CHAPTER III
METHODOLOGY

The perusal of review of literature related to the theme of the present study brings out considerable agreement for the treatment of premenstrual dysphoric disorder. Two approaches of psychotherapy and pharmacotherapy are commonly employed. Everyone including the cognitive behavior therapies understands that emotions and moods are governed by factors in addition to one's own thinking and behavior. However, as a practical matter virtually the only means of access to our moods and emotions are the cognitive and behaving routes. In order to voluntarily change how we feel, we have to go about it indirectly, not directly. There is no direct way of influencing our feelings and moods. Brains simply aren't built so as to make this possible. Emotions are regulated at five points in the emotion generative process: (t) Selection of the situation, (2) modification of the situation, (3) deployment of attention, (4) change of cognitions, and (5) modulation of physiological responses.

The first, second and fifth targeted in behavior therapy, the third and fourth are the focus of cognitive therapy. For this reason we believe that in the treatment of disorders such as PMDD, some combination of behavioral and cognitive methods will be needed. Further, manipulation of the serotonergic system is associated with improvement in PMDD. At the, neurochemical level serotonin is transported back into the neuron through, transporter proteins' Serotonin reuptake Inhibitors (SRIS) work by blocking these transporter proteins' which results in a greater availability of serotonin neurotransmitter in the synaptic cleft'. SSRIs are first line agents in the treatment of PMDD. Currently, four SRIS, including clomipramine, Fluvoxamine, Fluoxetine, Sertraline, and Paroxetine, have been approved by the U.S. Food and Drug Administration for the treatment of adults with PMDD. Three of these, Fluoxetine and Sertraline' have been approved for treatment of PMDD.
DEFINITION OF VARIABLES

Premenstrual Dysphoric Disorders

In the Diagnostic and Statistical Manual of Mental Disorders, 4th ed. (DSM-IV), PMDD is classified as “depressive disorder not otherwise specified” and emphasizes emotional and cognitive-behavioral symptoms. At least five of the 11 specified symptoms must be present for a diagnosis of PMDD. These symptoms should be limited to the luteal phase and should not represent amplification of preexisting depression, anxiety, or personality disorder. In addition, they must be confirmed prospectively by daily rating for at least two consecutive menstrual cycles. A symptom-free period during the follicular phase of the menstrual cycle is essential in differentiating PMDD from preexisting anxiety and mood disorders.

Antidepressants. Of numerous options available, antidepressants from the class of the SSRIs may be considered the therapy of choice for PMDD in many patients. Currently, the only agents with an FDA indication for PMDD are fluoxetine hydrochloride, sertraline hydrochloride, and paroxetine hydrochloride. Unlike tricyclic antidepressants, which interact with several receptors, the SSRIs interact minimally with receptors other than the serotonin (5-HT) reuptake receptor. Fluoxetine has a recommended dose of 20 mg/day; in clinical studies, no added benefit was observed with increasing the dosage to 60 mg/day.

Yoga

Yoga is another form of exercise that can be beneficial for relieving PMDD. Through gentle stretches, yoga may help to release muscle tension, ease lower back stiffness, regulate breathing, improve circulation, and relieve stress.

Cognitive-Behavioral Therapy

Cognitive-behavioral therapy is an action-oriented form of psychosocial therapy that assumes that maladaptive or faulty thinking...
patterns cause maladaptive behavior and "negative" emotions. (maladaptive behavior is behavior that is counter-productive or interferes with everyday living) The treatment focuses on changing an individual's thoughts (cognitive patterns) in order to change his or her behavior and emotional state.

Theoretically, cognitive-behavioral therapy can be employed in any situation in which there is a pattern of unwanted behavior accompanied by distress and impairment. It is a recommended treatment option for a number of mental disorders, including affective (mood) disorders, personality disorders, social phobia, obsessive-compulsive disorder (OCD), eating disorders, substance abuse, anxiety or panic disorder, agoraphobia, post-traumatic stress disorder (PTSD), and attention-deficit/hyperactivity disorder (ADHD). It is also frequently used as a tool to deal with chronic pain for patients with illnesses such as rheumatoid arthritis, back problems, and cancer. Patients with sleep disorders may also find cognitive-behavioral therapy a useful treatment for insomnia.

Precautions

Cognitive-behavioral therapy may not be suitable for some patients. Those who don't have a specific behavioral issue they wish to address and whose goals for therapy are to gain insight into the past may be better served by psychodynamic therapy. Patients must also be willing to take a very active role in the treatment process.

Cognitive-behavioral intervention may be inappropriate for some severely psychotic patients and for cognitively impaired patients (for example, patients with organic brain disease or a traumatic brain injury), depending on their level of functioning.

Description

Cognitive-behavioral therapy combines the individual goals of cognitive therapy and behavioral therapy. Pioneered by psychologists Aaron Beck and Albert Ellis in the 1960s, cognitive therapy assumes
that maladaptive behaviors and disturbed mood or emotions are the result of inappropriate or irrational thinking patterns, called *automatic thoughts*. Instead of reacting to the reality of a situation, an individual reacts to his or her own distorted viewpoint of the situation. For example, a person may conclude that he is "worthless" simply because he failed an exam or didn't get a date. Cognitive therapists attempt to make their patients aware of these distorted thinking patterns, or cognitive distortions, and change them (a process termed cognitive restructuring).

Behavioral therapy, or behavior modification, trains individuals to replace undesirable behaviors with healthier behavioral patterns. Unlike psychodynamic therapies, it does not focus on uncovering or understanding the unconscious motivations that may be behind the maladaptive behavior. In other words, strictly behavioral therapists don't try to find out why their patients behave the way they do, they just teach them to change the behavior.

Cognitive-behavioral therapy integrates the cognitive restructuring approach of cognitive therapy with the behavioral modification techniques of behavioral therapy. The therapist works with the patient to identify both the thoughts and the behaviors that are causing distress, and to change those thoughts in order to readjust the behavior. In some cases, the patient may have certain fundamental core beliefs, called schemas, which are flawed and require modification. For example, a patient suffering from depression may be avoiding social contact with others, and suffering considerable emotional distress because of his isolation. When questioned why, the patient reveals to his therapist that he is afraid of rejection, of what others may do or say to him. Upon further exploration with his therapist, they discover that his real fear is not rejection, but the belief that he is hopelessly uninteresting and unlovable. His therapist then tests the reality of that assertion by having the patient name friends and family who love him and enjoy his company. By showing the patient that others value him, the
therapist both exposes the irrationality of the patient's belief and provides him with a new model of thought to change his old behavior pattern. In this case, the person learns to think, "I am an interesting and lovable person; therefore I should not have difficulty making new friends in social situations." If enough "irrational cognitions" are changed, this patient may experience considerable relief from his depression.

A number of different techniques may be employed in cognitive-behavioral therapy to help patients uncover and examine their thoughts and change their behaviors. They include:

Behavioral homework assignments. Cognitive-behavioral therapists frequently request that their patients complete homework assignments between therapy sessions. These may consist of real-life "behavioral experiments" where patients are encouraged to try out new responses to situations discussed in therapy sessions.

Cognitive rehearsal

The patient imagines a difficult situation and the therapist guides him through the step-by-step process of facing and successfully dealing with it. The patient then works on practicing, or rehearsing, these steps mentally. Ideally, when the situation arises in real life, the patient will draw on the rehearsed behavior to address it.

Patients are asked to keep a detailed diary recounting their thoughts, feelings, and actions when specific situations arise. The journal helps to make the patient aware of his or her maladaptive thoughts and to show their consequences on behavior. In later stages of therapy, it may serve to demonstrate and reinforce positive behaviors.

Validity testing

Patients are asked to test the validity of the automatic thoughts and schemas they encounter. The therapist may ask the patient to defend or produce evidence that a schema is true. If the patient is
unable to meet the challenge, the faulty nature of the schema is exposed.

Initial treatment sessions are typically spent explaining the basic tenets of cognitive-behavioral therapy to the patient and establishing a positive working relationship between therapist and patient. Cognitive-behavioral therapy is a collaborative, action-oriented therapy effort. As such, it empowers the patient by giving him an active role in the therapy process and discourages any overdependence on the therapist that may occur in other therapeutic relationships. Therapy is typically administered in an outpatient setting in either an individual or group session.

Interventions may be suggested by a primary physician/caregiver. Treatment is relatively short in comparison to some other forms of psychotherapy, usually lasting no longer than 16 weeks. Many insurance plans provide reimbursement for cognitive-behavioral therapy services. Because coverage is dependent on the disorder or illness the therapy is treating, patients should check with their individual plans.

**Preparation**

Patients may seek therapy independently, or be referred for treatment by a primary physician, psychologist, or psychiatrist. Because the patient and therapist work closely together to achieve specific therapeutic objectives, it is important that their working relationship is comfortable and their goals are compatible. Prior to beginning treatment, the patient and therapist should meet for a consultation session, or mutual interview. The consultation gives the therapist the opportunity to make an initial assessment of the patient and recommend a course of treatment and goals for therapy. It also gives the patient an opportunity to find out important details about the therapist's approach to treatment, professional credentials, and any other issues of interest.
In some managed-care clinical settings, an intake interview or evaluation is required before a patient begins therapy. The intake interview is used to evaluate the patient and assign him or her to a therapist. It may be conducted by a psychiatric nurse, counselor, or social worker.

Normal results

Many patients who undergo cognitive-behavioral therapy successfully learn how to replace their maladaptive thoughts and behaviors with positive ones that facilitate individual growth and happiness. Cognitive-behavioral therapy may be used in conjunction with pharmaceutical and other treatment interventions, so overall success rates are difficult to gauge. However, success rates of 65% or more have been reported with cognitive-behavioral therapy alone as a treatment for panic attacks and agoraphobia. Relapse has been reported in some patient populations, perhaps due to the brief nature of the therapy, but follow-up sessions can put patients back on track.

This experimental research work is an attempt to ascertain the effectiveness of the different intervention strategies, namely (Cognitive behavior therapy), yoga therapy and drugs (fluoxetine) separately and together. The researcher intended to measure the therapeutic results of each cognitive behavior therapy and yoga therapy and fluoxetine separately, and combination, on a group in the age of 19 to 30 years old affected with Premenstrual Dysphoric Disorder. As a consequence, the investigation made an attempt to test various hypotheses.

Sampling

Sampling refers to the process of specifying and obtaining the participants for study. In this research, universe as the broad population to which eventual generalization of the findings is desired, includes all female married students between ages 19-30 years.

The researcher selected 120 female students out of 500 female
students who have been invited for participating in an explanatory
session. These 500 female students selected as a primary sample
showed some signs of dysphoric mood in this session they were told:
how to mark the daily symptoms report (COPE) and were asked to
return in one month time and get the second sheet for the following
months. When the two (COPE) were completed in the subsequence
month, screening was alone and 146 of these woman were
diagnosed as having PMDD. Out of these 146 students, were selected
randomly and distributed to have equal number of subjects in
different groups as mentioned below:

**Comparison of six different groups during pre-test and post-test**

As mention in the description of the sample as given below this:

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Keeping in view the objectives and hypotheses of the current
study, the final sample comprised of 120 female married students
suffering from PMDD. 120 female married students were identified
from an initial sample of female married students studying in
collages.

**INCLUSION CRITERIA**

The inclusion criteria for the study were:

1. A woman diagnosed as a sufferer of PMDD matched with DSM-
   IV criteria.
The age range should be from 19 to 30 years.

To have regular menstrual cycles (21-35 days).

A score of 48 to 68 with Daily Symptom Report on the Calendar of Premenstrual Experience (COPE).

Belonging to intact families.

- All groups should be following the same dietary program

EXCLUSION CRITERIA

The exclusion criteria for the study were:

1. Not to be under any kind of treatment whatsoever.
2. Not to be pregnant.
3. Not to have any major psychiatric illness.

Ethical principal of this research is based on the APA rules (APA, 2000). Therefore, only those subjects who were aware of the treatment and its processes were included in this study.

Instruments:

The following instruments were used:

A: Clinical interviews based on DSM-IV-TR criteria for Premenstrual Dysphoric Disorders (PMDD).


PMDD was first described in the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, revised (DSM-III-R), then refined and included in the fourth edition (DSM-IV). (American Psychiatric Association, 1994., Diagnostic and Statistical Manual of Mental Disorders, 1987). According to the DSM-IV criteria, the diagnosis of PMDD requires a woman to have had symptoms for at least a year. Symptoms also must occur during the last week of the...
luteal phase and remit during the follicular phase, as confirmed by Daily Symptom Report on the Calendar (COPE). Ratings during at least two consecutive symptomatic cycles. At least one of the symptoms must be a marked dysphoric mood change, such as depressed mood, hopelessness, anxiety, tension, anger, or irritability. Also, symptoms should not be due to exacerbations of other disorders.

The DSM-IV criteria for PMDD state that symptoms must be sufficiently serious to interfere with a woman’s work, social activities, and interpersonal relationships. Signs of psychosocial impairment include marital discord, parenting difficulties, poor work performance, and increased social isolation (Mortola, 1992).

Women who only experience severe physical symptoms of PMS without accompanying mood symptoms do not meet the criteria for PMDD, even though they also may experience psychosocial impairment (Mortola, 1992).

2- Daily Symptom Report on the Calendar of Premenstrual Experience (COPE):

Several diagnostic tools have been validated for diagnosing premenstrual syndrome (PMS) and premenstrual dysphoric disorder (PMDD). The Calendar of Premenstrual Experiences (COPE) is a symptom calendar that allows women to rate physical and behavioral symptoms on a 4-point Likert scale. The COPE was first introduced in Mortola et al., (1999). To establish a quantitative method for the diagnosis of premenstrual syndrome (PMS), a simple prospective inventory, the calendar of premenstrual experiences, was constructed. The validity and reliability of this instrument were assessed by administering it throughout two consecutive ovulatory cycles to 36 rigidly screened women with PMS and to 18 controls. To establish concurrent validity, scores on behavioral items were correlated with simultaneously obtained scores on lengthier, well-validated
psychiatric inventories designed to measure depression rather than PMS, the Beck Depression Inventory and the Profile of Mood States. The results showed that the calendar of premenstrual experiences luteal phase score distinguished PMS women from controls correctly in 104 of 108 cycles, with a 2.8% false negative rate and no false positives when used for two consecutive cycles. An upper limit follicular phase score was observed beneath which all PMS and normal control subjects fell, suggesting that a higher score is not consistent with PMS. Correlation coefficients of calendar item scores with Profile of Mood States scale scores were 0.58 for tension, 0.51 for depression, 0.46 for anger, 0.61 for fatigue, and 0.57 for confusion (P<.0001 for all correlations). The correlation of the calendar depression item with the Beck Depression Inventory score was 0.56 (P<.0001). The test-retest reliability of the calendar given in the same phase of two consecutive menstrual cycles was high (r=0.78, P<.0001). This instrument is a valid, reliable, and practical PMS inventory, applicable to clinical and some research settings.

The COPE total scores for the luteal phase needed to exceed 41 and double the follicular phase total scores during each of the 2 consecutive menstrual cycles. In addition, the follicular phase total score could not exceed 40 and the follicular-to-luteal phase increases summed COPE ratings needed to increase by 30% for at least 5 premenstrual symptoms. The primary outcome measure in the study was the COPE (Mortola, 1992). A 22-item patient-rated scale that assesses common behavioral and physical symptoms of PMDD on a 4-point Likert severity scale. The COPE diary is a reliable instrument for identifying fluctuations in behavioral and physical symptoms during the luteal phase, and PMS symptoms can be reliably conceptualized within four factors. Symptom expression may increase in response to daily self-monitoring.
Internal consistency (a) was high (.93-.94) for the COPE total score and behavioral subscale score and moderately high (.79) for the physical subscale score. Test-retest correlations produced lower estimates of reliability (.55-.59). Four factors, accounting for 64% of the total variance, were extracted: mood symptoms, somatic/cognitive symptoms, appetitive symptoms and fluid retention symptoms. Symptom reports increased in consecutive luteal phases for three of the four factors; however, the factor structure remained consistent in consecutive months. The cope diary is a reliable instrument for identifying fluctuations in behavioral and physical symptoms during the luteal phase, and PMS symptoms can be reliably conceptualized within four factors (Feuerstine & Shaw, 2002).

The PMDD criteria of the DSM-IV requires the presence of 5 out of 11 symptoms to make the diagnosis of PMDD. The eleven symptoms are as follows:

1) At least 1 of the first 4 symptoms must occur during the last week of the luteal phase, begin to remit within a few days of the onset of menstrual flow, and be absent in the week after menses.

2) The symptoms must be severe enough to interfere with social, occupational, sexual, or scholastic functioning. Symptoms must be discretely related to the menstrual cycle and must not merely be a worsening of preexisting depression, anxiety, or personality disorder.

3) All of the above criteria must be confirmed prospectively by daily ratings of at least 2 consecutive menstrual cycles. The diagnosis may be made provisionally before this confirmation.

Of the symptoms listed in the DSM-IV, 10 of 11 are emotional and behavioral in nature. Only one includes multiple common physical symptoms. As such, PMDD defines a narrow group of
women with the most severe premenstrual emotional symptoms, with
functional impairment, and without a concurrent axis I or axis II
disorder that is exacerbated premenstrually. Women who meet the
PMDD criteria are coded on axis I as depressive disorder not
otherwise specified. Obviously, this criterion excludes many women
presenting with predominantly physical premenstrual symptoms and
women with premenstrual exacerbation of underlying axis I or II
disorders. Interestingly, DSM-IV criteria state that PMDD may be
superimposed on axis I or II disorders. However, how to differentiate
between exacerbation of and superimposition on symptoms of an
axis I or II disorder is unclear.

Several scoring systems are available for symptom quantification. A recent suggestion is that a within-cycle increase
from follicular to luteal phase score (demonstrating “on-offness”) of at
least 50% is necessary to confirm the diagnosis of PMDD and to
merit psychopharmacologic intervention. The within-cycle
percentage change is calculated by subtracting the follicular
score from the luteal score, divided by the luteal score, and
multiplied by 100.

\[(\text{luteal} - \text{follicular} / \text{luteal}) \times 100\].

More than 60 instruments have been used for symptom recording. A 24-item form called the Daily Record of Severity of
Problems incorporates all DSM-IV symptoms of PMDD. As one may
expect from this large number of instruments, a review of scoring
methods used in most studies failed to identify a uniquely favorable
method (Thwe, 2006).

Methodology:

120 subjects recruited from different university were systematic
order they were assigned in different groups, every groups consisted
of 20 subject. The first group was a control group (waiting List).the
another groups were toga therapy (YT).Cognitive-behavior therapy
Pharmacotherapy (PT), Combination of yoga and CBT and CBT and PT. The PT group referred to psychiatrically. The women fulfilled DSM-IV criteria for PMDD confirmed by daily symptom report on the COPE (Mortola, Beck et al., 1990). This 22-item scale including 22 premenstrual symptoms rated daily throughout the cycle on a four-point scale (0 = not at all, 1 = slightly, 2 = moderately, 3 = severely). Further inclusion criteria were age between 19 and 30 years, not currently taking hormonal or psychotropic medication or experiencing major psychiatric illness, not being pregnant or locating within the previous 12 month, and having regular menstrual cycles (21-35 days). The women completed questionnaires at baseline, 2 months before the start of treatment, and end of treatment (1 month after onset of treatment).

The Treatment Process:

A: The CBT Treatment: The treatment stage of this research began in 2005. Two months for preparing all the paper and getting permission from different university, and using their facilities. Two months for completing daily symptoms report. One month for measuring all scores report by the subject for screening. Two months for treatments. One month interning all the number score preparing the data and fill the statistical program.

The CBT was carried by female clinical psychologist and including relaxation, and Rational Emotive Behavior Therapy (REBT). In addition, it aimed to explore their cognitive appraisal of premenstrual phase and core assumptions that underpinned their premenstrual difficulties such as "I must be perfect" or "I should never be angry."

CBT involved 12 sessions over the 2 months. Each session was for 50 min.

B: Darg therapy (Fluoxetine).

The fluxoetine treatment was administered by female
psychiatric. The fluoxetine treatment consider of 20 mg of fluoxetine daily, for two month.

**C: Yoga therapy:**

The yoga therapy was administered by female yoga therapist. The yoga class was held every day in two different times 9-10 and 10:30 to 11:30 for two months. It aimed to help woman to mange their symptom by learning some asana such as:

Surya namskar, Shavaasana, Halasana, Chakra asana, Bhujanga asana, Butterfly posture, Ardha mastyendra asana, Nadi Shodhana, Dhanurasana, Bidalasana, Santulanasana, Sarvangaasana, Ushtraasana, Comukhasana, Chakrasana, Kandharasana, Saral, Shashankasana, Shashasana, Supta vajrasana, pranayama and simple meditation.

Each yoga session began with 5 minutes of meditation, continued with 40 minutes of asana, and concluded with 10 minutes of pranayama and shava asana.

**All groups should be following the same dietary program such as**

**Foods containing Calcium**

Dairy products, eggs, green leafy vegetables, salmon, sardines, soya beans, nuts, peanuts, tofu, sunflower seeds, seeds, pulses and bread.

**Foods containing Iron**

Oatmeal, pork liver, molasses, beef kidney, asparagus, heart, liver, nuts, beans, shellfish, sardines, wheat germ, whole meal bread, green vegetables, raw clams, oysters, dried peaches, red meat and egg yolks.

**Foods containing Magnesium**

Wheat germ, nuts, almonds, seeds, apples, brewer’s yeast, buckwheat flour, beans, grains, fish, dark green vegetables, meat, figs, lemons, grapefruit, garlic, raisins, green peas, potato skins and crab.
Foods containing vitamin B1

Whole grains, oats, pasta, soy flour, wheat germ beans, peas, meat especially pork and duck, fish and seafood, peanuts, nuts, pulses, Brewer’s yeast, yeast extracts, rice husks, bran, milk and most vegetables

Vitamin B3 (niacin, nicotinic acid) is a water soluble vitamin and is the only vitamin that can be produced by the body via tryptophan. Sources of vitamin B are legumes, peanut butter, whole grain, cereals, seeds, nuts, broccoli, potatoes, tomatoes, avocados, figs, prunes and bananas.

Foods containing Vitamin B6

Whole grains cereals, nuts, meat, oily fish, soy products, egg yolk, royal jelly, yeast, bananas, legumes, potatoes, corn, green vegetables, seeds, wheat germ, avocados, lentils, liver, kidney, cantaloupe, cabbage, milk, beef, turkey, and tuna.

Foods containing vitamin B12

Fish, meat, eggs, dairy, poultry

Foods containing Vitamin C

Citrus fruits, green and red peppers, parsley, broccoli, Brussels sprouts, tomatoes, cabbage, greens, potatoes, yams, cauliflower, strawberries, melons, guava, mangoes and papaya.

Foods containing Calcium

Dairy products, eggs, green leafy vegetables, salmon, sardines, soya beans, nuts, peanuts, tofu, sunflower seeds, seeds, pulses and bread.

The Data analysis

The data were analyses by making use of t-test of significance. Process variable, will be examined using measures by applying the SPSS, version16. The research plan, as an experimental plan, included CBT, Fluoxetine, Yoga, CBT&Yoga; Fluoxetine& CBT.