded the adolescent girls about keeping the daily symptom diary. Adolescent girls maintained daily symptom diary throughout the study period.

Scoring and administration

To keep the daily symptom diary handy and to rule out the problem of misplacement, the diary was compiled in three papers and was filed and kept in class room. Students were requested to fill the diary at the end of the day after school hours. As the daily symptom diary was used to identify luteal phase symptoms and also used to complete Moos menstrual distress questionnaire, no scores were assigned to them

3.8.8 Information booklet on PMS and steps of YRT

The booklet on menstrual hygiene, PMS, its management and steps of yoga relaxation technique prepared by the researcher had the similar content that was imparted to adolescent girls during the ITLS session. The “Easy way to feel good” information booklet was used as a visual aid during the ITLS session for adolescent girls in the study group. This module was handed over to the adolescent girls after the ITLS (Appendix-H & I).

3.9 Validity and Reliability of the tool

All the instruments were reviewed for face and content validity by medical and nursing experts and they were pilot tested to assess the usability and ease of administration. Content validity of the tool was established by experts comprising of
two educationists, one psychologist, one psychiatrist, four nurse educators, one yoga practitioner, and one gynecologist (Appendix-G).

3.9.1 Premenstrual syndrome knowledge questionnaire (PMSKQ)

The content and face validity of the premenstrual syndrome knowledge questionnaire was determined by four experts. The PMSKQ was also translated into local language by four experts, two nurses with M.Sc nursing qualification who had fluency in the chosen language and two experts with M.A, M. Phil qualification in English. Using combined translation technique (Jones 2001) 2 experts translated to local language and 2 experts translated the tool to English. The translated version at PMSKQ was then pre-tested on a sample of 50 secondary school girls to identify potential problems in data collection and no problem was found. The reading level of the instrument was found to be appropriate and easy to understand.

Four experts rated the questionnaire in three point rating scale as not necessary (0), useful (1), essential (2). All comments were scored to calculate content validity ratio (CVR) and content validity index (CVI) using the following formula (Lawshe 1975).

To calculate the CVR (a score for individual scale item)

$$\text{CVR} = \frac{\text{ne}-\frac{N}{2}}{\frac{N}{2}}$$

Note. ne = The number of experts who rated an item as essential.

N= the total number of experts.

The CVI is the mean CVR for all retained items.

CVI was calculated from the average score of the four experts, thus CVI of the PMSKQ was 0.978. The stability reliability of the tool was established by test-retest method at two weeks for 30 samples and the calculated correlation coefficient was
0.91. The equivalence reliability of the tool was established and the Cornbach’s alpha coefficient for this sample was 0.80.

3.9.2 Menstrual distress questionnaire Form c (MDQ)

It is a standardized tool. Re-test reliability of the whole test as well as the eight sub components have been reported. These values range from \( r = 0.993 \) to \( r = 0.998 \). The original tool has established validity. The adapted tool was translated into the local Tamil language and checked by three experienced bilingual researchers. Second, the Tamil version was back-translated into English to ensure the stability of the meaning of each test item (Chatterjee, 2006). The Tamil version of MDQ was tested using the test-retest method at two weeks with a sample of 100 students. The \( r \) value obtained was 0.84 (significant correlation). Questionnaire was utilized with permission of Psycho press, Australia (purchased).

3.9.3 Beck depression inventory (BDI)

It is a standardized tool. The original tool has established validity. The adapted tool was translated into Tamil and back translated into English. The Tamil version of BDI was tested using the test-retest reliability method with a sample of 100 students. The reliability coefficients were obtained with Pearson’s product moment correlations, indicating significant correlation (\( r=0.82 \)) and Cronbach’s alpha coefficients in this study was 0.96.

3.9.4 State Trait Anxiety Inventory – STAI

It is a standardized tool. The original tool has established validity. The adapted tool was translated and back translated into Tamil. The Tamil version of STAI was tested for reliability using test-retest method at two weeks with a sample of 100 students. The \( r \) value obtained was 0.9 (significant correlation). Cronbach’s alpha coefficients in this study was \( \alpha = 0.86 \).
3.9.5 Yoga relaxation technique performance check list

The performance checklist reliability was checked using interrater method. The inter-rater observer was also a trained yoga instructor, familiar with yoga practices used for the study. The obtained `r' value for practice score was 0.8 (significant correlation).

Since these tools were found to be reliable and valid they were used further to proceed with the data collection to the study.

3.9.6 Information booklet on PMS and steps of YRT

The criteria for content validity of the booklets included objective based relevance of the content, language, accuracy, feasibility and clarity on a three point rating scale ( 0=not necessary, 1=useful,  2= essential ). Four experts rated the module. Mean expert ratings given for the module were relevance of content, accuracy, feasibility and clarity. The average overall rating for module was 7.88 for 10 score.

3.10 Cognitive Behavioral Nursing Strategies

The strategies included (a) Cognitive nursing strategies and (b) Behavioral nursing strategies

3.10.1 Cognitive nursing strategies

It refers to the interactive teaching learning- sessions (Appendix-E). It was designed by the researcher and reviewed by four experts in this area. The development of the teaching package was based on an extensive review of literature. Lecture, discussion, demonstration teaching methods were used with various visual aids to add interest and to aid memory. Pilot teaching was performed by the researcher with a group of 50 secondary school students of another school that was not in the main study, in order to obtain feedback from them about the appropriateness of
teaching methodologies that were used. Students in this pilot group also helped in
determining the understandability of the questionnaire and helped in identifying
potential problems.

There were a total of three teaching sessions and each session lasted for 40 minutes.
The teaching sessions were carried out by the researcher in the adolescent girls’
regular class room, after the school hours (4 to 4.40 pm). The objectives and content
outline for each session were as follows.

**Session 1: Content outline**

- Appreciate the changes that happen during puberty/adolescence
- Review structure and function of female reproductive organs
- Explain the physiology of menstruation
- Discuss and clarify myths and misconceptions about menstruation
- Realize the personal care and hygienic measures during menstruation

**Session 2: Content outline**

- Identify the problems associated with menstruation
- Discuss measures to deal with menstrual cramps
- Understand the meaning of PMS
- Discuss in detail about causes, symptoms and management of PMS.
- Explain self-help and lifestyle measures for managing premenstrual syndrome
- Discuss self-care measures related to dietary change

**Session 3: Content outline**

- Understand Yoga Relaxation Techniques (YRT)
- State the importance and benefits of regular exercise
- Demonstration of YRT by the researcher
- Return demonstration of YRT by the students
3.10.2 Behavioral nursing intervention

It includes demonstration of YRT. Such as Asanas, Pranayamas, and Yoga Relaxation

<table>
<thead>
<tr>
<th>Asanas</th>
<th>Pranayamas</th>
<th>Yoga Relaxation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vajrasana</td>
<td>Surya Anuloma Viloma</td>
<td>Yoga Nidhra</td>
</tr>
<tr>
<td>Bhujangasana</td>
<td>Candro Anuloma viloma</td>
<td></td>
</tr>
<tr>
<td>Matsyasana</td>
<td>Nadi Suddhi Pranayama</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bhramari Pranayama</td>
<td></td>
</tr>
</tbody>
</table>

Adolescent girls were grouped in to small groups of 20 and were asked to assemble in the room to start with group YRT session. YRT practice was given for about 30 minutes every day. A total of 8 groups with 20 adolescent girls in each group were grouped for YRT practice session. YRT was practised every day for 20 school days as a group session under researcher guidance. Soon after the intensive phase of YRT practice, adolescents were assessed through YRT performance check list for their level of practice on YRT. Lacunas made during the practice by adolescent girls were corrected and reinforced. Adolescent girls practised YRT for another 20 school days under researcher supervision.

3.11 Pilot Study

A pilot study was conducted during the month of Jun 2008 to Dec 2008 at selected schools in Kanchipuram District. Administrative approval was obtained from the headmistress to conduct the pilot study.

The pilot study was conducted to ensure validity and reliability of the tool and feasibility for giving the intervention. Though the pilot study demonstrated feasibility some modification were done in the tool as suggested by the experts.
Modifications done after pilot study

- Religion was removed from demographic variables as per the ethical and research committee of SRU (Sri Ramachandra University) recommendation
- Loss of Libido was removed from BDI scale as per the ethical and research committee of SRU recommendation
- Preliminary assessment was done for three menstrual cycles, it was changed to 2 cycles after extensive review support.
- Three yoga poses were included for relieving menstrual pain, as most of the adolescent girls had requested to teach measures to deal with menstrual cramps.
- PMSKQ was included after expert suggestion

3.12 Ethical consideration

An approval to conduct the study in private schools was obtained from the headmistress and for government schools from district education officer of Thiruvallur district (Appendix B). Then an approval to conduct the study was obtained from the SRU institutional ethics committee (Appendix A). The ethical consideration criteria were based on the Indian Council of Medical Research guidelines on biomedical research in human beings.

Information essential for consent included description of the purpose of the study, the research activities and the usefulness of the study outcome, assurance of privacy and confidentiality, the opportunity to answer any questions that a potential subject might have, and the option to withdraw from the study at any time.
3.13 Data Collection Procedure

The data collection procedure was conducted from 6.1.2009 to 9.11.2010

The data were collected in two phases

First phase data collection was done for study group in two settings

Survey phase

1. After assigning school to either study group or control group, a complete survey was done among 9th and 11th standard students of the study group to identify adolescent girls who fulfilled the inclusion criteria. On the first day a detailed summary of the proposed study was informed to the adolescent girls and consent form was given to read. Students were given the opportunity to ask any further questions and then made to sign the consent form. As students were minors they were requested to get a consent from the parents too (Appendix). On the third day consent forms were collected from the students and then MDQ and BDI questionnaire were handed over and requested to recall their previous month premenstrual phase experience retrospectively to fill the form, after 20 minutes forms were collected back. This retrospective assessment was done to assess premenstrual distress and depression.

2. After the first retrospective assessment, adolescent girls were requested to maintain premenstrual daily symptoms diary from 4th day to 40th day for prospective record of symptoms, the researcher described the daily symptom diary and taught them how to record the symptom in the daily record. Adolescent girls were instructed to record the symptoms for one menstrual cycle in the evening. Weekly the researcher reminded the adolescent girls about keeping the daily symptom diary. 40 days after the first visit, the same adolescent girls were asked to complete a baseline assessment using the completed daily symptom diary. Thus, the baseline assessment included the
data from two consecutive menstrual cycles (Diagnosis of PMS need symptom assessment from two consecutive menstrual cycles).

3. These retrospective and prospective cross sectional data were used to identify adolescent girls with mild, moderate, or strong PMS and mild or borderline depression. Based on this preliminary assessment, the adolescent girls excluded from the study were those who had (1) Severe premenstrual distress as measured by Moos Menstrual Distress Questionnaire or no premenstrual distress for consecutive two menstrual cycles (2) Moderate depression, severe depression, very severe depression, or no depression as measured by the Beck Depression Inventory. After this preliminary assessment, a list was prepared comprising 9th and 11th standard students. With the help of a random number generator, 40 adolescent girls were selected from each class. Adolescent girls who had severe and very severe depression were referred to Sri Ramachandra Hospital for further treatment. Same was informed to the class teacher and parents through phone. Few students were identified to have symptoms of reproductive tract infection and they were also referred to Sri Ramachandra Hospital for further treatment.

In the first setting (government school) among ninth standard students out of 197 adolescent girls surveyed a total of 76 adolescent girls had premenstrual distress and depressive symptoms, in 11th standard out of 153 adolescent girls surveyed, a total of 69 adolescent girls had premenstrual distress and depressive symptoms.

In the second setting (private school) a total of 53 adolescent girls were identified to have premenstrual distress and depression from 158 of the 9th standards and a total of 64 adolescent girls were identified to have premenstrual distress and depression from 135 of the 11th standards (Figure 3). After this preliminary
assessment a list was prepared separately of 9th and 11th standard adolescent girls. Using a random number generator 40 adolescent girls were selected from each class.

**Data collection phase**

4. After selection of subjects the adolescent girls were asked to complete the pretest forms that are STAI form Y1 and form Y2 and the PMSKQ. For depression and premenstrual distress survey score itself used as pretest score.

**Intervention phase for the study group adolescent girls**

5. After the pretest study group adolescent girls attended Cognitive Behavioral Nursing Strategies programme which is an interactive teaching - learning session for a period of 120 minutes and YRT demonstration session for 40 minutes followed by continuation of YRT practice for a period of 40 days.

6. The intervention group of 160 adolescent girls was further divided into 8 groups of 20 students each. The teaching sessions were conducted by the researcher and took place in the adolescent girls’ regular class room after the school hours between 4 to 4.40 pm. Teaching was imparted by the researcher, through lecture cum discussion and demonstration, using visual aids like charts, pamphlet and black board in a group session for 120 minutes, three teaching sessions for 40 minutes were conducted on 3 days within one week, seven days after the teaching session that is 16th day after pretest the subjects were asked to complete the PMSKQ.

7. YRT practice - Adolescent girls were grouped into small groups of 20 and were asked to assemble in the room to start with group YRT session. YRT was practised for about 30 minutes. A total of 8 groups with 20 adolescent girls in each group were grouped for YRT practice session.

YRT was practised every day for 20 school days (from 8th day to 38th day after cognitive nursing strategies) as a group session, under researcher guidance.
(intensive phase). Soon after the 20 school days practice of YRT, adolescents were assessed with an YRT performance check list for their level of adherence to practice of YRT. Lacunas made during the practice were corrected and reinforced. Adolescent girls practiced YRT for another 20 school days (from 39\textsuperscript{th} day to 60\textsuperscript{th} day after cognitive nursing strategies) under the researcher’s supervision. Adolescent girls were encouraged of perform YRT daily at home.

8. All Adolescent girls who participated in Cognitive Behavioral Nursing Strategies programme were given the “Easy way to feel good” information booklet on menstrual hygiene, PMS, its management and steps of yoga relaxation technique at the end of ITLS session. This was given mainly to reinforce practice of life style modification to reduce PMS and to practice YRT regularly.

Setting for Yoga Relaxation Technique practice

The headmistress of each school was approached by the researcher to locate an ideal common place to perform group YRT sessions in the school. The suggested place had a hall with adequate windows and good lighting facility. This place was used by the school for their group activities. Oral permission was obtained from the headmistress by the researcher to conduct the group YRT session in the suggested place.

9. The first and second post assessment was done for knowledge on the 16\textsuperscript{th} day and 38\textsuperscript{th} day after pretest, by administering PMSKQ to all the adolescent girls who participated in Cognitive Behavioral Nursing Strategies programme to determine the level of PMS knowledge.

10. The first and second post assessment were done for premenstrual distress, anxiety and depression on 38\textsuperscript{th} day and 68\textsuperscript{th} day after pretest, by administering MDQ, BDI and STAI to all the adolescent girls who participated in
CBNS programme to determine the level of premenstrual distress, depression, anxiety and practice of YRT were also assessed in the same interval, only for study group adolescent girls.

**The second phase data collection was done for the control group in two settings**

The control group adolescent girls continued with their normal school activities and were requested to complete the assessments at the same time intervals as the study group. The control group subjects received same intervention at the completion of the study period.

The details of the control group participants are as follows;

In the first setting (government school) among 9th standard students out of 198 adolescent girls surveyed a total of 59 adolescent girls had premenstrual distress and depressive symptoms, among 11th standard students out of 168 adolescent girls surveyed a total of 63 adolescent girls had premenstrual distress and depressive symptoms.

In the second setting (private school) a total of 61 adolescent girls were identified to have premenstrual distress and depression from 143, 9th standards and a total of 63 adolescent girls were identified to have premenstrual distress and depression from 121 eleventh standards. After this preliminary assessment a list was prepared separately of 9th and 11th standard adolescent girls (Figure 3). Using a random number generator, 40 adolescent girls were selected from each class.

**3.14 Attrition of Samples**

In the study group two were lost to follow-up due to long leave, three adolescent girls had fever for almost a week, two had sprain and three were went to participate NSS program, these 10 Adolescent girls were discontinued intervention. Hence these 10 Adolescent girls were dropped from the study and a total of 150
Adolescent girls participated in the YRT practice at the end. There is no drop out in the control group.

**Table 5** Schematic representation of data collection procedure

<table>
<thead>
<tr>
<th>Visit day details</th>
<th>Activities</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Survey phase</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st day</td>
<td>Informed consent from for adolescent girls and their parents were handed over to all adolescent girls</td>
<td>Study &amp; control</td>
</tr>
<tr>
<td>3rd day</td>
<td>Adolescent girls were requested to fill background variable form, MDQ form and BDI form to collect preliminary retrospective data to assess level premenstrual distress and depression of previous menstrual cycle.</td>
<td>Study &amp; control</td>
</tr>
<tr>
<td>4th to 40th day (weekly once)</td>
<td>Reminder to maintain PMS daily symptom dairy every day in the evening to record the symptoms prospectively</td>
<td>Study &amp; control</td>
</tr>
<tr>
<td>41st day</td>
<td>Adolescent girls requested to fill MDQ form and BDI form with help daily symptom dairy to record prospective data for one menstrual cycle (diagnosis of PMS need data from 2 cycles). After preliminary assessment a list of adolescent girls who fulfilled inclusion criteria was prepared and using a random number generator needed adolescent girls were selected.</td>
<td>Study &amp; control</td>
</tr>
<tr>
<td><strong>Data collection phase</strong></td>
<td></td>
<td>Study &amp; control</td>
</tr>
<tr>
<td>1st day (Mon)</td>
<td>Pretest assessment of anxiety and PMS knowledge and for premenstrual distress, depression prospective survey score itself utilized as pretest score</td>
<td></td>
</tr>
<tr>
<td>Mon, Wed, Friday of the 1st week</td>
<td>CBNS &amp; Routine activities</td>
<td>Study</td>
</tr>
<tr>
<td>Routine activities</td>
<td>Control</td>
<td></td>
</tr>
<tr>
<td>8th to 60th day</td>
<td>practice of YRT under researcher guidance &amp; Routine measures (5 days in a week for 40 school days)</td>
<td>Study</td>
</tr>
<tr>
<td>Routine activities</td>
<td>Control</td>
<td></td>
</tr>
<tr>
<td>16th day after pretest</td>
<td>Posttest assessment of Knowledge</td>
<td>Study &amp; control</td>
</tr>
<tr>
<td>38th day after pretest</td>
<td>Posttest assessment of premenstrual distress, Anxiety, Depression &amp; knowledge</td>
<td>Study &amp; control</td>
</tr>
<tr>
<td>YRT Performance</td>
<td>Study</td>
<td></td>
</tr>
<tr>
<td>68th day after pretest</td>
<td>Posttest assessment of premenstrual distress, Anxiety &amp; Depression</td>
<td>Study &amp; control</td>
</tr>
<tr>
<td>YRT Performance</td>
<td>Study</td>
<td></td>
</tr>
</tbody>
</table>
3.15 Data Analysis Plan

Descriptive statistics was used to arrange the data in a scientific way. Inferential statistics was used to test the hypothesis. Data were analyzed using the Statistical Package for the Social Sciences (SPSS version 16). A p value of < 0.05 was considered significant.

Table 6 Plan for data analysis

<table>
<thead>
<tr>
<th>Methods</th>
<th>Type of statistics</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descriptive statistics</td>
<td>Frequency, Percentage, Mean, SD</td>
<td>Assess the sample characteristics and study variables.</td>
</tr>
<tr>
<td>Inferential Statistics</td>
<td>Paired ‘t’ test</td>
<td>Compare the outcome variables before and after intervention within the group.</td>
</tr>
<tr>
<td></td>
<td>Student ‘t’ test</td>
<td>Compare the outcome variables before and after intervention between the groups.</td>
</tr>
<tr>
<td></td>
<td>Chi square</td>
<td>Assess the homogeneity of samples between the groups.</td>
</tr>
<tr>
<td></td>
<td>Pearson’s correlation</td>
<td>Associate selected background variables with selected outcome variables.</td>
</tr>
<tr>
<td></td>
<td>ANOVA</td>
<td>Compare the level of premenstrual distress, depression and knowledge between the groups.</td>
</tr>
<tr>
<td></td>
<td>RM ANOVA</td>
<td>Identify the relationship between premenstrual distress, depression, anxiety and YRT.</td>
</tr>
<tr>
<td></td>
<td>Multiple Linear Regressions</td>
<td>Associate selected background variables with selected outcome variables.</td>
</tr>
<tr>
<td></td>
<td>Fisher’s exact test</td>
<td>Assess differences in outcomes over time.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All the significant variables were grouped into final regression analysis to evaluate the role of the different independent variables on the dependant variable.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Because of an expected cell count of less than 5, Fisher’s exact test was used to associate selected background variables with selected outcome variables.</td>
</tr>
</tbody>
</table>