The Efficacy of Traditional Chinese Medicine on Reducing Premenstrual Syndrome and Premenstrual Dysphoric Disorder.

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Abstract

This research synthesis assessed the effectiveness of Traditional Chinese Medicine (TCM) reducing symptoms of Premenstrual Syndrome and Premenstrual Dysphoric Disorder. Thirty-one articles and 7 studies summarized in textbooks were reviewed and organized into a chart. The topics included in this synthesis relate to PMS, PMDD, dysmenorrhea, low back pain, Major Depressive Disorder, and migraine prophylaxis. In the studies reviewed, the following acupuncture points were most commonly chosen for PMS treatment: SP 6 (82% of treatments), Ren 2, 3, 4, or 6 (64%), LV 3 (55%), DU 20 (45%), and LI 4 (27%). Two of the textbooks had 7 CHM studies or trials on PMS, breast distention, headache, depression, and insomnia. Those 7 studies totaled 302 females treated with CHM. The averaged improvement of the combined 5 trials was 95.6% improvement. The results of 30 PMS studies utilizing CHM on 861 patients was 651 (75.6%) full recovery, 177 (20.6%) some effect and 33 (3.8%) no effect. In a 6 month trial of CHM 81% of participants who were originally diagnosed with PMDD no longer fit the criteria of the DSM-V. In a 6 month trial of acupuncture a 76% reduction in PMS was the outcome. Four trials of acupuncture versus a control group (sham or medication) consistently showed a 30% higher success rate compared to the control. In a PMDD trial, acupuncture was 38% more efficient at reducing anxiety than sham acupuncture, and 31% more effective in reducing depression (based off pre and post HAM-A and HAM-D scores). Based on the results reviewed, TCM does reduce unpleasant cyclic symptoms during the luteal phase. Therefore, TCM is an effective treatment that may be considered for PMS and PMDD. A weakness of the current research reviewed was that acupuncture and Chinese Herbal Medicine (CHM) were assessed individually. Further research of TCM (acupuncture and CHM combined) should be conducted on symptom reduction of PMS and PMDD.
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Chapter One: Introduction

Premenstrual Syndrome consists of emotional/mood and physical symptoms that appear during the luteal phase of the menstrual cycle and abate within a few days of menstruation occurring. The more severe version, Premenstrual Dysphoric Disorder, needs to be diagnosed according to the DSM-V criteria to rule out any other conditions (Gallenberg, 2012). Both disorders are cyclic in nature, and affect reproductive aged females, 15-49 (World Health Organization, 2015). PMS is more common in women who have given birth to at least one child and have a history of depression or mood disorders (Office on Women’s Health, U.S. Department of Health and Human Services, 2012). If not treated it could remain the same or worsen, and interfere with daily activities, work and relationships.

My personal interest in PMS developed after treating multiple patients for the symptoms associated with PMS. Most people expect PMS to occur, and think this is a normal part of “that time of the month”. PMS physically affects only women, but it may affect exogenous relationships as well. PMDD can interfere with daily living, whether it is social activities, work or relationships. Observing reduction and alleviation in my clinical practice prompted me to seek scientific information to substantiate effective treatments for PMS and PMDD using Traditional Chinese Medicine.

Glossary of Relevant Terms

Abbreviations:

ACU: Acupuncture

CHM: Chinese Herbal Medicine

COPE: Calendar of Premenstrual Experiences

DSM-V: Diagnostic and Statistical Manual of Mental Disorders, 5th edition
**OCP’s:** Oral Contraceptive Pills

**PMDD:** Premenstrual Dysphoric Disorder

**PMS:** Premenstrual Syndrome

**RCTs:** Randomized Controlled Trial

**SSRI:** Selective Serotonin Reuptake Inhibitors

**TCM:** Traditional Chinese Medicine

**Definitions:**

**Acupuncture:** Traditional Acupuncture involves stimulation with very fine needles inserted into defined sites on the body to achieve balance (Mayo Clinic, 2015).

**Affective symptoms:** Present as behavioral or mood symptoms e.g. depression, angry outbursts, irritability, confusion, social withdrawal, fatigue (Fritz & Speroff, 2011).

**Dysmenorrhea:** Pain, typically cramping in nature, presenting in the lower abdomen during menstruation (Fritz & Speroff, 2011).

**Dysphoric mood:** A state of feeling unwell, unhappy, and dissatisfied with life.

**DSM-V:** A manual to diagnose mental disorders.

**Follicular phase:** This phase is from day one of menstruation until ovulation occurs. Premenstrual symptoms should reduce within the first few days of menstruation.

**Luteal phase:** This phase is from ovulation until the first day of the menstrual cycle. Premenstrual symptoms occur during this phase.

**Premenstrual Dysphoric Disorder:** A recurring cyclic cluster of predominately behavioral symptoms developing 7-14 days prior to menstruation (during the luteal phase) and dissipating when menstruation or the follicular phase begins. Symptoms are only present during the luteal
phase, and cause functional impairment (McPhee & Papadakis, 2010) and must be diagnosed according to the DSM-V (Fritz & Speroff, 2011).

**Premenstrual Syndrome:** A Recurring cyclic cluster of physical and behavioral symptoms developing 7-14 days prior to menstruation (during the luteal phase) and dissipating when menstruation or the follicular phase begins. Symptoms are only present during the luteal phase (McPhee & Papadakis, 2010).

**Qi:** Is the life force that flows throughout the organ systems of the body, and is a fundamental substance that helps maintain activities in the body. It’s the foundation for the zang-fu (organs) and meridians (acupuncture points are located on these) (Cheng & Deng, 1999).

**Somatic symptoms:** Present as physical symptoms e.g. breast tenderness, abdominal bloating, headache, swollen extremities (Fritz & Speroff, 2011).

**Chapter Two: Literature Review**

**Overview:**

This chapter will review and analyze studies conducted on Premenstrual Syndrome (PMS) and Premenstrual Dysphoric Disorder (PMDD) and the effectiveness of TCM in reducing the symptoms associated with PMS and PMDD. PMS and PMDD can have psychological and physical symptoms occurring before and during menstruation including: acne, headaches, fever, body pain, edema, abdominal pain and bloating, abdominal cramps, diarrhea, nausea, dizziness, abnormal emotional changes, anxiety, breast tenderness, irritability, anger outbursts, self esteem issues, decreased quality of life or sense of wellbeing (Biggs & Demuth, 2011; Dickerson, Mazyck, & Hunter, 2003; Qiao et al., 2012; Yonkers, O'Brien & Eriksson, 2008). “Premenstrual Syndrome refers to a collection of cyclical physical and/or
psychological symptoms that appear during the late luteal phase of the menstrual cycle,” Zhou & Qu (2009).

**Resources:**

Research Synthesis data was compiled through the extraction of data from: published books, Yo San library resources, and online searches of medical journals, Pubmed, EBSCO host, and Google Scholar. Search words used included: acupuncture, acupuncture and PMS, acupuncture and PMDD, PMS and Chinese herbs, Traditional Chinese Medicine, Traditional Oriental Medicine, mood disorders, and acupuncture side effects. This researcher found few articles regarding the treatment of PMS and PMDD treated by acupuncture and/or CHM. The search was expanded to include symptoms of both disorders as search words to gather more data.

“Headaches and acupuncture”, “acne and acupuncture”, “nausea and acupuncture” are examples of expanded search terms to broaden the data collections since PMS and PMDD singularly were too limited. Searches for acupuncture and herbal medicine articles on PMS and PMDD resulted in very few articles being identified. This researcher therefore expanded the search to include associated symptoms of both syndromes.

**Menstrual cycle synopsis:**

A menstrual cycle’s length can vary between 21 and 35 days with an average cycle length of 28 days. Day one of the menstrual cycle begins on the first day of menstrual bleeding, which typically lasts for three to five days. PMS or PMDD symptoms can occur seven to fourteen days prior to day one of bleeding. There are four phases of the menstrual cycle: follicular, ovulatory, secretory, and luteal. This cycle is hormone driven. The hypothalamus produces follicle stimulating hormone releasing factor (FSH-RF). The messenger, FSH-RF, is a
chemical that travels to the anterior pituitary and stimulates the release of follicle stimulating hormone (FSH). A small amount of lutenizing hormone (LH) is also released from the pituitary, and is needed to mature the follicles. When one of the follicles is “mature” it bursts open and typically one egg is released from the ovary, and travels into the fallopian tube to await fertilization. The LH surge triggers ovulation on approximately day 14, in an average length cycle. The ovaries, an endocrine gland, secrete estrogen and progesterone to help thicken and maintain the thickness of the uterine lining. The leftover remains of the burst follicle then become the corpus luteum, which secretes its’ own progesterone as well to prepare for possible fertilization. The corpus luteum remains in the ovaries. If fertilization occurs the corpus luteum has a life span of about ten weeks after ovulation, then the placenta takes over progesterone production. If no fertilization occurs, the corpus luteum decays after twelve to fourteen days. Progesterone levels drop signaling menstruation to occur, the shedding of the uterine lining (Flaws, 2005).

**PMS and PMDD Diagnosis & Differentiation:**

PMS is a multifaceted disorder and considered a diagnosis of exclusion, having in surplus of over 200 possible symptoms that reproductive aged women can experience (Dickerson et al., 2003). The World Health Organization (2015) notes that reproductive aged females are from 15-49 years of age. Sources vary in the percentage of women affected by PMS (either experiencing one to numerous symptoms). Seventy five to eighty five percent of women experience PMS in the luteal phase of their menstrual cycle, and then have a decrease in these symptoms a few days after the onset of the follicular phase (Dickerson et al., 2003; Zaafrane, Faleh, Melki, Sakouhi, & Gaha, 2007). The etiology of PMS is still unknown, and there is no specific test that can be conducted to substantiate a diagnosis of PMS. Blood work can be
completed to rule out thyroid disorders, anemia, or electrolyte imbalance as the etiology for the present symptoms (Association of Reproductive Health Professionals, 2008). It is important to rule out any other medical disorder, disease, or differential diagnoses that are continuously present and not only in the luteal phase. Keep a symptom journal or calendar for one to three months to be sure the symptoms are cyclic (coinciding with multiple menstrual cycles), and/or cause impairment or interfere in the life of the patient (Dickerson et al., 2003; Zaafrane et al., 2007).

The American College of Obstetricians and Gynecologists (2000) listed the following diagnostic criteria for PMS. One affective and one somatic symptom must be experienced five days prior to menses and be present in three consecutive menstrual cycles. The symptoms must abate within four days of menstruation and not reoccur until day 13 or later of the cycle. These symptoms are existent in the privation of alcohol, drugs, hormones and pharmaceutical treatments. The patient must also experience a disruption in their daily life (social, relationships, work, etc). Affective symptoms experienced during PMS are: depression, angry outbursts, irritability, anxiety, confusion, and social withdrawal. Somatic symptoms experienced during PMS are breast tenderness, abdominal bloating, headache and swelling of extremities.

The Calendar of Premenstrual Experiences (COPE) is a quantitative and reliable method to assist in finalizing the diagnosis and treatment approach. Mortola, Girton, Beck & Yen, (1990) found the following:

The results showed that the calendar of premenstrual experiences luteal phase score distinguished PMS women from controls [women without PMS] correctly in 104 of 108 cycles, with a 2.8 % false negative rate and no false positives when used for two consecutive cycles.
PMS should not be mistaken for PMDD. There are similarities in the symptoms but the severity is significantly increased in PMDD (Biggs & Demuth, 2011).

PMDD is a more severe form of PMS that has the potential to be debilitating, and interfere with quality of life, relationships, and jobs. A smaller percentage of premenopausal women, 3-8%, are affected by PMDD in comparison to PMS, 75-85% (Biggs & Demuth, 2011; Luisi, & Pawasauskas, 2003; Yonkers et al., 2008). According to the current version of the Diagnostic and Statistical Manual of Mental Disorders (5th ed., text rev.; DSM-V-TR; American Psychiatric Association, 2013) the following research criteria is needed for a diagnosis of Premenstrual Dysphoric Disorder:

A. In most menstrual cycles during the past year, five (or more) of the following symptoms were present for most of the time during the last week of the luteal phase, began to remit within a few days after the onset of the follicular phase, and were absent in the week after menses, with at least one of the symptoms being 1, 2, 3, or 4:

1. Markedly depressed mood, feelings of hopelessness, or self depreciating thoughts
2. Marked anxiety, tension, or feelings of being “keyed up” or “on edge”
3. Marked affective lability (e.g., feeling suddenly sad or tearful or increased sensitivity to rejection)
4. Persistent and marked anger or irritability, or increased interpersonal conflicts
5. Decreased interest in usual activities (e.g., work, school, friends, hobbies)
6. Subjective sense of difficulty in concentrating
7. Lethargy, easy fatigability, or marked lack of energy
8. Marked change in appetite, overeating, or specific food cravings
9. Hypersomnia or insomnia

10. A subjective sense of being overwhelmed or out of control

11. Other physical symptoms, such as breast tenderness or swelling, headaches, joint or muscle pain, a sensation of “bloating” or weight gain

NOTE: In menstruating females, the luteal phase corresponds with the period between ovulation and the onset of menses, and the follicular phase begins with menses. In nonmenstruating females (e.g., those who have had a hysterectomy), determining the timing of the luteal and follicular phases may require measurement of circulating reproductive hormones.

B. The disturbance markedly interferes with work or school, or with social activities and relationships with others (e.g., avoidance of social activities, decreased productivity, and efficiency at work or school).

C. The disturbance is not merely an exacerbation of the symptoms of another disorder, such as major depressive disorder, dysthymic disorder or a personality disorder (although it may be superimposed on any of these disorders).

D. Criteria A, B, and C must be confirmed by prospective daily ratings during at least two consecutive symptomatic cycles. (The diagnosis may be made provisionally before this confirmation.)

E. The symptoms are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication or other treatment) or a general medical condition (e.g., hyperthyroidism).

F. In oral contraceptives users, a diagnosis of Premenstrual Dysphoric Disorder should not be made unless the premenstrual symptoms are reported to be present, and as severe,
when the woman is not taking the oral contraceptive.

The American Psychiatric Association utilizes the DSM-V for a diagnosis of PMDD, and for exclusion of other possible diagnoses that PMDD could be confused with. The Daily Record of Severity of Problems can be utilized for diagnosis of PMDD. Established from the DSM-IV in the year 2000, this diagnostic tool is still utilized today (Biggs & Demuth, 2011). Speculative etiologies of PMS and PMDD are expansive and lacking in substantiation. Since the epidemiology of PMS and PMDD are not fully identified or understood, hypothetical postulations and implications of continued research have deduced the subsequent possibilities: genetic factors, sensitivities to the decrease and increase of progesterone (pre and post ovulatory respectively), rise in estrogen pre-ovulation, increased aldosterone and plasma renin activity, deficiencies of prostaglandins, hypoglycemia, nutritional deficiencies, and imbalance of various neurotransmitters (serotonin and GABA) (Association of Reproductive Health Professionals, 2008; Bhatia & Bhatia, 2002; Biggs & Demuth, 2011; Dickerson et al., 2003; Luisi, & Pawasauskas, 2003; Yonkers et al., 2008; Zaafrane et al., 2007). Bhatia and Bhatia, 2002, reported,

Biologic, psychologic, environmental and social factors all seem to play a part [in PMDD]. Genetic factors are also pertinent: 70 percent of women whose mothers have been affected by PMS have PMS themselves, compared with 37 percent of women whose mothers have not been affected.”

Additionally the Association of Reproductive Health Professionals (2008) states that a higher occurrence of PMS is probable in women with the following: had one live birth, experienced postpartum depression or possible mood disorders, advanced reproductive age, and familial
history of depression.

This researcher wants to clarify that a diagnosis of PMS/PMDD is not the same as dysmenorrhea. “Dysmenorrhea is one of the most common menstrual disorders directly influencing a woman’s quality of life. Dysmenorrhea refers to lower abdominal pain or other discomforts before, during or after menstruation,” Zhou & Qu (2009). PMS and PMDD are experienced cyclically during the luteal phase, and the symptoms decrease with the onset of menses or the follicular phase. Dysmenorrhea is only a physical symptom, and PMS is physical and emotional (Fritz & Speroff, 2011; McPhee & Papadakis, 2010). For a diagnosis of PMS, affective and somatic symptoms must be present. PMDD diagnosis requires affective symptoms only, but somatic symptoms can also exist (Fritz & Speroff, 2011).

**PMS and PMDD Western Treatments**

Non-pharmacologic interventions are utilized initially if possible, unless the PMS or PMDD is severe enough and requires pharmaceuticals immediately. Some physicians start with lifestyle changes and recommend regularly exercising, eating small carbohydrate meals throughout the day and decreasing intake of caffeine, sodium, and refined sugar (Biggs & Demuth, 2011; Gallenberg 2008; Yonkers et al., 2008).

Nutritional supplementation and herbal or botanical remedies have also been utilized. Success in treatment is not thoroughly researched, and yields inconsistent results due to study design, clinical trial size, etc (Dickerson et al., 2003). The U.S. Food and Drug Administration (FDA) has not approved chasteberry and evening primrose oil for PMDD (Bhatia & Bhatia, 2002).

Oral contraceptives (OCPs) are utilized, ceasing ovulation and thereby decreasing fluctuations of gonadal hormones (progesterone and estrogen) (Gallenberg, 2008; Yonkers et
al., 2008). OCPs are frequently used for treatment, yet they can exacerbate the same symptoms hoping to be alleviated. Consistently reliable results from OCPs are not yet attainable (Bhatia & Bhatia, 2002; Dickerson et al., 2003).

Selective Serotonin Reuptake Inhibitors (SSRIs) are recognized as a safe first drug of choice when it comes to pharmaceutical treatment for PMS and PMDD (Bhatia & Bhatia, 2002; Dickerson et al., 2003; Yonkers et al., 2008). FDA approval is only for fluoxetine (Prozac) and sertraline (Zoloft) as SSRIs for treatment of PMDD (Bhatia & Bhatia, 2002; Dickerson et al., 2003). Steiner et al., (1995) accomplished a multicenter, randomized, double blind, placebo-controlled trial assessing safety and effectiveness of fluoxetine treatment in females experiencing premenstrual dysphoria. Differentiation of findings among the three groups was measured by either moderate or marked improvement. Moderate improvement was 50% from baseline and marked was 75%. Within the first of six cycles both fluoxetine factions were moderately improved (at least 50%), and the placebo group was only 22% improved. Steiner et al., (1995) found that dosing fluoxetine at 20mg a day was tolerated with minimal side effects compared to the dose of 60 mg daily. Thirty three percent of the women in the 60 mg group discontinued treatment because of the side effects. The exact side effects experienced in the 60mg group were not expounded upon. Twenty six percent discontinued placebo treatment due to lack of results. Therefore the dose of 20 mg was concluded to be the most effective, with minimal side effects and most marked improvement in the symptoms of tension, irritability, and dysphoria (Steiner et al., 1995). PMS treatment with SSRIs found participants to have a faster response time compared to participants receiving SSRI treatment for depression who had a longer response time. Depression symptoms required approximately one month to show signs of improvement (the time frame for PMS improvement was not specifically noted) (Biggs &
Demuth (2011). Reed et al., (2008) conducted a study with 29 reproductive aged females, having normal menstrual cycles. The control was 15 females without PMDD and the remaining 14 met the criteria of DSM-IV for PMDD. Reed et al., summarized the results of the study:

…Women with PMDD experience dysphoric mood, a greater desire and actual intake of certain foods and show impaired cognitive performance during the luteal phase. An altered serotonergic system in women with PMDD may be the underlying mechanism for the observed symptoms; correspondingly, treatment with specific serotonin reuptake inhibitors (SSRIs) remains the preferred treatment at this time.

Luisi & Pawasauskas (2003) concluded that SSRIs improved patient quality of life, and specifically improved behavioral and psychological symptoms. The aforementioned researchers also noted certain common side effects: “headache, fatigue, insomnia, and anxiety…a decrease in libido or sexual dysfunction was also reported.” SSRI treatment as intermittent therapy is optimal (taking the drug during the luteal phase), and preferred over continuous daily dosing (Luisi & Pawasauskas, 2003).

Some last resort and controversial options are gonadotropin-releasing hormone agonist (GnrH) and Danazol. The possible side effects dampen the likelihood of these medications being used in replacement of SSRIs. Danazol may cause masculinization (due to the androgenic properties), increased appetite for sweets and weight gain (Bhatia & Bhatia, 2002; Reed, Levin, & Evans, 2008). “However these medications [referring to hormonal therapies, such as GnRH agonists] can induce menopausal symptoms such as hot flushes, vaginal dryness, fatigue, irritability, cardiac problems, and osteopenia,” reported Bhatia and Bhatia (2002). GnRH cannot safely be used long term due to the side effects (Biggs & Demuth, 2011).
Lastly, if all of these options are exhausted, a hysterectomy (removal of uterus) with a bilateral oophorectomy (removal of ovaries) may be considered. Surgical risks, adverse effects, and irreversibility make surgery the least appealing. Therefore other gynecological symptoms (not including PMS/PMDD) typically are present along with poor response to previous treatment methods for PMS/PMDD (Dickerson et al., 2003).

PMS Diagnosis from TCM Perspective

Finding the origin of each individual’s cause of PMS is not the objective in Western treatment, but to treat symptomatically and control or abate the present symptoms (Biggs & Demuth, 2011). In contrast, TCM employs the method of treating not only the symptoms or “branch”, but also the underlying pathology or “root” cause. Symptomatic relief is just one aspect of the solution to care, and TCM attempts to encompass all aspects of the disorder (Zhou & Qu, 2009).

TCM treats the branch, root, and possibly averts any potential new diseases or symptoms (Zhou & Qu, 2009). The importance of treating the root is to improve the current health of the patient, not just mask present symptoms. The future health of the patient should be of vital importance, and correcting problems now will hopefully prevent or decrease possible problems later in life. The United Nations has a document entitled *Guidelines on Reproductive Health* (n.d. para 5) prepared by the Secretariat of the United Nations Inter-Agency Task Force. The document states:

At each stage of life individual needs differ. However, there is a cumulative effect across
the life course of events at each phase having important implications for future well-being. Failure to deal with reproductive health problems at any stage in life sets the scene for later health and developmental problems.

Traditional Chinese Medicine diagnosis is based on many signs and symptoms as well as the evaluation of the pulse, and the presentation of the tongue. Color, coat, veins, cracks, teeth marks, thickness, and the thinness of the tongue are evaluated. These signs assist the practitioner to determine the diagnostic pattern or condition the patient is experiencing. TCM patterns can be broken down into four basic divisions: interior or exterior, hot or cold, deficient or excess, and yin or yang. An overall evaluation of the chief complaint, presenting symptoms, tongue and pulse, and any other information pertinent at that time are considered when determining the diagnostic pattern. The treatment plan is based on the pattern diagnosis (Cheng & Deng, 1999).

The earliest documented discussion of PMS in Chinese medical records is the Appendix of Dan-Xi’s Experimental Methods from the Ming Dynasty (1368-1644 AD). Fang expounded that delineation of chronic feverish sensation versus feverish sensations connected to the menstrual cycle needs to be clearly separated (Zhou & Qu, 2009). During the Qing Dynasty (1644-1911) up to 22 premenstrual symptoms were noted according to Chou & Morse (2005) and Zhou & Qu (2009), “edema, feverish sensation, pain in the hypochondrium, diarrhea, body aches, abdominal cramps, and reduced appetite”. The most common TCM pattern in regards to PMS is Liver Qi stagnation. Liver Qi stagnation has the ability to lead to fire or heat symptoms, or invasion of the Liver into the Spleen or Stomach (Chou & Morse, 2005; Zhou & Qu, 2009; Jang, Dong & Choi, 2014.) Chou & Morse (2005) reference Gao & Chen (1994) and their 10
year summary of categorized journal papers to show that the most diagnosed pattern was not only Liver Qi Stagnation, but also Liver and Kidney yin xu. Zhou & Qu (2009) list the common symptoms during menstruation “headache, fever, body pain, edema, diarrhea, dizziness, abnormal emotional changes” as stemming from a Liver (LV) etiology (with involvement of Heart, Spleen, and Kidney).

The liver is meant to flourish and be unfettered, allowing for free flow and movement of Qi for itself and the remaining zangfu. The liver stores blood and controls the regulation of it. A deficiency of Liver blood can be a possible etiology of liver qi stagnation, the number one cause of PMS in TCM. The liver also has roles in: digestion, emotional activity, vision, tendons, and finger nail health (Cheng & Deng, 1999).

Maciocia (2005) categorizes the possible liver patterns seen in patients; these three would be possible PMS/PMDD diagnosis: Liver Qi Stagnation, Stagnant Liver Qi turning into heat, and Rebellious Liver Qi.

Liver Qi Stagnation Clinical Manifestations, according to Maciocia (2005):

- Feeling of distention of hypochondrium, chest, epigastrium or abdomen, sighing.
- Melancholy, depression, moodiness, fluctuation of mental state, ‘feeling wound-up’, feeling of a lump in the throat.
- Irregular periods, distention of breasts before the periods, premenstrual tension and irritability.

The symptom breakdown allows for a visual aid of how encompassing the symptoms can be by affecting (1) physical body/symptoms, (2) emotional manifestations, and (3) internalization of LV Qi causing stagnation disrupting menstruation via the Ren and Chong meridians. Feeling of
distention is what most people describe as bloating, and a common complaint prior to the onset of menses. The main etiology for a diagnosis of Liver Qi Stagnation is emotional based: frustration, anger, and pent up emotions not being processed properly lead to stuck Qi or stagnation. Emotions can be compared to a beaver and can build a dam in the river, blocking or decreasing the flow of the water. When the blockage becomes larger than what the body can handle greater disruptions or symptoms start to emerge. Predominantly heat signs begin to appear and the diagnosis of Stagnant Liver Qi turning into heat would be given. The tongue, pulse, and reported signs and symptoms allow for the practitioner to assess the degree of stagnation, underlying root etiology, treatment plan to most efficiently resolve it, and decrease or prevent future problems that could surface.

Tongue: normal, possibly red. Pulse: wiry, especially on left (L).

Liver Qi Stagnation point prescription is GB 34, LV 3, 13,14, SJ 6 and PC 6. Herbal formula recommendations are Yue Ju Wan (stagnation is root) and Xiao Yao San (stagnation preceded by LV blood deficiency).

In the second diagnosis, if stagnation and heat are also present, in addition to the base clinical manifestations of LV Qi stagnation, the following symptoms “feeling of heat, red face, thirst, propensity to anger outburst, and heavy periods,” (Maciocia, 2005) also manifest simultaneously with LV Qi symptoms. The etiology for Stagnant Liver Qi turning into heat is consistent with LV Qi stagnation, but does not have indications of possible deficiency. Excess root cause predominates for this pattern.

Tongue: red on sides. Pulse: Wiry, especially on (L), slightly rapid.
Stagnant Liver Qi turning into heat point prescription adds LV 2 to the base treatment for LV Qi Stagnation. The formula Dan Zhi Xiao Yao San (base formula Xiao Yao San from LV Qi Stagnation with addition of Mu Dan Pi and Zhi Zi) is used.

In the third diagnosis, Rebellious Liver Qi, emotional symptoms decrease and digestive symptoms are more pronounced due to the lateral movement/invasion of LV into SP and disruption of descending Stomach Qi. Breast distention (a common PMS presentation) could be present from the LV qi rebelling towards the chest and therefore affecting the breast. Tongue: similar to Liver Qi stagnation, possibly red on sides if more severe. Pulse: pronounced wiry on LV and ST positions (R Guan & L Guan) Point prescription: LV Qi Stagnation point prescription minus LV 13, with the addition of LI 4, ST 21 and 19. Chai Hu Shu Gan Tang, Yi Gan San and Si Ni San are possible herbal formulas (Maciocia, 2005).

Amelioration of symptoms is the principle goal upon the beginning of treatment, but the underlying cause is not ignored. Depending on the approach of the practitioner, the root cause is usually addressed in conjunction with the branch treatment. The focus of the treatment shifting from branch to root is dependent on the etiology of the diagnosis and the practitioner’s treatment principle. The tongue and pulse diagnostic tool is also implemented to further deduce the pattern presenting at the current time (Zhou & Qu, 2009).

**Acupuncture and PMS/PMDD (supporting studies)**

Acupuncture is the placement of a sterile needle into an exact anatomical location, measured by cun, causing penetration of the skin and stimulation of de qi (energy). The sensory receptors are stimulated via the needle and transmit the message to the brain and impact the body allowing for homeostasis (Singh et al., 2005). Fabiana et al., (2013) explain it thusly:

Acupuncture’s action is based on the activation of afferent A and C fibres in the muscles
that transmit signals, via dorsal horn neurons, to the higher centres in the brain, 
stimulating the release of endogenous neurotransmitters, such as opioid peptides and 
4serotonin (5-hydroxytryptamine, 5-HT).

The following acupuncture section is broken down into trials that demonstrate the effectiveness 
in treating symptoms that could appear in the luteal phase. These trials were conducted in 
regards to PMS, but their results show that acupuncture is successful. Therefore it can by 
hypothesized that acupuncture based off the following results would be able to reduce PMS 
symptomology as well.

Dysmenorrhea, pain in the lower abdominal region, can negatively impact quality of life 
and daily tasks. Stresses can intensify how sensitive a body is to pain by activating sympathetic 
responses and inhibiting parasympathetic responses (Wang, Hsu, Yeh & Lin, 2013). Wang et al., (2013) state:

Stress and pain both activate the sympathetic nervous system to release epinephrine and 
norepinephrine, which increases heart rate (HR), cardiac contractility, vascular smooth 
muscle contraction, and blood pressure. At the same time, stress and pain reduce 
activation of the parasympathetic nervous system (PNS) responses.

Acupuncture encourages homeostasis to occur resulting in a balance between the 
parasympathetic and sympathetic system. Auricular acupressure could possibly stimulate the 
auricular branch of the vagus nerve. Thereby, possibly allowing for an increase in 
parasympathetic activity, affecting both autonomic and central nervous system activity (Wang et al., 2013). Auricular acupressure was conducted during one menstrual cycle on 32 women, 
and the results showed that in a high stress life this treatment increases parasympathetic activity 
possibly reducing menstrual pain. This one group experimental trial needs to be retested in a
larger trial with clear parameters of the goals of the trial, and for a longer duration allowing for more interpretive results. In another trial, SP 6 was stimulated with electro-superficial acupuncture and superficial acupuncture for dysmenorrhea. Needling at this acupuncture point was more effective than Brufen for analgesic effects (no further details were documented on the specific aspects of the trial) (Zhou & Qu, 2009). The Affiliated Hospital of Hubei College of Medicine and Pharmacy divided 90 women into Group 1 and Group 2 for a three-month trial on menstrual pain and cramps. Daily treatment started one week prior to menstruation and ended with commencement of menstrual flow, for a total of six treatments per cycle. Three cycles were completed, 18 treatments in total. Group 1 had acupuncture, herbal hot compresses and moxibustion administered to them. Group 2 received 300 mg of ibuprofen three times daily. Both groups were given dietary recommendations of increasing fruits and vegetables, and strictly limiting raw, cold and pungent foods. The results showed that acupuncture was more effective than ibuprofen at pain relief (Acupuncture & herbs best drugs for menstrual pain and cramps, 2014; Smith & Carmady, 2010). The acupuncture points SP 6, ST 36, REN 4, REN 6 were used. For excess conditions LV 3 and SP 8 were additionally used, and for deficiency SP 10 and UB 17 were included. Needle retention time was 30 minutes. Dan Shen, Yan Hu Suo and Yi Mu Cao were used in the 15 minute herbal compress over the umbilical and lower abdominal region. No other details were documented for group allocation, adverse reactions in the two groups, or the researcher who conducted the trial. The results were very positive for acupuncture being more effective than ibuprofen, but a larger randomized controlled trial needs to be conducted to better confirm these results. Due to conventional treatments failing 20-25% in treatment of primary dysmenorrhea or being poorly tolerated by women an option for treatment could be acupuncture and CHM (Zhou & QU, 2009).
Published evidence from a Cochrane system review, in regards to chronic low back pain, determined that, “... acupuncture is more effective for immediate and short term pain relief and functional improvement than no treatment or sham treatment,” Kelly (2009). This meta analysis results presented acupuncture as an effective modality for chronic low back pain, but could not determine that it was more efficient than other active therapies (Kelly, 2009). Acupuncture is frequently utilized for chronic musculoskeletal pain, and more evidence from research is amassing in support of TCM treatments (Kelly, 2009).

Kelly (2009) states that individualized treatment for migraine prevention was significantly superior to sham treatment in the first two months of a randomized controlled trial. Another study reported that acupuncture was equal to or more effective than the beta-blocker, metoprolol for migraine prophylaxis (prevention). The trial also stated there were fewer adverse effects from acupuncture than metoprolol. According to the author Rapoport (n.d.) of the American Headache Society metoprolol’s common side effects are lethargy, depression, exercise intolerance, hypotension and sleep disorders. Avoiding use of metoprolol in patients with asthma, diabetes, bradycardia and congestive heart failure is recommended. The National Headache Foundation endorses acupuncture as a treatment option for migraine prophylaxis (Guirguis-Blake, 2010). Patients dealing with a painful condition and unable to take certain medications, or unresponsive to conventional treatment could be candidates for acupuncture. Since it is generally safe and has a low risk of adverse effects (Kelly, 2009).

Blitzer & Atchinson-Nevel (2005) employed acupuncture treatments for Major Depressive Disorder on 25 men and women aged 34-66 years of age. The clinical psychologist screened candidates with the Structured Clinical Interview for DSM-I (SCID) then administered the Beck Depression Inventory (BDI) and the Reynolds Depression Inventory (RDSI). The
SCID is the tool for diagnosing Major Depressive Disorder. BDI and RDSI are self-report measures of severity of depression. RDSI has a very high test-retest consistency (Blitzer & Atchinson-Nevel, 2005). Acupuncture treatments were administered twice a week for the first month, and then once a week the next month equaling 12 treatments. Following the two-month study none of the 25 participants met the criteria of the SCID, therefore were no longer diagnosed as having Major Depressive Disorder. Also the pre and post BDS and RDSI scores were significantly lower. BDS had a pre score of 23.9 and post score of 8.8, a reduction of 37%. RDSI had a pre score of 29.3 and a post score of 11.8, a reduction of 40%. These results support acupuncture as an efficient modality for treating Major Depressive Disorder. Even though credible results were exhibited, a larger sample size should be done in future studies.

**Acupuncture and PMS/PMDD (PMS or PMDD studies)**

A single blind controlled clinical trial on acupuncture treating PMS was completed by Wang (1998), and indicated positive results for reducing symptoms. The trial also exposed a need for further clinical trials (based off the limited follow through of participants at the conclusion). Wang noted that the real weakness in his trial was only three out of twenty six participants completed the follow up menstrual diary for three months following the trial. The menstrual diary (composed of 12 behavioral and 10 physical symptoms) was recorded daily for three months; the participants were then evaluated based off their scores. The scores were tabulated from days three to nine during the follicular phase, and the last seven days of the menstrual cycle during the luteal phase (when symptoms typically are more severe). The menstrual diary allowed the researcher to see if PMS was the correct diagnosis. The luteal phase needed to be two times the score of the follicular phase. The luteal number was required to be at least a score of 42, and the follicular number could be no less than 40 or else it could possibly...
be another disorder. After the researcher evaluated the women with this scoring method, the Calendar of Premenstrual Experiences (COPE), and Basal Body Temperature, 30 were chosen to participate (only 26 completed the trial). These women then continued keeping the menstrual diary daily, and started receiving acupuncture or sham acupuncture two times a week (except for the symptom free days of 5-12). Wang’s trial was a three stage design: three months of tracking symptoms, three months of tracking symptoms while receiving treatment, and three months of tracking symptoms with no treatment. The study was designed to encompass nine months, but technically was only six months due to only 13 participants (12%) completing the last three months. The participants were grouped by age (the age was 24-45), then by TCM diagnosis. The participants were randomly assigned to either the Real Acupuncture Group (RAG) or the Sham Acupuncture Group (SAG). SAG was treated with the same needles, retention time, and practitioner as the RAG. The difference was that no point was chosen on a meridian, so no true acupuncture points were used. When the pre and post mean values were calculated the percentage of improvement in reducing symptoms (from the score at the end of month 3 to the end of month 6) was 23% at the end of two months of treatment and then it decreased to only 10% improvement at the completion for the SAG. The RAG had a reduction of symptoms by 55% at the close of two months of treatment, and at the completion of three months a reduction of 76% was recorded. The researcher stated that behavioral (affective) symptoms improved more than somatic (physical) symptoms. Dysmenorrhea was a common symptom (which is outside the definition of PMS) and improvement was shown in the severity of menstrual cramps, even though it was not the primary focus. A breakdown of individual symptomology improvement in RAG, taken directly from Wang’s Doctoral Dissertation:
A randomized prospective, placebo-controlled trial comprised of 35 women was conducted to evaluate the effectiveness of acupuncture in treating PMS (Habeck et al., 2002). Medication was introduced if PMS symptoms were not eliminated by acupuncture or placebo acupuncture. The participants were randomly divided into two groups: 18 in the acupuncture (AP) group and 17 in the placebo AP group. The AP group received acupuncture on identified therapeutic acupuncture points on the body while the placebo group received acupuncture on areas of the lateral arm and thigh that did not have documented therapeutic AP points. Habeck et al., concluded the following:

<table>
<thead>
<tr>
<th>SYMPTOMS</th>
<th>MEAN 1</th>
<th>MEAN 2</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue</td>
<td>1.70</td>
<td>0.94</td>
<td>45%</td>
</tr>
<tr>
<td>Increased appetite</td>
<td>1.57</td>
<td>0.50</td>
<td>68%</td>
</tr>
<tr>
<td>Emotional over-sensitivity</td>
<td>1.49</td>
<td>0.48</td>
<td>68%</td>
</tr>
<tr>
<td>Irritability</td>
<td>1.44</td>
<td>0.63</td>
<td>56%</td>
</tr>
<tr>
<td>Bloating</td>
<td>1.37</td>
<td>0.67</td>
<td>51%</td>
</tr>
<tr>
<td>Breast tenderness</td>
<td>1.33</td>
<td>0.68</td>
<td>49%</td>
</tr>
<tr>
<td>Mood swings</td>
<td>1.32</td>
<td>0.43</td>
<td>67%</td>
</tr>
<tr>
<td>Anxiety</td>
<td>1.29</td>
<td>0.63</td>
<td>51%</td>
</tr>
<tr>
<td>Expressed anger</td>
<td>1.22</td>
<td>0.48</td>
<td>61%</td>
</tr>
<tr>
<td>Food cravings</td>
<td>1.17</td>
<td>0.52</td>
<td>56%</td>
</tr>
<tr>
<td>Crying easily</td>
<td>1.12</td>
<td>0.37</td>
<td>67%</td>
</tr>
<tr>
<td>Depression</td>
<td>1.12</td>
<td>0.87</td>
<td>32%</td>
</tr>
<tr>
<td>Isolation</td>
<td>1.05</td>
<td>0.27</td>
<td>74%</td>
</tr>
<tr>
<td>Swelling</td>
<td>0.98</td>
<td>0.29</td>
<td>70%</td>
</tr>
<tr>
<td>Forgetfulness</td>
<td>0.91</td>
<td>0.22</td>
<td>76%</td>
</tr>
<tr>
<td>Acne</td>
<td>0.88</td>
<td>0.50</td>
<td>43%</td>
</tr>
<tr>
<td>Headaches</td>
<td>0.66</td>
<td>0.31</td>
<td>53%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>0.38</td>
<td>0.12</td>
<td>68%</td>
</tr>
<tr>
<td>Heart palpitations</td>
<td>0.32</td>
<td>0.08</td>
<td>75%</td>
</tr>
<tr>
<td>Hot flushes</td>
<td>0.23</td>
<td>0.09</td>
<td>61%</td>
</tr>
</tbody>
</table>

*mean 1 = the mean value of the total score pre-treatment
mean 2 = the mean value of the total score post-treatment
# = percentage of symptoms reduced after treatment
The success rate of AP in treating PMS symptoms was 77.8% in the AP group, and 5.9% in the placebo group. The positive influence of AP in treating PMS symptoms can be ascribed to its’ effects on the serotoninergic and opioidergic neurotransmission that modulates various psychosomatic functions. The initial positive results of treating PMS symptoms with a holistic approach are encouraging and AP should be suggested to the patients as a method of treatment.

AP treatments were regarded effective if PMS ceased. Sixty percent of women had PMS presenting with anxiety, mastalgia, insomnia, nausea and gastrointestinal disorders. Forty percent of the females experienced more severe symptoms of headaches, migraines and phobic disorders (Habeck et al., 2002). It is unclear from the article when medication was introduced into the treatment along with AP. This researcher thinks it was after 4 consecutive months of treatment and no improvement (improvement was considered elimination of PMS symptoms).

The number of acupuncture treatments necessary, in the AP group, to relieve symptoms of PMS was 2 treatments for 9 women, 3 treatments for 8 women, and 4 treatments for 1 woman. Four participants in AP group needed medication in addition to AP to experience relief. In the control group (sham AP) the number of sham AP treatments necessary to relieve symptoms of PMS was 2 treatments for 1 woman, 3 treatments for 1 woman, and 4 treatments for 15 women. Additionally 16 women in the sham group needed medication since their PMS was not alleviated by treatment alone. No adverse effects were reported in placebo group; one subcutaneous hematoma occurred in the AP group.

Guo & Ma, (2013) performed a literature review on PMS and discussed that differences in patient outcomes after treatment between the acupuncture and control group may be due to
the low quality of the methodology of the clinical trials reviewed. Reviews frequently did not include important information about study design, randomization, and allocation concealment. These four subsequent trials all show an approximate 30% difference in the success rate of acupuncture versus the control group. Trial one was forty patients divided into two acupuncture groups. The control group was given acupuncture but not based on the proper syndrome differentiation. The acupuncture for group one was based on tonifying SP and soothing LV Qi with HT 7, DU 20, Ren 17, SP 10, LV 3, SP 6, and UB 18. Control acupuncture group was treated with HT 7, DU 20, Ren 17 and not on pattern treatment. After two menstrual cycles of daily acupuncture (treatment days one to fourteen of the cycle) totaling 28 treatments, improvement was 95% in the acupuncture group and 60% in the control acupuncture group. Pattern differentiation may improve success rate. Trial two was 35 patients with PMS receiving treatment fourteen days prior to the onset of menses (day 14) for a continuous ten days at one treatment a day. Trial two was conducted for three menstrual cycles. Medroxyprogesterone acetate tablet along with valium was the treatment for the medication group resulting in a 64.5% improvement after three months. A 91.4% improvement was shown in the acupuncture group with the following treatment: HT 7, REN 17, REN 4, SP 6, PC 6, and LV 3. As soon as De Qi was present the needles were removed on the Back-Shu points of UB 17,18, 20 and 23. Trial three was comprised of 60 patients divided into an acupuncture group and a medroxyprogesterone group. Physical, emotional, and behavior changes were the measurement of how successful the study was. Ninety percent improvement was shown in the acupuncture group, the points were needled towards the next acupuncture point (penetrating technique). DU 8-7 (meaning the needle was threaded from the point DU 8 to the point DU 7), DU 6-5, DU 4-3 was needled. The points comprising the treatment n the UB line: 20-21,18-19,22-23,47-48,49-
50, and 51-52. Oral doses of medroxyprogesterone (exact dose not documented) were given and a 60% improvement was achieved. Three menstrual cycles and 10 acupuncture treatments per cycle were given once daily (which cycle days was not documented). Trial four was scalp acupuncture with electroacupuncture from cycle days 14-28 with three treatments a week. The acupuncture group was 35 participants, and the medication group (oral medroxyprogesterone acetate and valium) was 31 participants. Following the three menstrual cycles of treatment the results were 91.4% improvement for acupuncture and 64.5% for medication group. Guo & Ma’s, (2013) literature review shows promising success with acupuncture (with the proper pattern treatment) for the treatment of PMS. No adverse effects were mentioned in the studies for any of the groups, the medications doses were not mentioned, and needle retention time was not clear in every trial.

Kim, Park, Lee & Lee (2011) reviewed four trials pertaining to acupuncture versus medication therapy in 232 women. Participants received approximately 30 acupuncture treatments, and were compared to women taking progestin. The results between the four trials showed 75% more probable symptom improvement in the acupuncture group versus the medication group. The medication group consisted of the hormone progestin, dosed at 4-6 mg daily and varied between the four trials. Anxiolytics were occasionally taken with the hormone group, but not in consistently in each trial. Due to these findings acupuncture appears to be more effective than progestin alone or progestin combined with anxiolytics in PMS management.

A study (Anil, Peker, Göktaş, Kilic & Erbas, 2011) on eleven women diagnosed with PMS, aged 23-40, were treated for three menstrual cycles. The acupuncture points used were REN 2, REN 6, REN 12, LI 4, LI 11, PC 6, LV 3, SP 6, ST 36 and DU 20. Needle retention,
which phase the treatment was completed in, and possible side effects were not listed. Prior to the first treatment, blood values were done on nitric oxide (Nox), malondialdehyde (MDA), and glutathione (GSH) and repeated at the end of the three months. Nox and GSH showed improvement, but MDA had no change. Myalgia (muscle pain), mastalgia (breast pain), and dysmenorrheal complaints improved the most. Other PMS complaints were reduced or eliminated (Anil et al., 2012).

A systematic review completed by Jang et al., (2014) yielded eight acupuncture and eleven herbal studies. No serious side effects were reported in the interventions. In regards to PMS and PMDD, acupuncture and herbal medicine improved symptoms by at least 50% compared to baseline measures. The acupuncture interventions consistently showed greater improvement than the control groups. The number of acupuncture treatments from the collection of data ranged from a total of two treatments to thirteen treatments per trial. Treatments were employed during luteal and follicular phases. Hand acupuncture, hand moxa, traditional acupuncture, and auricular acupuncture were allowed in the review since the studies utilizing them met the inclusion criteria of diagnosis of PMS or PMDD, randomized controlled clinical trials (RCTs), control groups, and employment of outcome measures. Theoretical methods and case reports were excluded. Blinding for the majorities of the studies was considered poor; no side effects or research bias was documented.

Carvalho et al., (2013) conducted a single blind randomized two-month clinical trial on 26 females between the ages of 20 and 45. These participants were all menstruating regularly in regards to cycle length, and met the DSM-IV criteria for the PMDD diagnosis. A psychologist administered the Hamilton Anxiety Rating Scale and Hamilton Depression Rating Scale pre and post trial. The participants were randomly separated into Group 1 (acupuncture) and Group 2
(sham acupuncture) based upon their order of arrival. The presiding acupuncturist had five plus years of experience. The trial had sixteen visits total, two times per week for two menstrual cycles. Improvement was exhibited in both groups, yet substantially higher success in Group 1 (acupuncture). The HAM-A % decrease in-group 1 was 59%; HAM-D % decrease score in-group 1 was 52%. Therefore the acupuncture group presented with at least 50% improvement using specific acupuncture points (PC6, SJ5, LI4, SP6, GB 34, LV3). These points were needled with a .20x40mm needle bilaterally for a retention time of 30 minutes. Group 2 or sham acupuncture group had the needle inserted and quickly removed and left in the foam cube for the remainder of the treatment. Sham acupuncture was performed 2 cm from the anatomical acupuncture points mentioned previously. Both groups used foam cubes to “blind” the participants as to whether or not they were receiving an authentic acupuncture treatment. The HAM-A % decrease in-group 2 was 21%; HAM-D % decrease score in-group 2 was 19%.

“Sham treatments often have been criticized as being too similar to actual treatment…this suggests the possibility of a nonspecific needling effect,” Kelly (2009). Kelly’s explanation of sham could explain why the results of sham acupuncture though lower than actual acupuncture still positively affect the body.

Ernst, Strzyz, & Hagmeister (2003) completed a study of 3,535 acupuncture visits, the total from the combined number of treatments of 409 patients. Adverse effects were observed in 402 of these treatments (11.4%). Adverse effects ranged from a hematoma to dizziness. Less than 1% reported worsening of pain, fainting, parathesia of limbs, and nausea. One case of aphasia was reported, and lasted an hour before it wore off. Severe side effects were not listed since none were present. “Acupuncture has adverse effects, like any therapeutic approach. If it is used according to established safety rules and carefully at appropriate anatomic regions, it is a
safe treatment method,” (Ernst, Strzyz, & Hagmeister, 2003). Thirteen general practitioners (not stated if licensed acupuncturist), and 16 other (no description) practitioners were included in the survey for the study. The adverse effects mentioned above are mild in comparison to possible ones from Western treatment (see the above section of PMS and PMDD Western Treatment for a list of adverse effects). Kelly (2009) comes to the same conclusion as Ernst et al., (2003) with acupuncture being well tolerated and relatively safe since “no hospital admissions, permanent disability or death occurred” in the two large studies (no exact study was named) reviewed (Kelly, 2009). These same studies reported mild side effects in only 10% of patients:

“Tiredness, local pain, headache, temporary exacerbation of symptoms” transiently occurred (Kelly, 2009). Moderate level adverse effects were: “Severe nausea, fainting, severe or prolonged exacerbation of symptoms occurred at a rate of 1.3 out of 1,000 treatments,” (Kelly, 2009). Kelly (2009) and Ernst et al., (2003) provide evidence of acupuncture being a low risk treatment; consequently, TCM could be considered for recommendation prior to medications on a case-by-case basis (depending on the patient symptom severity and treatment approach of the medical doctor).

**CHM and PMS**

Historical references date back 4,700 years ago with Shen Nong “testing” Chinese Herbal Medicine on himself. Legend says that he tasted 70 different medicines and if he reacted to that particular one he then treated the adverse reaction with a different herb, thereby learning which herbs treated certain conditions. *Shen Nong Ben Cao Jing*, the first book of CHM, was written 2,500 years following the death of Shen Nong, and recorded 365 different herbal
medicines by taste, temperature and toxicity. The majority of these herbs are still used in practice today (Chan, 1939).

The herbal medicine of Japan, known as Kampo, is integrated into the national western healthcare system (Golden, 2011; Gepshtein, Plotnikoff & Watanabe, 2008). Kan means Chinese and initially was called Kan-po, but now termed Kampo. Chinese medicine is not novel to Japan, and has been employed for over 1,400 years in this country. Roughly 70% of the 200,000 physicians in Japan prescribed Kampo medicine reported the Lancet medical journal in the August, 1993 edition (Golden, 2011). Gynecologists are among the top three doctors to prescribe Kampo, along with urologists and cardiologists. Japan’s Ministry of Health and Ministry of Labor and Welfare authoritatively recognize and acknowledge Kampo medicine (Golden, 2011). Since the government of Japan recognizes the value of Kampo, the research is more focused on the effect of Kampo on the body versus the effectiveness of the herbal formulas in research settings (Gepshtein, Plotnikoff & Watanabe, 2008).

Kampo Clinic, Keio University Hospital in Tokyo recruited 30 women for a six-month trial using Kamishoyosan (TJ-24) instead of traditional SSRI treatment. The same psychiatrist did pre and post evaluations with DSM-IV criteria for PMDD diagnosis, along with Global Assessment Functioning (GAF) Scale and Hamilton Depression Rating (HAM-D) Scale. The GAF and HAM-D were completed in the luteal phase or as close to it as possible. Women, ranging from 18-48, were included in the trial. The ingredients of Kamishoyosan (TJ-24) are the following: Chai Hu (Bupleuri Radix), Shao Yao (Paeniao radix), Bai Zhu (Attracylodis lancae rhizome), Dang Gui (Angelica radix), Fu Ling (Hoelen), Zhi Zi (Gardenia Fructus), Mu Dan Pi (Moutan Cortex,) Zhi Gan Cao (Glycyrrhizae radix), Pao Jiang (Zingiberis rhizoma), and Bo He (Mentha Herba). Kamishoyosan (TJ-24) is the Chinese herbal formula known as Jia Wei Xiao
Yao San, a modified version of Xiao Yao San used when excess heat is present along with Liver Qi Stagnation and Blood Deficiency. A daily dose of 7.5 grams was given (2.5g three times a day) for six menstrual cycles. Thirty women originally started in the trial and 26 finished; three did not return to the hospital, and one had an adverse reaction of hot flushes and resigned. No other adverse reactions were documented. A complication of dysmenorrhea affected 18 women in the trial (it is unclear whether dysmenorrhea was present before the trial or commenced during the trial). The GAF and HAM-D were recalculated after the six months and separated into remission (score < 7), improvement (score ≥ 7 or decrease of HAM-D of > 50%), and thirdly no change. Fourteen patients (46.7%) had remission, five (16.7%) showed improvement, and seven (23.3%) showed no change. The diagnosis of PMDD did not apply to 21 out of the 26 patients at the end of the trial. The significance of these reported findings, by the same psychiatrist, indicated that 81% of women at the conclusion of the six-month trial no longer met the DSM-IV criteria for PMDD (Yamada & Kanba, 2007). “Although clinical data on Kampo are scarce, the more than 30 years of governmental regulation accumulated extensive data...[and] the high quality of Kampo formulas make them suitable for clinical practice and Western countries,” (Gepshtein, Plotnikoff & Watanabe, 2008).

Flaws (2005) discusses Wang (2000) and the 62 cases Dr. Wang treated with CHM. Age range was 21-42 years, and PMS had been present four months to two years in each patient. The treatment time frame was two to four months. The common symptoms presenting the week prior to onset of menstruation were edema, headache, breast distention/pain, abdominal distention/pain, agitation, easily angered, and possible menstrual irregularities (Wang, 2000). Dr. Wang’s basic formula was modified per patient, according to symptoms, and included the following ingredients: Chai Hu, Dang Gui, Bai Shao, Xiang Fu, Yu Jin, Bai Zhu, Fu Ling, Yi
Mu Cao and Gan Cao. His base formula with modifications was begun approximately a week prior to menstruation. When menstruation started Xiao Yao Wan was given to the patient, and Wu Ji Bai Feng Wan if severe deficiency was present. Flaws (2005) summarizes the study outcomes, “Of the 62 cases treated with this approach, 35 were judged cured, 27 markedly improved, nine got some effect and only one got no effect.” Another study Flaws (2005) notes is of 32 women between 23-40 years of age, diagnosed with premenstrual tension. Symptoms are experienced 7-14 days prior to menstruation. Qian (1999) administered Zhu Yang Jie Yu Tang, comprised of: Yin Yang Huo, Tu Si Zi, Ba Ji Tian, Lu Jiao Pian, Dang Gui, Chi Shao, Bai Shao, Shan Zhu Yu, Yu Jin, Chai Hu, Qing Pi, and Chen Pi. Zhu Yang Jie Yu Tang was taken twice daily starting ten days prior to menstruation, and ceased during menstruation. Treatment was dispensed for two cycles. The effects were not considered until three more menstrual cycles were completed. No clinical symptoms, normal BBT chart, and no recurrence of symptoms after three months Qian stated as cured. Marked effect meant improvement of symptoms, normalization of BBT chart and no worsening of symptoms in the three months. Some effect was interpreted as symptoms not completely diminished and possibly returned, but not worse than prior to treatment. No effect refers to indiscernible change in symptoms or worsening of symptoms. Flaws (2005) states the outcome as, “Based on these criteria [previously mentioned] 20 cases were judged cured, seven got a marked effect, three more got some effect and only two cases failed to register any positive effect.” CHM yielded substantial results for Wang (2000) and Qian (1999). There were no control groups as these were not trials, but patient treatments complied from their own practices.

Zhou & Qu (2009) reviewed a controlled study administering Chinese Herbal Medicine (CHM) to 61 Australian women. The participants were randomly assigned to either a CHM or
placebo group. The symptoms assessed were: premenstrual physical symptoms, depression, anxiety, anger, as well as additional psychological symptoms (none specifically stated by study). The groups were diagnosed and treated according to Traditional Chinese Medicine. At the end of the three-month study the researchers’ findings conclude that, “The results support the hypothesis that the symptoms occurrence and severity of PMS can be effectively reduced by the use of CHM,” Zhou & Qu (2009).

Chou & Morse (2005) documented a trial, compiled from 30 studies, with 861 female patients experiencing PMS. CHM was the therapy and yielded the following results: 651 patients fully recovered (75.6%), 177 participants showed some improvement (20.6%), and no effect was a minimal 3.8% of the remaining 33 participants.

Guo & Ma (2013) reviewed a trial that compared acupuncture to medication and Chinese herbs. A daily acupuncture treatment for ten days (length of study not documented) with 40-minute needle retention time was done with DU 20, HT 3, and SP 6. The medication group received an IV drip of glucose, Acanthopanax senticosus (Siberian Ginseng) and oral dosing of diazepam and Xiao Yao Pills. The exact dosages were not disclosed. The acupuncture group improved 98.4% and the medication group improved 86.0%. In the acupuncture and PMS/PMDD section three trials were mentioned where acupuncture was approximately 30% more effective than the medicine. Only a 13% difference between the acupuncture and medication group was observed. The trials with just medicine were not as effective as this trial with medicine and Chinese herbs. Implications could be assumed that Chinese herbs are also effective in treating PMS, and aided the medicine.

The formula Xiao Yao San (used in the above-mentioned study) is comprised of the following single herbs: Chai Hu, Dang Gui, Bai Shao, Bai Zhu, Fu Ling, and Zhi Gan Cao. It is
further prepared with Wei Jiang (baked ginger) and Bo He. Xiao Yao San harmonizes and regulates the Liver and Spleen. It is translated Rambling Powder or Free and Easy Wander in English, and treats the pattern of Liver Qi Congestion (stagnation) with Blood Deficiency (mainly Spleen Deficiency). It is commonly used for certain Western diagnoses (if the pattern is appropriate): anxiety, depression, constipation, insomnia, migraine, tension headache, fatigue, breast distention, and PMS. Those individual symptoms can be experienced during PMS singularly or collectively and this formula has the capability to address them. Xiao Yao San outshines Si Ni San, which Xiao Yao San was varied from. Si Ni San treats PMS from the perspective of heat constraint blocking the flow of Qi to the extremities, in conjunction with Liver and Spleen being unregulated (Scheid, Bensky, Ellis & Barolet, 2009).

Chen & Chen (2009) list three studies with excellent results on the effectiveness of Xiao Yao San in treatment of PMS. The details describing the nature of the trial, control group, and length of treatment are lacking. The dose, frequency, and side effects (if any) of herbal formulas were not included. A study of 32 women had 96.88% effectiveness on PMS. A second study, modified Xiao Yao San with the addition of Xiang Fu and Yu Jin, had an improvement of 98%. Edema, breast distention, headache, and emotional disturbance were the symptoms present in the 62 female participants. The third trial treated Liver stagnation transforming into heat with Xiao Yao San plus Gou Teng, Mu Dan Pi, Qing Pi and others (not clear on which other herbs included). The effectiveness was 93.3%.

Chen & Chen (2009) also mention a depression study with 93.3% effectiveness in the 60 participants. The herbal formula, Xiao Yao San, was used in conjunction with counseling. The style of counseling was not mentioned, and psychological or talk therapy is assumed. Xiao Yao San (modified with single herbs based on pattern) had “complete recovery in 32 patients,
significant improvement in 16 patients, moderate improvement in 8 patients, and no
improvement in 4 patients (Chen & Chen, 2009).” Chen & Chen (2004) reference Bai Shao, He
Huan Pi, Qing Pi, and Xiang Fu for use as single herbs to treat PMS in combination with other
herbs or for use in modifying a formula. Single herbs are added dependent on the present
pattern at the discretion of the practitioner.

Another variation of Si Ni San (the base for Xiao Yao San) is Chai Hu Shu Gan San. It
is comprised of: Chai Hu, Xiang Fu, Chen Pi, Zhi Ke, Bai Shao, Chuan Xiang and Zhi Gan Cao.
The therapeutic actions are smooth and regulate LV Qi, disperse Qi for optimal circulation, and
harmonize blood to relieve pain. A modified version of Chai Hu Shu Gan San (Chai Hu, Bai
Shao, Chen Pi Chuan Xiong, Xiang Fu, Zhi Qiao, Yu Jin, Tong Cao, Bai Zhi, Ru Xiang, Mo
Yao, Pu Gong Ying and Gan Cao) produced, “complete relief of breast distention and pain was
reported in 21 of 24 patients”. These raw herbs were decocted in water and taken three times
daily for 7 days. Treatment length was not documented (Chen & Chen, 2009). Treatment of
insomnia with modified Chai Hu Shu Gan San with the addition of Chi Shao, Dan Shen, Ju Ha,
Zhi Zi, Dan Nan Xing, and Shi Chang Pu, was completed on 30 patients. A 96.7% effectiveness
was shown in stubborn insomnia after an indeterminate timeframe (not documented). Complete
recovery was attained in 26 participants, advancement was shown in 3 participants, and no
effect was present in one individual (Chen & Chen, 2009).

“Large-scale, multicenter, randomized, double-blind and placebo-controlled clinical
researches are needed to further demonstrate the efficacy of CHM and acupuncture in treating
PMS,” Zhou & Qu (2009). Hu et al., (2011) recommended that TCM practitioners be more
involved in the reviewing process of studies since their knowledge base of TCM on the etiology
of symptoms and patterns is beneficial and allows for a more thorough explanation of the
results. “…More than 60% of reviews did not have one TCM practitioner on the author list, which might lead to insufficient consideration of the characteristics of TCM and incorrect results,” Hue et al., (2011). In general, these factors tend to be lacking and hamper the validity of TCM trials and studies, despite affirmative outcomes.

**Integration:**

TCM may be beneficial in treatment of current symptoms, maintenance of general health, and possible prevention of future symptoms or diseases. TCM provides a comprehensive, holistic approach to acute or chronic conditions, with minimal adverse side effects (Ernst et al., 2003; Zhou & Qu, 2009). Minimal studies have been conducted properly on TCM reducing PMS and PMDD. The majority of current studies are imprecise regarding the following:

- diagnosis completed by a licensed acupuncturist (L.Ac.)
- treated by L.Ac. or a non-licensed acupuncturist, L.Ac.
- years in practice
- needle retention time
- depth and angle of needle
- brand and size of needle
- if de qi was elicited
- additional symptoms relieved or exacerbated that did not fall within the parameters of PMS
- adverse side effects
- treatments during luteal and follicular or luteal only
This researcher’s purpose was to determine if TCM can reduce symptoms of PMS and PMDD, allowing TCM to be a viable option for patients to utilize instead of only Western medicine or to be integrated with Western treatments. Comparative documentation (possible adverse effects and safety measures) is needed in future studies to confidently recommend TCM has fewer adverse reactions than Western medicine for patients that are sensitive to medications, do not want surgery, or prefer alternative care. Due to the limited research available on the subject, this literature research synthesis attempted to fill in the gaps, identify current research, and identify areas requiring further research.

Chapter Three: Methodology

Introduction

It is hypothesized that acupuncture treatments and/or Chinese herbal medicine can reduce the symptoms of, or prevent the occurrence of, premenstrual syndrome and premenstrual dysphoric disorder. The purpose of the study was to explore whether acupuncture and/or Chinese herbal medicine reduce the following symptoms occurring before and during menstruation: headaches, fever, body pain, edema, bloating, diarrhea, nausea, dizziness, abnormal emotional changes, breast tenderness, irritability, acne, anger outbursts, and overall sense of wellbeing.

General Statement of Methodology

To decipher the subtle nuances in the articles reviewed a qualitative literature synthesis method was conducted. The qualitative methodology allowed for concurrent observation and interpretation without being limited by numerical representation only. Scientific rules alone are
not an efficient way to encompass a practitioner’s observation, experience and decisions are needed to properly manage individual patient care (Green & Britten 1998). The research method style, synthesis literature review, was chosen because it allowed for the most cohesive presentation of the data collected due to time constraints and limited data.

**Procedures**

To synthesize the data extracted from the articles in a proficient manner, the researcher chose to focus on the symptoms most commonly experienced with PMS and/or PMDD. Data was then recorded into tables and graphs. The limited data collected on articles of PMS and PMDD utilizing TCM for treatment could be an alleged risk to the validity of this research synthesis. Research Synthesis data was compiled through online searches of medical journals, Pubmed, EBSCO host, Google Scholar, Yo San University databases, and published books.

Search Words used: acupuncture, acupuncture and PMS, acupuncture and PMDD, PMS and Chinese herbs, PMDD and Chinese herbs, Traditional Chinese Medicine, Traditional Oriental Medicine, mood disorders, headaches and acupuncture, acne and acupuncture, acupuncture side effects, CAM, PMS, and TCM.

**Inclusion/Exclusion Criteria**

Due to the small number of pertinent articles this researcher included all published years. Female and male were included in the articles reviewed. Even though PMS is pertinent to females, non-gender specific data collection was needed to draw conclusions regarding the treatment of PMS by TCM. Headaches, pain, depression, and anxiety are a few of the symptoms included to support the current data. These symptoms were included to address the effectiveness of TCM treatments. Instead of limiting the articles to reproductive aged females, data collection was extracted on both genders for certain symptoms to be funneled from generalizations to the
specificity of PMS and help validate TCM’s potential worth in reducing these symptoms. This researcher was able to draw conclusions and see trends that occurred. Children were excluded from this research synthesis.

**Human Subjects Research Ethical Considerations**

This study was exempt through the University IRB process as there were no human subjects.

**Chapter Four: Results**

Thirty-one articles were reviewed for this research synthesis, and 7 studies summarized from textbooks. All the articles were in English. The collection of articles was from 9 different study designs. The articles can be dissected into the following: 10 synthesis reviews, 7 clinical trials, 5 educational/informative, 3 meta analyses, 3 surveys, 1 systematic review, 1 group experimental research, 1 case report, and 1 open labeled pilot study. Detailed breakdown of the 7 clinical trials shows: 3 clinical trials, 1 single blind randomized clinical trial, 1 single blind controlled clinical trial, 1 randomized prospective placebo controlled trial, and 1 multicenter, random, double blind placebo controlled trial. Sixteen articles were related to PMS, 7 articles were related to PMDD, and 3 articles were related to both topics of PMS and PMDD. One of the articles related to PMDD was specifically focused on anxiety and depression resulting from PMDD. Dysmenorrhea was associated with 3 articles, and mentioned in other articles as a symptom that was present in addition to PMS and benefitted from PMS treatment. Two articles discussed prophylaxis treatment in regards to migraines. Low back pain and Major Depressive Disorder had 1 article each.

The articles analyzed by therapy yielded these results: 9 acupuncture, 4 CHM, 2 acupuncture in conjunction with CHM, 7 Western (medication, treatment options, definitions),
3 acupuncture versus medication articles, 1 acupuncture versus medication and CHM, and 1 acupressure (auricular). Three of the CHM were Kampo articles. Two of the textbooks had 7 CHM studies or trials on PMS, breast distention, headache, depression, and insomnia. Those 7 studies totaled 302 females treated with CHM. The averaged improvement of the combined 5 trials was 95.6% improvement. Cured, marked improvement, some improvement and no effect were the improvement markers for 94 out of the 302 treated with CHM. The results were: 37 subjects were cured, 34 displayed marked improvement, 12 showed some improvement, and 3 had no effects. Interpretation of these scores as a percentage means 99% of patients had at least some improvement, 1% had no improvement, and 12% were completely symptom free. Seven of the acupuncture trials listed the months of treatment, ranging from 1 to 6 months. Adverse effects from acupuncture were present in 11% of 3,535 treatments. This total treatment number was compiled from 409 patients. Out of those patients, 38% had one of the following adverse effects: hematoma, slight hemorrhage, dizziness, or systemic symptom. Fainting, nausea, paresthesia, and increased pain occurred in less than 1% of those patients.

The formula Xiao Yao San was mentioned 6 times in the synthesis review. Jiao Wei Xiao Yao San and Dan Zhi Xiao Yao San were mentioned once. Chai Hu Shu Gan San was mentioned 3 times. Since Si Ni San is the base formula for these formulas, it stands to reason that Si Ni San was used in one form or another after modifications at least 11 times. These results show that Si Ni San (modified) is a fundamental formula in the treatment of PMS and PMDD by CHM. Further research should be conducted on Si Ni San, and subsequently Xiao Yao San and Chai Hu Shu Gan San.

Three trials reported acupuncture to be more effective than ibuprofen for menstrual cramps. In one trial the only acupuncture point used was SP 6, and it was still more effective
than ibuprofen. Specific acupuncture points were not noted in every trial. The acupuncture trials that did document specific points most frequently used the following: SP 6 (82% of treatments), Ren 2, 3, 4, or 6 (64%), LV 3 (55%), DU 20 (45%), and LI 4 (27%). In the majority of studies needle retention time was 30 minutes. Treatments per week varied from once a week to daily treatments during the luteal phase leading up to menstruation. The majority of the trials did not perform acupuncture during menstruation (days 1-5).

Chapter 5: Discussion

Summary of Findings

The topics included in this synthesis relate to PMS, PMDD, dysmenorrhea, low back pain, Major Depressive Disorder, and migraine prophylaxis. Limited data retrieval pertaining to the hypothesis of TCM (not singularly acupuncture or CHM) reducing symptoms resulted in the use of 16 PMS, 7 PMDD, and 2 PMS/PMDD articles. Articles with symptoms that could possibly be experienced during the luteal phase were included to support the hypothesis. Studies included were delineated via study type, treatment method, TCM, Western, and trial time frame.

The results for acupuncture effectively treating PMS were supported by Wang (1998) in a 6-month trial of 26 females. The participants were divided into real acupuncture group (RAG) and sham acupuncture group (SAG). The concluding results were 76% reduction of symptoms in RAG, and 10% reduction in SAG at the completion of 3 months of treatment. Based on these results further studies should be continued in an effort to establish acupuncture as a viable treatment for PMS.

Implications for Theory

According to the Office on Women’s Health, U.S. Department of Health and Human Services (2012) women have a higher propensity to suffer from PMS if they are between 20-40
years of age, gave birth to at least one child, have a family history of depression, or were diagnosed with postpartum depression or a mood disorder in the past. In the treatment of PMS, afferent symptoms respond better than somatic symptoms, implying that patients should be made aware not all symptoms reduce at the same rate (Wang, 1998). PMS, and even more so PMDD, can interrupt normal life functions, and affect relationships, jobs, family, and self image. Population base may influence the prevalence of PMS. Qiao et al., (2012) reported a higher percentage of PMS in the Chinese population in China compared to the population in Switzerland, Japan, and the state of Virginia. PMS and PMDD had similar prevalence in Spanish women as women in other Western countries concluded Dueñas et al., (2011).

**Implications for Practice**

Based off the studies reviewed, treatment for PMS and PMDD can be performed during the follicular (except days 1-5), luteal, or both phases to reduce symptoms. The patient and practitioner have more flexibility when scheduling appointments, and could possibly encourage better patient compliancy. Patients might also experience menstrual regulation, which could possibly reduce fertility issues, menopause symptoms, and positively impact their future health. Traditional Chinese Medical Practitioners would have more learning resources, references, and patient education through a more in depth look at PMS and PMDD. Western and TCM pathophysiologies, diagnoses, and possible treatment would be more cohesive, allowing for ease of use in clinical and classroom settings. This research synthesis would be of value to Medical Doctors wanting more research supporting the hypothesis that Traditional Chinese Medicine can make a measurable change in symptoms preceding menstruation. TCM could be another treatment utilized by persons intolerant to OCPs or SSRIs, lack of response to Western treatment, or too many side effects from conventional methods. TCM typically does not
interfere with other treatments, and has a low risk if performed properly, assuming the treatment is conducted by a licensed acupuncturist. CHM needs to be monitored closely when taken with medication. This research synthesis would be of value to reproductive aged females to minimize potential daily life interruptions from affective and somatic symptoms associated with PMS and PMDD. Their activities of daily life ranging from work, relationships, and hobbies would not be so limited, and fewer interferences of “normal” life would occur.

**Limitations of Current Study**

The limitation of short trial times, the longest being 6 months, hampers longitudinal viewing of symptom progression for thorough data analysis. The reviewers of the trials reported a possible high risk of bias in the interpretation of the results. This researcher thinks the results were reported accurately, but since few adverse reactions were documented some reviewers appeared to believe such success meant inaccurate results. Adverse reactions should always be included in the trials, and if none occurred, that should be documented additionally. The lack of details about the studies prompts assumptions in regards to the type of needle used, if *de qi* sensation was elicited, treatments by pattern diagnose or generalizations, and whether the treatments were performed by a licensed acupuncturist. The grouping of the participants was unclear if it was by age, symptoms, TCM patterns, or all of these factors combined. The tongue and pulse evaluations, pre and post trial, were not documented in the majority of the trials. Tongue and pulse evaluation is another measurement of progress that should be utilized. Sham acupuncture points have been hypothesized to influence sensory, cognitive, and emotional responses. These points could possibly cause a placebo effect and misinterpretation of the clinical trials (Linde, Niemann, Schneider & Meissner, K, 2010). This research synthesis was hypothesized in regards to TCM being the modality of treatment. Acupuncture and CHM fall
under the umbrella of TCM. However, the research reviewed separates them, and only individually uses acupuncture or CHM. Pairing of acupuncture and CHM would represent a TCM approach, and more accurate findings that could support the hypothesis of the efficacy to reduce symptoms of PMS and PMDD. Limited studies evaluated acupuncture and CHM collaboratively.

**Recommendations for Future Research**

Longitudinal studies of PMS progression, as well as studies where follow up is reported every 3, 6, or 9 months would be beneficial to measure long term results. In clinical practice patients are not recommended to cease treatments abruptly. In clinical trials once the study is finished the treatment is terminated. Maintenance treatments could be done once a month, twice a month, or every other month to determine if consistent treatment (even though not weekly) could maintain the reduced symptoms. Only one study documented recommended diet modifications in both the acupuncture and medication group. Diet and lifestyle questionnaires could be incorporated to future studies to determine if there is an impact on symptom progression and/or maintenance of reduced symptoms. A retrospective questionnaire could be completed by menopausal women experiencing severe symptoms (from menopause) to see if they had a past diagnosis of PMS or PMDD. A longitudinal prospective study could be conducted on females diagnosed with PMS or PMDD to determine if severity of symptoms during the reproductive age possibly correlate to predict the severity of perimenopause and menopausal transitions. Further research needs to be completed regarding acupuncture and CHM used simultaneously versus SSRIs for the treatment of PMDD. The formula Si Ni San was modified frequently in treatment. Therefore, a future study looking at this formula and modifications pertaining to TCM pattern diagnosis and the effectiveness of each formula would
be useful. To reduce compliance issues a possible option would be to develop a PMS questionnaire phone application, that electronically submits once the person completes it. This phone application could possibly have assisted in the Wang (1998) study. The main weakness of that study was during the three months following treatments, very few participants completed the menstrual diary. Further research should be conducted on PMDD treatment with acupuncture and CHM since these trials showed significant reduction in symptoms. In a 6 month trial of 26 females, CHM (specifically Kampo) treatments were utilized instead of SSRI therapy. The findings were: 14 patients went into remission (46.7%), 5 patients experienced improvement (16.7%), and 7 patients showed no change (23.3%). The participants were all diagnosed with PMDD, according to the DSM-V, prior to treatment. Upon completion of the trial, 81% of the females no longer met the criteria for a PMDD diagnosis. In a different trial focusing on anxiety and depression as a complication of PMDD, HAM-A, and HAM-D decreased significantly in the acupuncture group versus the sham group. Group 1 HAM-A decreased by 59%, and 52% in HAM-D. Group 2 HAM-A decreased by 21%, and 19% in HAM-D. Acupuncture was 38% more efficient at reducing anxiety than sham acupuncture, and 31% more effective in reducing depression.

**Conclusion**

This research synthesis was intended to determine if TCM was effective in reducing symptoms associated with PMS and PMDD. This researcher reasons based on the results reviewed that TCM does reduce unpleasant cyclic symptoms during the luteal phase. Therefore, TCM is an effective treatment that may be considered for PMS and PMDD. Patient education
and practitioner education (Western and Oriental Medical Doctors) is necessary. Obstetrician/gynecologist, psychologist, psychiatrist, school nurses, etc. are the most likely practitioners to be dealing with PMS/PMDD, and would have an opportunity to explain to patients the treatment options. Instead of only masking the symptoms, TCM should be considered as a viable treatment to reduce symptoms, and also address the underlying cause. TCM should then be considered to prevent future health issues. “The concept of PMS was developed in the West based on observations and studies of Western populations. PMS has become an international clinical concept, central to research and treatment of monthly discomforts across cultures,” (Gepshtein, Plotnikoff, & Watanabe, 2008). Even though the term PMS was conceptualized in the West, treatments for symptoms of PMS have been established for thousands of years in populations whose healthcare is centralized around Oriental Medicine. Solutions originating from the East may be the answer to treating PMS/PMDD deriving from the West.

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Alternative Medicines, 6(4).
March 28th, 2014

Stacy Frerking, L.Ac., MSTOM
1082 Buena Vista Rd.
Branson, MO 65616

Dear Stacy,

Your revised research proposal has been approved, with no additional recommendations effective through March 31, 2015.

Should there be any significant changes that need to be made which would alter the research procedures that you have explained in your proposal, please consult with the IRB coordinator prior to making those changes.

Sincerely,

Penny Weinraub, L.Ac.
IRB Coordinator
THE EFFICACY OF TCM ON REDUCING PMS AND PMDD

How to Use the Daily Record of Severity of Problems (DRSP) Short Form to Assess DSM-IV Criteria for PMDD

These instructions and the following DSM-IV research criteria for premenstrual dysphoric disorder are intended for use by your clinician. These will assist your clinician in interpreting your two months of ratings on the DRSP.

1. During the mid-follicular phase (days 8-10 after the onset of menses), does the patient have an average daily symptoms rating score greater than 3 (mild) on any of the symptoms; i.e., is there any evidence of an unrelated disorder?
   Some clinicians do not count increased appetite (8) in obese patients, or insomnia (9) for those with good reasons (e.g., infants or ill children), or pain from a physical illness (11). Note here if this patient has “excused” symptoms.
   ——— If greater than mild symptoms during the mid-follicular phase (and they are not “excused”), patient does not meet PMDD criteria – STOP
   ——— If essentially symptom free or has only “excused symptoms” during the mid-follicular phase, proceed to step 2.

2. During the week prior to menses, does the patient score at least 4 (moderate) for at least 2 days on one or more of the following:
   - Depression
   - Anxiety
   - Mood lability
   - Anger/irritability
   ——— If all ‘No,’ does not meet criteria – STOP
   ——— If at least one ‘Yes,’ proceed to step 3

3. During the week prior to menses, does the patient score at least 4 (moderate) for at least 2 days on at least FIVE of the symptoms (1 through 11) listed?
   ——— If NO, does not meet criteria – STOP
   ——— If YES, has sufficient symptoms and severity, proceed to step 4

4. During the week prior to menses, does the patient have scores of at least 4 (moderate) for at least 2 days on at least one of the following impairment items?
   - Work, school, home, daily routine
   - Hobbies, social activities
   - Relationships with others
   ——— If all ‘No,’ does not meet criteria – STOP
   ——— If at least one ‘Yes,’ proceed to step 5

5. Do you agree with the daily ratings assessment (i.e., does the patient meet criteria for Premenstrual Dysphoric Disorder)?
   - Yes
   - No
   If No, specify reason(s)

   ———

   If Yes, is this the first or second cycle of ratings that meet criteria?
   ——— First cycle
   ——— Second cycle

Patient Name ___________________________ Date ____________ Clinician Name ______________________

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From: Premenstrual Syndrome and Premenstrual Dysphoric Disorder: Issues of Quality of Life, Stress and Exercise by M. Kathleen B. Lustyk . W. G. Gerrish
Beck's Depression Inventory

This depression inventory can be self-scored. The scoring scale is at the end of the questionnaire.

1. 0 I do not feel sad.
    1 I feel sad
    2 I am sad all the time and I can't snap out of it.
    3 I am so sad and unhappy that I can't stand it.

2. 0 I am not particularly discouraged about the future.
    1 I feel discouraged about the future.
    2 I feel I have nothing to look forward to.
    3 I feel the future is hopeless and that things cannot improve.

3. 0 I do not feel like a failure.
    1 I feel I have failed more than the average person.
    2 As I look back on my life, all I can see is a lot of failures.
    3 I feel I am a complete failure as a person.

4. 0 I get as much satisfaction out of things as I used to.
    1 I don't enjoy things the way I used to.
    2 I don't get real satisfaction out of anything anymore.
    3 I am dissatisfied or bored with everything.

5. 0 I don't feel particularly guilty
    1 I feel guilty a good part of the time.
    2 I feel quite guilty most of the time.
    3 I feel guilty all of the time.

6. 0 I don't feel I am being punished.
    1 I feel I may be punished.
    2 I expect to be punished.
    3 I feel I am being punished.

7. 0 I don't feel disappointed in myself.
    1 I am disappointed in myself.
    2 I am disgusted with myself.
    3 I hate myself.

8. 0 I don't feel I am any worse than anybody else.
    1 I am critical of myself for my weaknesses or mistakes.
    2 I blame myself all the time for my faults.
    3 I blame myself for everything bad that happens.

9. 0 I don't have any thoughts of killing myself.
    1 I have thoughts of killing myself, but I would not carry them out.
    2 I would like to kill myself.
    3 I would kill myself if I had the chance.

10. 0 I don't cry any more than usual.
    1 I cry more now than I used to.
    2 I cry all the time now.
    3 I used to be able to cry, but now I can't cry even though I want to.
11. I am no more irritated by things than I ever was.
   0 I am slightly more irritated now than usual.
   1 I am quite annoyed or irritated a good deal of the time.
   2 I feel irritated all the time.

12. I have not lost interest in other people.
   0 I am less interested in other people than I used to be.
   1 I have lost most of my interest in other people.
   2 I have lost all of my interest in other people.

13. I make decisions about as well as I ever could.
   0 I put off making decisions more than I used to.
   1 I have greater difficulty in making decisions more than I used to.
   2 I can't make decisions at all anymore.

14. I don't feel that I look any worse than I used to.
   0 I am worried that I am looking old or unattractive.
   1 I feel there are permanent changes in my appearance that make me look unattractive.
   2 I believe that I look ugly.

15. I can work about as well as before.
   0 It takes an extra effort to get started at doing something.
   1 I have to push myself very hard to do anything.
   2 I can't do any work at all.

16. I can sleep as well as usual.
   0 I don't sleep as well as I used to.
   1 I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
   2 I wake up several hours earlier than I used to and cannot get back to sleep.

17. I don't get more tired than usual.
   0 I get tired more easily than I used to.
   1 I get tired from doing almost anything.
   2 I am too tired to do anything.

18. My appetite is no worse than usual.
   0 My appetite is not as good as it used to be.
   1 My appetite is much worse now.
   2 I have no appetite at all anymore.

19. I haven't lost much weight, if any, lately.
   0 I have lost more than five pounds.
   1 I have lost more than ten pounds.
   2 I have lost more than fifteen pounds.
20.  
0     I am no more worried about my health than usual.  
1     I am worried about physical problems like aches, pains, upset stomach, or constipation.  
2     I am very worried about physical problems and it's hard to think of much else.  
3     I am so worried about my physical problems that I cannot think of anything else.  

21.  
0     I have not noticed any recent change in my interest in sex.  
1     I am less interested in sex than I used to be.  
2     I have almost no interest in sex.  
3     I have lost interest in sex completely.  

INTERPRETING THE BECK DEPRESSION INVENTORY

Now that you have completed the questionnaire, add up the score for each of the twenty-one questions by counting the number to the right of each question you marked. The highest possible total for the whole test would be sixty-three. This would mean you circled number three on all twenty-one questions. Since the lowest possible score for each question is zero, the lowest possible score for the test would be zero. This would mean you circles zero on each question. You can evaluate your depression according to the Table below.

<table>
<thead>
<tr>
<th>Total Score</th>
<th>Levels of Depression</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-10</td>
<td>These ups and downs are considered normal</td>
</tr>
<tr>
<td>11-16</td>
<td>Mild mood disturbance</td>
</tr>
<tr>
<td>17-20</td>
<td>Borderline clinical depression</td>
</tr>
<tr>
<td>21-30</td>
<td>Moderate depression</td>
</tr>
<tr>
<td>31-40</td>
<td>Severe depression</td>
</tr>
<tr>
<td>over 40</td>
<td>Extreme depression</td>
</tr>
</tbody>
</table>

Retrieved from:

http://www.med.navy.mil/sites/NMCP2/PatientServices/SleepClinicLab/Documents/Beck_Depression_Inventory.pdf
Global Assessment of Functioning (GAF) Scale

(From DSM-IV-TR, p. 34.)

Consider psychological, social, and occupational functioning on a hypothetical continuum of mental health-illness. Do not include impairment in functioning due to physical (or environmental) limitations.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>Superior functioning in a wide range of activities, life's problems never seem to get out of hand, is sought out by others because of his or her many positive qualities. No symptoms.</td>
</tr>
<tr>
<td>90</td>
<td>Absent or minimal symptoms (e.g., mild anxiety before an exam), good functioning in all areas, interested and involved in a wide range of activities. socially effective, generally satisfied with life, no more than everyday problems or concerns (e.g. an occasional argument with family members).</td>
</tr>
<tr>
<td>80</td>
<td>If symptoms are present, they are transient and expectable reactions to psychosocial stressors (e.g., difficulty concentrating after family argument); no more than slight impairment in social, occupational or school functioning (e.g., temporarily failing behind in schoolwork).</td>
</tr>
<tr>
<td>70</td>
<td>Some mild symptoms (e.g. depressed mood and mild insomnia) OR some difficulty in social, occupational, or school functioning (e.g., occasional truancy, or theft within the household), but generally functioning pretty well, has some meaningful interpersonal relationships.</td>
</tr>
<tr>
<td>60</td>
<td>Moderate symptoms (e.g., flat affect and circumstantial speech, occasional panic attacks) OR moderate difficulty in social, occupational, or school functioning (e.g., few friends, conflicts with peers or co-workers).</td>
</tr>
<tr>
<td>50</td>
<td>Serious symptoms (e.g., suicidal ideation, severe obsessional rituals, frequent shoplifting) OR any serious impairment in social, occupational, or school functioning (e.g., no friends, unable to keep a job).</td>
</tr>
<tr>
<td>40</td>
<td>Some impairment in reality testing or communication (e.g., speech is at times illogical, obscure, or irrelevant) OR major impairment in several areas, such as work or school, family relations, judgment, thinking, or mood (e.g., depressed man avoids friends, neglects family, and is unable to work; child frequently beats up younger children, is defiant at home, and is failing at school).</td>
</tr>
<tr>
<td>30</td>
<td>Behavior is considerably influenced by delusions or hallucinations OR serious impairment in communication or judgment (e.g., sometimes incoherent, acts grossly inappropriately, suicidal preoccupation)</td>
</tr>
<tr>
<td>20</td>
<td>OR inability to function in almost all areas (e.g., stays in bed all day; no job, home, or friends).</td>
</tr>
<tr>
<td>10</td>
<td>Some danger of hurting self or others (e.g., suicide attempts without clear expectation of death; frequently violent; manic excitement) OR occasionally fails to maintain minimal personal hygiene (e.g., smears feces) OR gross impairment in communication (e.g., largely incoherent or mute).</td>
</tr>
<tr>
<td>1</td>
<td>Persistent danger of severely hurting self or others (e.g., recurrent violence) OR persistent inability to maintain minimal personal hygiene OR serious suicidal act with clear expectation of death.</td>
</tr>
<tr>
<td>0</td>
<td>Inadequate information.</td>
</tr>
</tbody>
</table>

Prenomenstrual Symptom Diary

Name: ________________________________  Month: ________________________________

Write the date in the first row, starting with today. Circle the days of your menstrual period.
Each day, rate the severity of your symptoms: 1 = no symptoms; 2 = mild symptoms; 3 = moderate symptoms; 4 = severe symptoms.

| Date | Day of the month | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|------|-----------------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
|      | Irritability or tension |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Anger or short temper |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Anxiety or nervousness |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Depression or sadness |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Crying or tearfulness |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Relationship problems |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Tiredness or lack of energy |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Insomnia |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Changes in sexual interest |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Food cravings or overeating |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Difficulty concentrating |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Feeling overwhelmed |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Headaches |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Breast tenderness or swelling |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Back pain |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Abdominal pain |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Muscle and joint pain |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Weight gain |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Nausea |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Other (please specify) |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
|      | Other (please specify) |   |   |   |   |   |   |   |   |   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |

Hamilton Anxiety Rating Scale (HAM-A)


Rating: Clinician-rated

Administration time: 10–15 minutes

Main purpose: To assess the severity of symptoms of anxiety

Population: Adults, adolescents and children

Commentary

The HAM-A was one of the first rating scales developed to measure the severity of anxiety symptoms, and is still widely used today in both clinical and research settings. The scale consists of 14 items, each defined by a series of symptoms, and measures both psychic anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety). Although the HAM-A remains widely used as an outcome measure in clinical trials, it has been criticized for its sometimes poor ability to discriminate between anxiolytic and antidepressant effects, and somatic anxiety versus somatic side effects. The HAM-A does not provide any standardized probe questions. Despite this, the reported levels of inter-rater reliability for the scale appear to be acceptable.

Scoring

Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0–56, where <17 indicates mild severity, 18–24 mild to moderate severity and 25–30 moderate to severe.

Versions

The scale has been translated into: Cantonese for China, French and Spanish. An IVR version of the scale is available from Healthcare Technology Systems.

Additional references


Address for correspondence

The HAM-A is in the public domain.
The Hamilton Anxiety Rating Scale (HAM-A) is a widely used tool for assessing the severity of anxiety. Below is a list of phrases that describe certain feelings that people have. Rate the patients by finding the answer which best describes the extent to which he/she has these conditions. Select one of the five responses for each of the fourteen questions.

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<th>No.</th>
<th>Item</th>
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<th>4</th>
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<td>Anxious mood</td>
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<td>Tension</td>
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<td>Feelings of tension, fatigability, startle response, moved to tears</td>
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<td>easily, trembling, feelings of restlessness, inability to relax</td>
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<td>3</td>
<td>Fears</td>
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<td>Of dark, of strangers, of being left alone, of animals, of traffic,</td>
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<td>Insomnia</td>
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<td>Difficulty in falling asleep, broken sleep, unsatisfying sleep and</td>
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<td>fatigue on waking, dreams, nightmares, night terrors</td>
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<td>Intellectual</td>
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<td>Difficulty in concentration, poor memory</td>
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<td>waking, diurnal swing</td>
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<td>Pains and aches, twitching, stiffness, myoclonic jerks, grinding of</td>
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<td>teeth, unsteady voice, increased muscular tone</td>
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<td>8</td>
<td>Somatic (sensory)</td>
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<td>Tinnitus, blurring of vision, hot and cold flushes, feelings of</td>
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<td>weakness, pricking sensation</td>
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<td>Cardiovascular symptoms</td>
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<td>fainting feelings, missing beat</td>
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<td>Respiratory symptoms</td>
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<td>Pressure or constriction in chest, choking feelings, sighing,</td>
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<td>dyspnea</td>
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<td>Gastrointestinal symptoms</td>
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<td>Difficulty in swallowing, wind abdominal pain, burning sensations,</td>
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<td>abdominal fullness, nausea, vomiting, borborygmi, looseness of</td>
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<td>bowels, loss of weight, constipation</td>
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<td>12</td>
<td>Genitourinary symptoms</td>
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<td>Frequency of micturition, urgency of micturition, amenorrhea,</td>
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<td>menorrhagia, development of frigidity, premature ejaculation, loss</td>
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<td>of libido, impotence</td>
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<td>Autonomic symptoms</td>
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<td>Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension</td>
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<td>headache, raising of hair</td>
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<td>14</td>
<td>Behavior at interview</td>
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<td>Fidgeting, restlessness or pacing, tremor of hands, furrowed brow,</td>
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<td>strained face, sighing or rapid respiration, facial pallor,</td>
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<td></td>
<td>swallowing, etc</td>
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Retrieved from:

# The Hamilton Rating Scale for Depression

(to be administered by a health care professional)

Patient’s Name

Date of Assessment

To rate the severity of depression in patients who are already diagnosed as depressed, administer this questionnaire. The higher the score, the more severe the depression.

For each item, write the correct number on the line next to the item. (Only one response per item)

1. **Depressed Mood** (Sadness, hopeless, helpless, worthless)
   - 0: Absent
   - 1: These feeling states indicated only on questioning
   - 2: These feeling states spontaneously reported verbally
   - 3: Communicates feeling states non-verbally—i.e., through facial expression, posture, voice, and tendency to weep
   - 4: Patient reports VIRTUALLY ONLY these feeling states in his spontaneous verbal and non-verbal communication

2. **Feelings of Guilt**
   - 0: Absent
   - 1: Self reproach, feels he has let people down
   - 2: Ideas of guilt or rumination over past errors or sinful deeds
   - 3: Present illness is a punishment. Delusions of guilt
   - 4: Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. **Suicide**
   - 0: Absent
   - 1: Feels life is not worth living
   - 2: Wishes he were dead or any thoughts of possible death to self
   - 3: Suicidal ideas or gesture
   - 4: Attempts at suicide (any serious attempt rates 4)

4. **Insomnia Early**
   - 0: No difficulty falling asleep
   - 1: Complains of occasional difficulty falling asleep—i.e., more than 1/2 hour
   - 2: Complains of nightly difficulty falling asleep

5. **Insomnia Middle**
   - 0: No difficulty
   - 1: Patient complains of being restless and disturbed during the night
   - 2: Waking during the night—any getting out of bed rates 2 (except for purposes of voiding)
6. **INSOMNIA LATE**
   0 = No difficulty
   1 = Waking in early hours of the morning but goes back to sleep
   2 = Unable to fall asleep again if he gets out of bed

7. **WORK AND ACTIVITIES**
   0 = No difficulty
   1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
   2 = Loss of interest in activity; hobbies or work—either directly reported by patient, or indirect in listlessness, indecision and vacillation (feels he has to push self to work or activities)
   3 = Decrease in actual time spent in activities or decrease in productivity
   4 = Stopped working because of present illness

8. **RETARDATION: PSYCHOMOTOR** (Slowness of thought and speech; impaired ability to concentrate; decreased motor activity)
   0 = Normal speech and thought
   1 = Slight retardation at interview
   2 = Obvious retardation at interview
   3 = Interview difficult
   4 = Complete stupor

9. **AGITATION**
   0 = None
   1 = Fidgetiness
   2 = Playing with hands, hair, etc.
   3 = Moving about, can’t sit still
   4 = Hand wringing, nail biting, hair-pulling, biting of lips

10. **ANXIETY (PSYCHOLOGICAL)**
    0 = No difficulty
    1 = Subjective tension and irritability
    2 = Worrying about minor matters
    3 = Apprehensive attitude apparent in face or speech
    4 = Fears expressed without questioning

11. **ANXIETY SOMATIC:** Physiological concomitants of anxiety, (i.e., effects of autonomic overactivity, “butterflies,” indigestion, stomach cramps, belching, diarrhea, palpitations, hyperventilation, paresthesia, sweating, flushing, tremor, headache, urinary frequency). Avoid asking about possible medication side effects (i.e., dry mouth, constipation)
    0 = Absent
    1 = Mild
    2 = Moderate
    3 = Severe
    4 = Incapacitating
12. SOMATIC SYMPTOMS (GASTROINTESTINAL)

   0 = None
   1 = Loss of appetite but eating without encouragement from others. Food intake about normal
   2 = Difficulty eating without urging from others. Marked reduction of appetite and food intake

13. SOMATIC SYMPTOMS GENERAL

   0 = None
   1 = Heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability
   2 = Any clear-cut symptom rates 2

14. GENITAL SYMPTOMS (Symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances)

   0 = Absent
   1 = Mild
   2 = Severe

15. HYPOCHONDRIASIS

   0 = Not present
   1 = Self-absorption (bodily)
   2 = Preoccupation with health
   3 = Frequent complaints, requests for help, etc.
   4 = Hypochondriacal delusions

16. LOSS OF WEIGHT

   A. When rating by history:
   0 = No weight loss
   1 = Probably weight loss associated with present illness
   2 = Definite (according to patient) weight loss
   3 = Not assessed

17. INSIGHT

   0 = Acknowledges being depressed and ill
   1 = Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc.
   2 = Denies being ill at all

18. DIURNAL VARIATION

   A. Note whether symptoms are worse in morning or evening. If NO diurnal variation, mark none
   0 = No variation
   1 = Worse in A.M.
   2 = Worse in P.M.

   B. When present, mark the severity of the variation. Mark “None” if NO variation
   0 = None
   1 = Mild
   2 = Severe
19. DEPERSONALIZATION AND DEREALIZATION (Such as: Feelings of unreality; Nihilistic ideas)

0 = Absent
1 = Mild
2 = Moderate
3 = Severe
4 = Incapacitating

20. PARANOID SYMPTOMS

0 = None
1 = Suspicious
2 = Ideas of reference
3 = Delusions of reference and persecution

21. OBSESSIOINAL AND COMPULSIVE SYMPTOMS

0 = Absent
1 = Mild
2 = Severe

Total Score ____________

Retrieved from http://healthnet.umassmed.edu/mhealth/HAMD.pdf
## THE EFFICACY OF TCM ON REDUCING PMS AND PMDD

### Calendar of Premenstrual Experiences

<table>
<thead>
<tr>
<th>Name</th>
<th>Month/Year</th>
<th>Age</th>
<th>Unit #</th>
</tr>
</thead>
</table>

Begin your calendar on the first day of your menstrual cycle. Enter the calendar date below the cycle day. Day 1 is your first day of bleeding. Shade the box above the cycle day if you have bleeding (■). Put an X for spotting (x).

If more than one symptom is listed in a category, i.e., nausea, diarrhea, constipation, you do not need to experience all of these. Rate the most disturbing of the symptoms on the 1-3 scale.

**Weight:** Weigh yourself before breakfast. Record weight in pounds in the box below date.

**Symptoms:** Indicate the severity of your symptoms by using the scale below. Rate each symptom at about the same time each evening.

- **0 = None** (symptom not present)
- **1 = Mild** (noticeable but not troublesome)
- **2 = Moderate** (interferes with normal activities)
- **3 = Severe** (intolerable, unable to perform normal activities)

**Other Symptoms:** If there are other symptoms you experience, list and indicate severity.

**Medications:** List any medications taken. Put an X on the corresponding day(s).

<table>
<thead>
<tr>
<th>Date</th>
<th>Bleeding</th>
<th>Cycle Day</th>
<th>Weight</th>
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<td>Swelling (hands, ankles, breast)</td>
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<td>Angry outbursts, arguments, violent tendencies</td>
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<td>Anxiety, tension, nervousness</td>
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<td>Confusion, difficulty concentrating</td>
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<td>Depression</td>
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<td>3. Pseudoephedrine</td>
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