ACUPUNCTURE AND PREMENSTRUAL SYNDROME

針灸與經前期綜合症

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I dedicate this thesis to my father who encouraged me to study medicine, and to my mother who cared for me and loved me throughout my whole life.

ABSTRACT

Thesis Title: Acupuncture and Premenstrual Syndrome

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Premenstrual syndrome (PMS) is a common syndrome experienced by women during their reproductive years . Up to 95% of women experience PMS with 30% experiencing moderate to severe symptoms and in 5-10% of women, the symptoms of PMS often result in work and/or social impairment which disrupts the quality of their lives.

The aetiology of PMS from a Western medical perspective still remains unclear even though numerous theories has been proposed. Although some pharmacological agents have proven effective and are widely used to treat the disorder, at present there are no approved medications for this disorder. In addition, most of these agents have adverse effects which limits their use in some patients. On the other hand, the aetiology of PMS from a Traditional Chinese Medicine (TCM) point of view is quite clear. However, until now, there have been no rigorous TCM clinical trials on PMS. Many clinical trials in acupuncture are seriously flawed by methodological problems.

This study was designed to evaluated the efficacy of Traditional Chinese Acupuncture (TCA) for the treatment of PMS. Twenty-six subjects were grouped according to age and then the TCM pattern of disharmony. The subjects within each age and TCM pattern group, were then randomly assigned to a treatment group which received real acupuncture treatment or to a control group which received sham acupuncture treatment.

Treatment was provided twice a week by the researcher for both groups, except during cycle days 5-12 (the symptom-free interval). Subjects in both the real acupuncture group (RAG)

and the sham acupuncture group (SAG) were treated in the same way in order to maintain the blind nature of the trial. The same style, brand and size needles were used for both the RAG and the SAG, and the same needling techniques were used on subjects in each group.

The pre- and post-treatment luteal phase scores were calculated both in the RAG and in the SAG by adding the scores of the last seven days prior to menstruation over the course of six months. The statistical analysis of data was undertaken using these scores. The difference between pre- and post-treatment in the RAG was statistically significant ($p<0.05$). There was no significant difference between pre- and post- treatment in the SAG ($p>0.05$).

This study demonstrated that acupuncture is effective in providing substantial relief for women experiencing PMS, especially with respect to the affective (behavioural) symptoms

TABLE OF CONTENTS

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LIST OF TABLES, DIAGRAMS AND CHARTS

CHAPTER 1 : INTRODUCTION

1.1 Introduction

Premenstrual syndrome (PMS) is a common syndrome experienced by women during their reproductive years (Backstrom, 1992). It is characterised by cyclical physical, psychological and behavioural changes which occur from two to fourteen days before menstruation begins, cease within four days after menstruation commences and does not reoccur until at least cycle day 12 (Mortola, 1992; Maria, 1994). Up to 95% of women experience PMS (McMurchie *et al*, 1989; Maria,1994). Approximately 30% of women between 18-45 years experience moderate to severe symptoms and in 5-10% of women, the symptoms of PMS often result in work and/or social impairment which disrupts the quality of their lives (Johnson, 1987; Rapkin, 1992; Backstrom, 1992; O'Brien, 1993; Maria 1994).

In recent years PMS has become a major health issue in our community and is attracting increasing attention in the popular press and medical journals (Chrisler *et al*, 1990; Andrews, 1994). The aetiology of PMS still remains unknown (Rapkin 1992; Parker 1994). Impressive gains have been made in differentiating PMS from other affective and personality disorders and in treating the symptoms of PMS. A range of treatments that are being employed can be classified into three groups: 1) those that eliminate the menstrual cycle such as oral contraceptives and Danazol (Danocrine, is a synthetic androgen derived from ethisterone); 2) those aimed at symptom relief of specific complaints such as dietary modification, exercise and psychoactive drugs; 3) those designed to correct the presumed causes of the disorder such as the luteal-phase

administration of progesterone.. This later approach remains presumptive, because the cause of premenstrual syndrome has not been established (Rausch *et al*, 1992).

Numerous treatments have been proposed over the past sixty years, and although some have been successful, each has adverse effects which may well outweigh their benefits (Mortola, 1994). O'Brien (1993, p1472) stated that the proposed treatments were

> "*either ineffective or that the high placebo effect in premenstrual syndrome leads to over optimistic conclusions being drawn*".

In Traditional Chinese Medicine (TCM), herbal medicine and acupuncture have long been used for gynaecological and obstetric problems. As early as the Ming Dynasty (987AD), Chinese physicians were prescribing a special herbal formula called *Xiao Yao San* (free and easy powder) for treating women who were suffering from congestion of *gan (liver meridian system) qi* and were deficient in *xue (blood)*. This condition is marked by the following major symptoms: hypochondria pain, headache, dizziness, fatigue, poor appetite, irregular menstruation and breast tenderness (Zhang, 1988a ; Pei, 1997). These above mentioned symptoms are similar to the presentation of PMS, even though the term PMS was only introduced into medical literature in 1950's.

Acupuncture as a remedy for premenstrual and menstrual problems has increased in popularity during this decade. Many reports have shown improvement of such problems following acupuncture therapy (Tsuei, 1984; Steinberger, 1981; Slagaski, 1984; Hu, 1989; Kehring, 1985; Helms, 1987; Zhan, 1990; Liao, 1990; Zheng, 1991), however, further investigations involving controlled clinical trials are needed to demonstrate the therapeutic value of acupuncture in this area.

This study evaluated the efficacy of Traditional Chinese Acupuncture (TCA) for the treatment of PMS. Twenty-six women were randomly assigned to a treatment group

or to a control group. All participants were required to keep a "menstrual diary" that recorded more than twenty somatic and affective symptoms on a four-point scale. Symptoms were recorded each day for three consecutive menstrual cycles, before the participant could enter the treatment phase. Symptoms were then recorded for three consecutive menstrual cycles during the treatment phase, and for three consecutive menstrual cycles following the treatment phase.

1.2 Definition of Terms and Abbreviations

PMS--Premenstrual Syndrome.

PMT--Premenstrual Tension or Premenstrual Tension Syndrome, is synonymous with PMS which is the term preferred by some other authors.

LLPDD--Late Luteal Phase Dysphoric Disorder, a defined diagnosis for a subgroup of women with PMS, whose symptoms are primarily affective (depression, mood swings, anger, anxiety) but restricted to the late luteal phase of the menstrual cycle. The terms PMS and LLPDD have wrongly been used interchangeably in some medical literature.

Follicular phase--defined from the first day (Day 1) of menstruation to ovulation. The duration of the follicular phase is variable.

Luteal phase--the time from ovulation to the onset of menses, during which time the corpus luteum is functional. It is usually about 14 days long.

Premenstrual phase--or called late luteal phase, which refers to the days immediately preceding menses, usually 5-7 days before.

TCM--Traditional Chinese Medicine.

TCA--Traditional Chinese Acupuncture.

Qi--Translates as vital activity of life energy. In TCM, health is considered to be a function of the smooth flow of *qi*, through a series of pathways or meridians, which link and unite all parts of the body into a single integrated whole. Disease is defined as an imbalance of, or disruption to, the movement of *qi* (Cheng, 1987).

Xue(blood)-- In TCM, blood is formed from food essence produced by the *pi* (spleen meridian system) and the *wei* (stomach meridian system). The blood then circulates throughout the body providing nourishment and moisture to all the organs and tissues. A deficiency of blood will affect the normal functioning of the body. Blood also provides nourishment for mental activities. A sufficient blood supply ensures clear consciousness and a vigorous spirit (Cheng, 1987).

***Yin* and *Yang* Theory**--*Yin* and *yang* theory is based on the philosophical construct of two polar complements. These complementary opposites are neither forces nor material entities, but are concepts used to explain the continuous process of natural change. *Yin* and *yang* are not only a set of correspondences; they also represent a way of thinking. In this system of thought, all things are seen as a part of a integrated whole. The *yin-yang* nature of a phenomenon is not absolute, but relative. *Yin* and *yang* exist in everything in nature. Such as:

YIN	*YANG*
Moon	Sun
Night	Day
Winter	Summer
Cold	Hot
Female	Male

The theory of *yin-yang* permeates all aspects of the theoretical system of TCM. It serves to explain the organic structure, physiological functions and pathological changes of to the human body. In brief, health is considered a balance of the *yin-yang* aspects of the whole person and disease is defined as an imbalance of the *yin* and *yang*. To adjust the balance of *yin* and *yang* is an important principle of TCM in the prevention and treatment of illness (Cheng, 1987).

Wu Xing(five phases)--the five phases are wood, fire, earth, metal and water. Each of these phases symbolises a particular pattern of motion. The theory of the five phases, based on the theory of the 'five substances' which are necessary for life, holds that every object in the world comes into being through the motion and change of these substances. The relationship of these five basic patterns of motion describes the way each promotes the growth of, or controls, another. It also describes the way all five interact in any system to maintain the constant motion and growth in a relatively balanced state. In the course of its development, TCM was profoundly influenced by the theory of the five elements, which, along with the theory of *yin-yang*, has become a component part of the unique theoretical system of TCM.

Real Acupuncture--acupuncture at classical points. In this study, subjects assigned to the Real Acupuncture Group (RAG) were given acupuncture therapy in accordance with TCM principles and differential diagnosis (Watson, 1991).

Sham Acupuncture--acupuncture at non-classical points. In this study, subjects assigned to the Sham Acupuncture Group (SAG) were needled in areas not recognised as acupuncture points (Watson, 1991).

Bian Zheng Shi Zhi--is a TCM principle for treatment. In the practice of TCM, before the practitioner selecting his /her treatment, the pattern of the disharmony must be identified first. Simply to say, the pattern of the disease has more meaning than the name of the disease and it is more important to TCM practice. In TCM, there is an important treatment principle called *same diseases different treatment and different diseases same treatment*. When the principle of differentiation of syndromes is used to guide clinical practice, several different patterns (syndromes) may be found in the same disease; by extension, the same syndrome may appear in a variety of diseases in the course of their development. This observation leads to two maxims of clinical relevance: *"applying different methods of treatment to the same disease"* and *"treating different diseases with the same method"*.

CHAPTER 2 : LITERATURE REVIEW

2.1 History and definitions of PMS

Premenstrual syndrome (PMS) is a relatively new term in the medical literature. In 1931, an American gynaecologist Dr. Robert Frank coined the phrase which he called "premenstrual tension". It described a variety of emotional and physical symptoms occurring seven to ten days prior to menstruation, which Dr. Frank saw in his sample of fifteen women. In 1953, Greene and Dalton proposed the term "premenstrual syndrome" and it has been used to describe this condition ever since (Peck, 1990; Andrews, 1994).

The definition of PMS remains somewhat ambiguous. In 1985, in an effort to facilitate more rigorous clinical research of the syndrome, an advisory committee to the working party set up to revise *The Diagnostic and Statistical Manual of Mental Disorders, third edition (DSM-III),* proposed a new category and added to the appendix of the manual. Late luteal phase dysphoric disorder (LLPDD) was added as "a diagnostic category needing further study" (Spitzer *et al*, 1989, p.897). LLPDD refers to a subset of PMS, in which the dominant symptoms are related to mood disturbance, and excludes women, who have symptoms throughout the luteal phase of the cycle. Thus terms PMS and LLPDD have wrongly been used interchangeably in the literature (Rapkin, 1992; O'Brien 1993).

Recently, premenstrual syndrome has been defined as the repeated occurrence of either irritability, or depression and fatigue, during the luteal phase of the menstrual cycle, accompanied by some somatic (physical) symptoms such as bloated sensations in the

abdomen or extremities, breast tenderness, or headache (Mortola, 1992). It is postulated, that the term PMS should be reserved for individuals, in whom at least one of these behavioural symptoms and one of these physical symptoms are present (Mortola, 1992). The definition of PMS needs to be sufficiently broad to allow for the great variability in symptoms and their severity, timing and duration. The timing of the symptoms of premenstrual syndrome is more important, than the nature of the symptoms, in distinguishing PMS from other organic diseases (O'Brien, 1993). The symptoms should be distressing and significantly cyclical in nature (O'Brien 1993; Andrews 1994).

2.2 Diagnostic Evaluation

The process of identifying a woman, who suffers from PMS, is more difficult than in many other medical disorders. Firstly, there are no laboratory tests that confirm a diagnosis, although a gonadotrophin-releasing-hormone analogue test is often useful for women experiencing severe symptoms in whom the diagnosis remains in doubt (O'Brien, 1993). Several other biochemical markers have been claimed to identify premenstrual syndrome. These include assays for thyroid hormones, cortisol, melatonin, platelet serotonin, oestradiol, progesterone, gonadotrophin, and sex hormone binding globulin. However, there is no evidence to support the use of any of these as a diagnostic test (O'Brien, 1987; O'Brien, 1993; Wallin et al, 1994). Nevertheless, there are methods to determine whether or not a woman has the disorder according to the definition mentioned above. It has been suggested that the diagnostic evaluation requires not only a retrospective history of PMS, but a comprehensive medical history and examination, a psychiatric history, and, most importantly, 3 months of prospective daily ratings of common menstrual cycle symptoms (Severino and Moline, 1989; Mortola, 1992; O'Brien, 1993).

The diagnostic value of retrospective histories has been disputed due to the fact that retrospective histories alone have been shown to be unreliable (O'Brien, 1987; Rubinow, 1987; Rapkin *et al*, 1988). Hart *et al* (1987) found that most of the discrepancy between retrospective recall and prospective reporting from a single cycle was due to intercycle variability. They concluded that women's' retrospective self-reports did reflect their average or usual experiences. Morse and Dennerstein (1988) reported that, in a group of 200 women seeking help for PMS at the Menstrual Disorder Clinic in the University of Melbourne, 195 (97.5%) met the retrospective criteria for PMS, while only 75 women (37.5%) met the prospective criteria. Even though the debate still continues, most researchers consider that prospective daily symptom ratings are mandatory to confirm the diagnosis of PMS (Severino *et al*, 1989). Although retrospective assessment is not adequate for the diagnosis of PMS, it is still used by practitioners in clinical practice, since many women want immediate treatment. Women find it difficult to keep rating their symptoms for several months before receiving treatment, although lengthy prospective ratings are required to identify a woman who truly suffers from PMS (Severino *et al*, 1989; Watson *et al*; Andrews, 1994).

Until the past few years, an accurate diagnosis of premenstrual syndrome was largely of academic interest since no effective treatment for the disorder had been found (Mortola, 1992). According to Mortola (1992), the diagnosis of PMS depends on the identification of a core symptom complex, including behavioural symptoms such as irritability, anxiety, depression and fatigue etc. (**Table 1**). At least one core physical symptom such as bloating of the abdomen or extremities, breast tenderness, or headache is also required to establish the diagnosis. Although these core symptoms are required, none are pathognomonic for the disorder, and the timing of the symptoms with respect to the menstrual cycle must also be established. This can be done accurately only by using valid and reliable prospective recording instruments. Because

of an inability to diagnose PMS based on the symptoms themselves as opposed to the timing of the symptoms, it is essential that the diagnosis be confirmed by using a prospective recording. Several prospective rating scales are available (Moos,1968; Sampson *et al*, 1979; Steiner *et al*, 1980; Abraham, 1983; Stout *et al*, 1985; Reid, 1987; Mortola *et al*, 1990). One prospective inventory, which establishes a quantitative method for the diagnosis of premenstrual syndrome, is the Calendar of Premenstrual Experiences (COPE). This useful diagnostic aid was first devised by Mortola *et al* (1990) from the Department of Reproductive Medicine, School of Medicine, University of California. The validity and reliability of this instrument were assessed by administering it throughout two consecutive ovulatory cycles to thirty-six rigidly screened women with PMS, as well as to eighteen controls. The results showed, that the COPE luteal phase score distinguished PMS women from controls correctly in 104 out of 108 cycles, with only a 2.8% false-negative rate and no false positives (Mortola *et al* 1990).

Concurrent validity has been established by correlating specific items from the COPE Scale with similar items on the profile of Mood States Scale (Mortola *et al*, 1990). Mortola *et al* (1990) concluded that the COPE instrument is a valid, reliable and practical PMS inventory, which can be used in clinical practice and some research procedures. Recording symptoms retrospectively is inaccurate and should not be used as a basis for diagnosis and treatment (Metcalf *et al*, 1985; Mortola 1990; O'Brien, 1993).

Table 1. Diagnostic Criteria of Premenstrual Syndrome (Mortola, 1992)

1. The presence of at least one of the following somatic and affective symptoms during the five days before menses in each of the three prior menstrual cycles:

AFFECTIVE	SOMATIC
Depression	Breast tenderness
Angry outbursts	Abdominal bloating
Irritability	Headache
Confusion	Swollen extremities
Social withdrawal	
Fatigue	

2. Relief of the above symptoms within 4 days of the onset of menses, without recurrence until at least cycle day 12.

3. The symptoms are present in the absence of any pharmacological therapy, hormone treatment, drug or alcohol use.

4. The symptoms occur during two consecutive cycles of prospective recording.

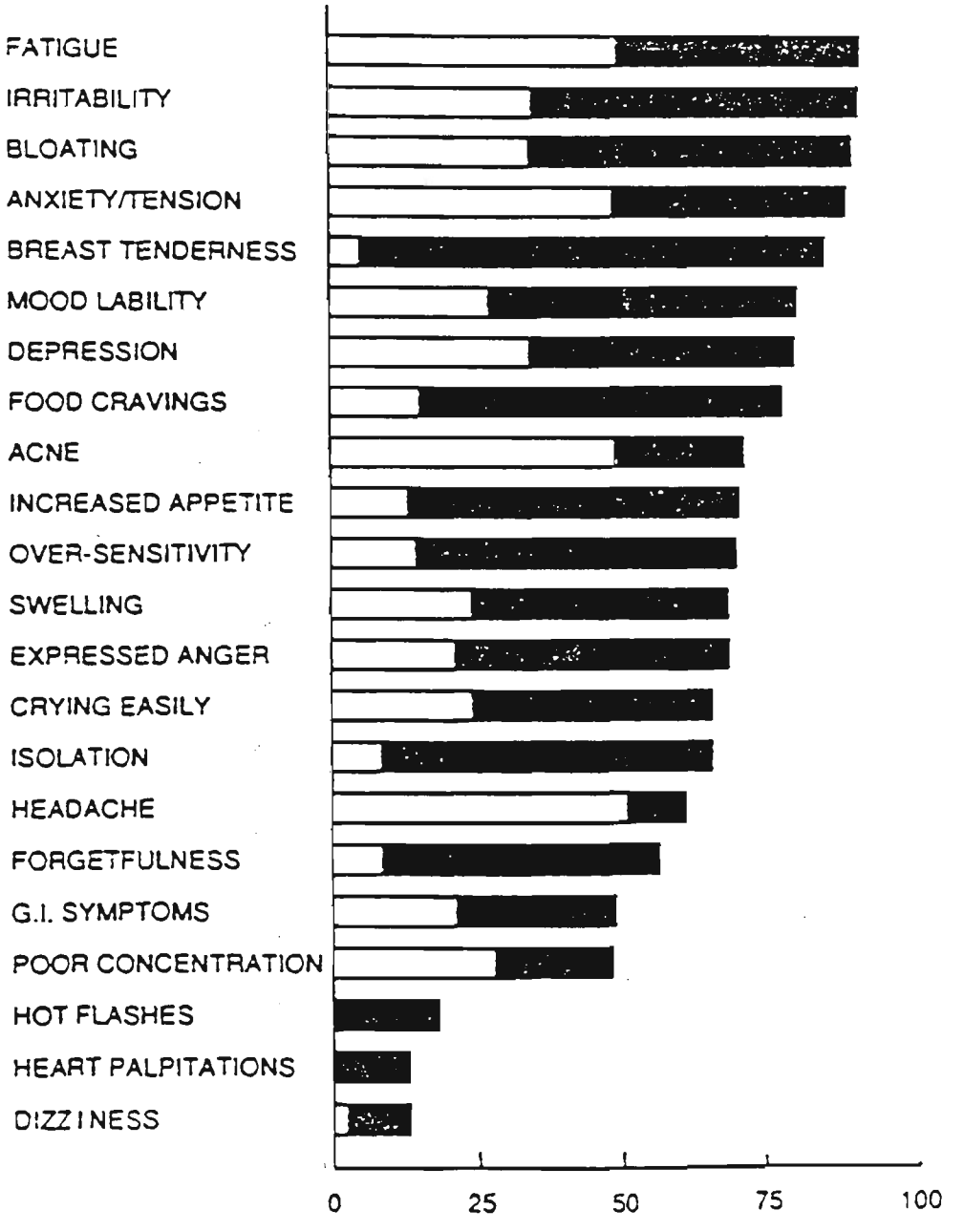
5. Identifiable dysfunction in social and/or economic performance.

The ease of administration of the instrument (COPE), which requires less than 2 minutes per day, appears to be a distinct advantage of the instrument over similar ones. The instrument was developed from an analysis of the most commonly reported symptoms of PMS collected over a 3-year period from 170 women who experienced the disorder. These symptoms are listed in **Diagram 1** (see page 12). They include the 12 most common behavioural symptoms and the 10 most common physical symptoms. Each symptom is rated daily on a scale of 0 to 3, where 0 indicates the symptom was not present; 1 indicates the symptom was noticeable but did not impair activity; 2 indicates the symptom interfered with the ability to function; and, 3 indicates incapacitation because of the symptom. A follicular phase score can be tabulated rapidly by summing the total points on days 3-9 of the menstrual cycle and a luteal phase score by summing the total points on the last 7 days of the cycle.

Robinson and Garfinkel (1990) stated that the lack of specificity of the symptoms attributed to PMS, as well as their overlap with many other physical and emotional disorders have made it hard to clarify an effective approach to treatment. Meanwhile, the aetiology of the disorder remains unclear with multiple theories suggested but none proven. These include progesterone deficiency, altered levels of oestrogen and progesterone, dysfunction of the serotoninerrgic system, circadian rhythm abnormalities, disorder of the renin-angiotensin-aldosterone system, psychological disorders, genetic disorders and disturbances resulting from social, environmental or dietary factors. Current consensus is that normal ovarian function rather than hormone imbalance is the cyclical trigger for biochemical events within the central nervous system and other target tissues. According to O'Brien (1994), a psycho-neuro-endocrine mechanism triggered by the normal endocrine events of the ovarian cycle seems the most plausible explanation. However, social factors also undoubtedly play an important role (Rodin 1992; Dennerstein *et al, 1993;* Andrew 1994). Indeed, it is not clear whether we are dealing with a syndrome with a single or multiple aetiology

or, in fact, whether there are many different varieties of PMS (Halbreich *et al*, 1982; Hargrove *et al*, 1982; Helvacioglu *et al*, 1993; O'Brien, 1993; Wallin *et al*, 1994).

Diagram 1. *"Incidence (percent of cycles) with which individual symptoms were reported in the follicular phase (open bars) and luteal phase (entire bars) in 170 women whose symptom reports were used to select items to be included in the construction of the calendar of premenstrual experiences (COPE)." G.I. = gastrointestinal* (Mortola *et al*, 1990)



2.3 Treatment Options

Treatment of premenstrual syndrome can be classified into at least three categories, although each category of treatment is currently limited in its effectiveness (Robinson *et al*, 1990; Rausch *et al*, 1992). The first category aims at eliminating the menstrual cycle. The second category aims at relieving symptoms of specific complaints, and the third category aims to correct the presumed cause of the disorder.

The first category of PMS therapy is designed to abolish ovulation, menstruation and the cyclic changes in oestrogen and progesterone. A number of approaches has been suggested.

Oral contraceptives contain a combination of various synthetic oestrogens and progestogens that may eliminate ovarian cyclicity. It has been used in minimizing premenstrual symptoms and it may be an ideal choice to help PMS symptoms if contraception is required (Maria, 1994). Several large-scale surveys (Graham *et al*, 1987; Smith *et al*, 1989; Severino *et al*, 1989) report that certain symptoms such as irritability and depression may be reduced by taking oral contraceptives, but other studies on the effectiveness of oral contraceptives appear to be equivocal (Mortola, 1994). There even appears to be a subgroup of women whose symptoms increased while on oral contraceptives (Cullberg, 1972; Severino *et al*, 1989).

Danazol is an attenuated androgen and used to suppress the menstrual cycle in several gynaecological conditions such as endometriosis and menorrhagia. Premenstrual syndrome frequently responds to Danazol therapy and three controlled clinical trials have described the benefit of that treatment (Watts *et al*, 1985, 1987; Gilmore *et al*, 1985; Sarno *et al*, 1987). Even though Danazol can treat PMS effectively, the unpleasant side effects of this drug such as weight gain, nausea and masculinization

make it very difficult to maintain patients on this treatment (Robinson *et al*, 1990).

For short term relief of severe symptoms, the use of gonadotrophin-releasing hormone agonists (Gn RH-a) have been demonstrated in well-controlled studies (Muse *et al*, 1984; Hammabach *et al*, 1988). Magos *et al* (1986) have reported the treatment of PMS with oestradiol implants and cyclical oral Norethisterone. They noted a significant improvement with this treatment after the first two months. It is interesting that even in this study of carefully selected women, 94% demonstrated an immediate placebo response.

Hysterectomy and oophorectomy have also been proposed as treatments for severe PMS (Reid, 1987; Casper *et al*, 1990; Casson *et al*, 1990). However, Dalton (1984) has reported the persistence of cyclic symptoms after hysterectomy in a small number of women.

The second category of PMS therapy applies to a symptomatic approach. Various therapeutic approaches such as dietary modification, exercise and psychoactive drugs have been suggested to manage the specific symptoms of PMS (Abraham *et al*, 1987; Harrison *et al*, 1987; Chuong *et al*, 1992).

Although dietary modification in PMS is widely recommended, there has been limited evaluation of this approach in controlled settings. Nevertheless, Chakmakjian *et al* (1985), found a significant improvement in two PMS subgroups using Optivite (a vitamin supplement) versus placebo. Unfortunately, this study has limited validity because it uses only the subjects' retrospective recall of one cycle to diagnose PMS. Massil *et al* (1987) has suggested that women eat small meals regularly and reduce tea, coffee and alcohol intake, especially in the premenstrual phase. Over the last few years, nutritional supplements have been used widely as treatments for PMS (Abraham

et al, 1987; Stewart, 1987; Kendall *et al*, 1987). Their use is based on the assumption that patients with PMS consume more refined sugar, refined carbohydrates, dairy products and less vitamins and minerals than do other women (Goei *et al*, 1982). However, an excess or deficiency of dietary factors, vitamins, and minerals has not been demonstrated well in patients with PMS compared with controls.

The symptoms of anxiety and depression that are reported in the premenstrual phase have led to psychoactive drugs being prescribed for PMS. The efficacy of Alprazolam, a benzodiazepine drug given during the luteal phase of menstruation has been demonstrated in controlled studies (Harrison *et al*, 1987; Smith *et al*,1987). Harrison *et al* (1987) assessed 34 women treated with Alprazolam in a double-blind placebo controlled study. Alprazolam was rated to be superior to placebo by both the women (73% versus 12% for placebo) and the researchers (60% versus 6% for placebo). Even though psychoactive agents are among the most commonly prescribed medications for PMS, Rausch *et al* (1992) stated that they often see women with complaints of PMS and chronic fatigue, who had been inappropriately started on a mild sedative, such as Meprobamate. The fatigue associated with this drug resolved immediately after cessation.

Some researchers believe that exercise is another approach with beneficial effects on PMS. Exercise has been said to result in a release of endorphin, with a significant reduction in depression scores in clinically depressed subjects (Brown *et al*, 1981). Both its effect on endorphin levels and its tendency to alter menstrual cycles have led to the suggestion that it may be of benefit in PMS. Preliminary research suggests that exercise training in sedentary women led to an improvement in mild premenstrual symptoms (Prior *et al*, 1987).

Stude (1991) examined a potential relationship between chiropractic spinal adjustment procedures and the management of PMS in his study. Protocols from this isolated case study are presented in his study as a basis for suggested future research.

The third category of PMS therapy is designed to correct the cause of the disorder. This approach still remains presumptive. However, the limitation to understanding PMS has not deterred some researchers from advocating specific treatments based on a presumed pathogenesis (Robinson *et al*, 1990). In this category, the most prominent hormonal treatment for PMS for many years was the luteal-phase administration of progesterone. It has received the most publicity and has probably been most abused in recent years. Dalton (1984) has been the major proponent of the effectiveness of this treatment, hypothesising that PMS is due to a deficiency or withdrawal of progesterone. A placebo-controlled study by Dennerstein and colleagues (1985) noted that administering oral micronized progesterone to patients with PMS improved their symptoms more than placebo treatment. Several other placebo-controlled, double-blind studies of progesterone therapy have been reported, and all of these studies showed that progesterone provided no better relief from PMS symptoms than placebo (Sampson, 1979; Van der meer *et al*, 1983; Andersch *et al*, 1985; Maddocks *et al*, 1986). The most recent study by Freeman and colleagues (1990) followed 121 patients taking vaginally administered placebo or progesterone each for 2 months. Daily prospective symptom charting was performed and it was concluded that progesterone was no better than the placebo. However, most patients are best served by avoiding progesterone therapy, as its adverse effects such as increased breast tenderness, bloating of the abdomen and extremities, and emotional lability are one of the most well established features in the PMS medical literature (Osofsky, 1990; Mortola, 1994).

Synthetic progestin that can be taken orally has been suggested as an alternative to progesterone therapy, despite the occurrence of troublesome side effects. Hellberg *et al* (1991) gave Methoxy progesterone acetate to 43 patients with PMS in a controlled study, and he noted the drug to be significantly better than the placebo at relieving 10 typical PMS symptoms. However, other controlled trials (Coppen *et al*, 1969; Haspels, 1981; Kirkham *et al*, 1991) failed to show any significant benefit.

Many studies (Meltzer, 1989; O,Brien, 1993) in the literature have suggested an interaction between neurotransmitters and behaviour. One of these, serotonin, is known to play a mediating role in the genesis of mood and behavioural disorders in which depression, irritability, and aggression are prominent (Meltzer, 1989).

Fluid retention has been hypothesised as causing not only weight gain and oedema, but also psychological symptoms (Greenhill *et al*, 1941). Several controlled studies have shown the effectiveness of diuretics in treating PMS (O'Brien *et al*, 1979; Vellacott *et al*, 1987). O'Brien *et al* (1979) demonstrated that administration of Spironolactone, a potassium-sparing diuretic, significantly improved PMS symptoms, including mood changes and decreased premenstrual weight gain. In these trials, Spironolactone was administered during the luteal phase of four menstrual cycles in a randomised double-blind crossover model.

In a study by Jakubowicz *et al* (1984), prostaglandin action was suggested as a cause of PMS. It was proposed that a prostaglandin synthetase inhibitor such as mefennamic acid might relieve symptoms. Jakubowicz *et al* (1984) demonstrated improvement with mefenamic acid in many of the psychological symptoms. Budoff (1983) and Mira (1986) also demonstrated support for prostaglandin inhibitor theory. It was suggested that mefenamic acid may be especially effective when PMS is associated with

dysmenorrhoea or menorrhagia. It may be argued here that the relief of menstrual, rather than premenstrual symptoms, makes women feel generally better.

Brush *et al* (1984) stated that some patients with PMS appear to have abnormal levels of certain fatty acids that are precursors in the synthesis of prostaglandins. In addition, serum levels of certain prostaglandin metabolites in these women are decreased. These data support the usefulness of evening primrose oil (EPO), which contains increased amounts of gamma-linolenic acid, in PMS therapy. Jakubowicz *et al* (1984) demonstrated lower serum levels of prostaglandin E2, prostaglandin F2-alpha, and prostaglandin F2 in PMS patients, compared with controls. Several studies demonstrated that EPO may indeed improve PMS under certain circumstances (Puolakka *et al*, 1985; Pye *et al*, 1985).

Bromocriptine, a dopamine agonist that suppresses the release of prolactin has been used to test the theory that PMS is related to an increase in prolactin levels, although the relationship has not been conclusively demonstrated (Robinson *et al*, 1990). The available studies on the effect of Bromocriptine on PMS are very confusing and contradictory. Even though a study by Harrison *et al* (1985) showed that there was no difference between Bromocriptine and a placebo, bromociptine does appear, however, to be effective in the treatment of premenstrual mastalgia (Anderson *et al*, 1977, Elsner *et al*, 1980).

It has been hypothesised that PMS is caused by endorphin deregulation of norepinephrine (NE) at the *locus ceruleus* (Reid, 1987; Giannini *et al*, 1988). This has led to studies of both catecholaminergic drugs and those which antagonise endorphin. Clonidine and Verapamil have been demonstrated to be helpful in the treatment of mania and opioid and nicotine withdrawal (Robinson *et al*, 1990). Several investigators have carried out small studies, that suggest, that these medications are

beneficial for the treatment of PMS symptoms, especially anxiety and irritability (Casper *et al*, 1987; Deicken, 1988; Giannini *et al* 1988). It is interesting to note that a medication that is helpful in the treatment of opioid withdrawal may also help relieve PMS symptoms. This would suggest that PMS symptoms may be due to a decrease in beta-endorphin.

2.4 Traditional Chinese Medicine and PMS

In Traditional Chinese Medicine (TCM), health is considered to be a function of the smooth flow of *qi* through a series of pathways (meridian system) which link and unite all parts of the body into a single integrated whole. Disease is defined as an imbalance of, or disruption to, the movement of *qi* (Watson, 1991).

TCM describes illness as "*zeng*" (a pattern of disharmony or a syndrome), a function of both internal and external phenomena adversely affecting the whole person. Illness is seldom thought of as being the sole result of a single causative agent (Watson,1991).

Kaptchuk (1983, pp.258-259) stated that:

> *"Chinese medicine offers a different vision of health and disease, one that is implicitly critical of Western medicine, because it refuses to see the individual as an entity separate from his or her environment. Most importantly, Chinese medicine attempts to locate illness within the unbroken context or field of an individual's total physical and psychological being. It aims to cure through treatments that encompass that whole of the individual as closely as possible."*

Everything in one's internal and external environment can contribute to the development of a pattern of disharmony. According to Western bio-medicine, a syndrome is a group of signs and symptoms which typically occur together and for which as yet there is no satisfactory explanation. As a pathological generalisation of a disease in its certain stage, a syndrome in TCM reflects the law and nature of a disease, serving as a basis for treatment. Therefore, a syndrome in TCM differ from symptoms (Kaptchuk, 1983; Zhang, 1988b; Watson, 1991).

Flaws (1991) states that TCM offers a better explanations for PMS, both individually and epidemiologically, as well as being a more effective treatment approach. He states that:

> *"Chinese medicine not only recognises the symptoms of this syndrome as a pattern, but does in fact define the aetiology of this pattern" (Flaws, 1991, p.1).*

According to TCM theory, the menstrual cycle is associated with the *shen* (kidney meridian system), the *gan* (liver meridian system), the *xin* (heart meridian system) and the *pi* (spleen meridian system), as well as the *chong mai* and *ren mai* meridians. A TCM classical text "*Huang Di Nei Jing*" (Yellow Emperor's Classic of Internal Medicine, Anon, Circa 100 BC) describes menstruation as *tian kui* (heaven water). It states that "at the age of seven, the kidney (*shen*) *qi* in females starts flourishing, the teeth change and hair grows in abundance, and at the age of fourteen the *tian kui* becomes full. At that time the *ren mai* which governs and transports all the *yin* of the body, flourishes and flows freely. Meanwhile, the *chong mai* is also full, and therefore menstruation can be starting" (Qiu *et al*, 1984).

When making a diagnosis in TCM, the practitioner not only considers the generic signs and symptoms of a pathology, but also considers the signs and symptoms peculiar to the individual, many of which would not be given significance within the Western medical framework (Watson, 1991). Diagnosis in TCM requires the application of

various diagnostic procedures, and the interpretation of that information in accordance with recognised patterns of disharmony. TCM diagnostic methods aim to collect signs, symptoms and other related diagnostic information from the client. These methods include interrogation, inspection, auscultation and olfaction, pulse-feeling and palpation. All these methods aim to provide a basis for differentiation in the patterns of disharmony. In this process, analysis and inferences are made on the basis of acquired clinical data.

Because PMS occurs during the menstrual cycle, the cause is seen by TCM as the energetic imbalance of the *gan* (liver meridian system), *shen* (kidney meridian system), *xin* (heart meridian system), *pi* (spleen meridian system) and *chong mai* and *ren mai* meridians. However, according to the TCM principle of *bian zheng* (pattern differentiation), the main cause of PMS is the *gan qi* congestion (Zhang, 1988c; Flaws, 1986). In TCM, the *gan* is responsible for spreading and regulating *qi* and *xue* (blood and its functions). Pathological changes to the *gan* in females usually results in:

(1) Emotional Changes

According to TCM theory, certain emotional activities are related to the function of the *gan* (liver meridian system), in smoothing and regulating the flow of *qi* and blood (*xue)*. When the *gan* is dysfunctional, the affected person will fail to coordinate their emotional activities. This is indicated by one or more of the following major symptoms of irritability, expressed anger, mood swings, anxiety, sighing or depression.

(2) Change to Digestive Function

According to TCM theory, the *pi* (spleen meridian system) is responsible for the transportation and transformation of nutrients from food and drink while stomach digests and subsequently sends food down the alimentary canal for further processing. However, since *gan* plays a part in ensuring the healthy function of the digestive system, the smooth flow of the gan *qi* is an important

requirement for the ascending and descending functions of the spleen and stomach. Moreover, the *gan* involves the production of bile in the liver and storage in the gall-bladder. If this function is disturbed, one or more of the following may be present: change of appetite, food craving, abdominal bloating, belching, nausea and vomiting, or diarrhoea.

(3) Obstruction to the Flow of *Qi*

Gan qi congestion exerts a direct influence on the flow of *qi* not only in the *gan* meridian but also in the related meridians and organs. This may result in one or more of the following: breast tenderness, abdominal bloating, fluid retention, pain and distension in the hypochondria, lumpiness in the breasts, headache, insomnia or fatigue.

In TCM, herbal medicine and acupuncture have long been used for gynaecological and obstetric problems. As early as the Ming Dynasty (987 AD), Chinese physician were prescribing a special herbal formula *Xiao Yao San* (free and easy powder) for treating women who were suffering from congestion of *gan qi* with deficiency of the *xue*. The symptoms could include hypochondriac pain, headache, dizziness, a bitter taste in the mouth, a dry throat, fatigue, a poor appetite, alternate attacks of chills and fever, irregular menstruation, distension in the breast, a light redness of the tongue, or a wiry and weak quality of the pulse (Pei *et al* 1997)

Contemporary TCM practitioners consider PMS as " *Xing Jing Qi Zhu Zheng* " (symptoms during menstruating) or "*Jing Qian Qi Zhong He Zheng*" (symptoms before menstruating). Following the principles of diagnosis (*Bian Zheng*) and treatment (*Shi Zhi*), TCM practitioners determine the corresponding therapeutic methods according to the different presenting patterns (*Zheng*). In a study by Liao *et al* (1990), women in a Chinese herbal treatment group had better outcomes than women in a Bromocriptine group. Flaws (1991) reported that the use of Chinese

herbal formulas can eliminate over 50% of all PMS symptoms within three menstrual cycles. Moreover, he claimed, that in many cases all symptoms of PMS can be eliminated within a single menstrual cycle. Oleson *et al* (1993) conducted a study on PMS using ear, hand and foot reflexology, this study demonstrated a significantly greater decrease in premenstrual symptoms for the treatment group than for the placebo group.

Acupuncture as a remedy for premenstrual and menstrual problems, has increased in popularity during this decade. Many reports have shown improvement in such problems using acupuncture therapy (Tsuei, 1984; Steinberger, 1981; Slagaski, 1984; Hu, 1989; Kehring, 1985; Helms, 1987; Zhan, 1990). Chang (1992), in a study involving 108 cases of PMS reported that using scalp acupuncture was very effective. Deng (1988) has needled acupuncture channel points in a large group of PMS women with very good response. Zheng (1991) reported stimulating channel and ear acupuncture points by laser acupuncture machine on 56 PMS women with success. But most were case reports and uncontrolled clinical trials, which paid little attention to the need for independent assessment of the results.

Extensive research in China, USA, France, Germany and Japan (Zhang 1988d) has shown that acupuncture directly influences the hormonal, neuroendocrine, and immune systems. Recently, many reports have shown that acupuncture has a remarkable effect on the pituitary gland and adrenal cortex system, the sympathetic nerve system, the adrenal medulla system, the pituitary and thyroid gland system, the sexual glands and the posterior pituitary system, and the actions at different sites of endocrine activity (Helms 1987; Zhang, 1988d). Even though some clinical studies of PMS have indicated that acupuncture affects neurotransmitter levels (Harrison, 1985), no controlled clinical study in this area has been undertaken.

Helms (1987) reported, that 10 out of 11 (90.9%) subjects treated with acupuncture for dysmenorrhoea showed improvement, compared with 4 out of 11 (36.4%) subjects treated with placebo acupuncture. These results are similar to the results of studies using non-steroidal anti-inflammatory drug therapy for dysmenorrhoea, where the range of subjects experiencing pain relief is 56-100%, and in the placebo group is 13-20%. Even though Helms's (1987) study is not on PMS, according to TCM theory, the cause of dysmenorrhoea and PMS is often the same, liver *(gan) qi* congestion. As acupuncture is considered an effective treatment for the liver *(gan) qi* congestion, its use in the treatment of PMS is worth investigating. This is further supported by Helms' (1987) study, where the subjects often reported an improvement, not only in cramping pain and the extra genital symptoms of nausea, headache, and backache, but also in premenstrual symptoms of fluid retention and breast tenderness.

2.5 The Problems with Acupuncture Clinical Trials

There are very few quality acupuncture clinical trials on internal diseases especially menstrual disorders. Since a popular perception in the Western world is that acupuncture is mainly used for pain relief, the majority of the clinical trials have focused on pain management and musculoskeletal disorders (Godfrey *et al*, 1878; Jensen *et al*, 1979; Loy, 1983; Tavola *et al*, 1992; Haker, 1993; Takeda *et al*,1994). Many of these studies were conducted by researchers who were not well enough trained in acupuncture to provide quality TCM diagnosis and treatment.

Moreover, many clinical trials are seriously flawed by methodological problems. Poor design, inadequate outcome measures and statistical analysis, inadequate controls, inadequate instruments, poor knowledge of TCM, formula treatment instead of individualised treatment and sham acupuncture at real acupuncture points are the most common problems (Vincent, 1993; Bensoussan *et al* 1996).

Furthermore, many "acupuncture" clinical trials have been conducted by using transcutaneous electrical nerve stimulation (TENS). Unfortunately, TENS is not acupuncture, as it does not accommodates the particular clinical requirements of acupuncture and is restricted only to identified trigger (tender) points not traditional acupuncture points (Vincent, 1993; Bensoussan *et al* 1996).

2.6 Summary of literature review

The aetiology of PMS from a Western medical perspective still remains unclear even though numerous theories has been suggested. Recent advances in the understanding of the pathogenesis of PMS have allowed the development of appropriate pharmacological interventions. Although some of the agents have been proven effective and are widely used to treat the disorder, at present there are no approved medications for this disorder. In addition, most of the pharmacological agents have adverse effects which limits their use in some patients. On the other hand, the aetiology of PMS from a TCM point of view is quite clear. How ever, until now, there are no rigorous TCM clinical trials on PMS. Many clinical trials in acupuncture are seriously flawed by methodological problem.

CHAPTER 3 : AIM AND OBJECTIVES OF THE STUDY

3.1 Aim

This study is designed to evaluate the efficacy of traditional Chinese acupuncture in the treatment of Premenstrual Syndrome (PMS).

3.2 Objectives

- To review the contemporary literature on PMS;
- To review the Traditional Chinese Medical literature, both classical and contemporary, on the treatment of conditions similar to PMS;
- and to
- Design and undertake a single blind controlled clinical trial on the treatment of PMS with traditional Chinese acupuncture.

CHAPTER 4 : METHODOLOGY AND TECHNIQUES

This trial is a single blind controlled clinical trial conducted by a qualified acupuncturist. The researcher gained a Bachelor of Medicine degree in Traditional Chinese Medicine after completing the five year program at the Nanjing University of Traditional Chinese medicine. Although double-blind trials are considered to be the preferred method in any clinical research (Pocock, 1985), an acupuncture trial cannot be double-blind, as the research needs to be conducted by a qualified acupuncturist for safety and ethical reasons.

4.1 Sample Group

Forty six women were interviewed by the researcher and evaluated for inclusion in the study. The diagnostic criteria used to determine a history of PMS (Mortola, 1992) are included in **Table 1**(see page 11). A synopsis of the criteria is:

(a) a three months recurrence of at least one behavioural (affective) symptom and one physical symptom during the 5 days before menses, both of which being documented by a self-maintained "Menstrual Diary" (see Appendix B);

(b) relief of the symptoms within 4 days of the onset of menses and a symptom-free interval lasting until at least cycle day 12;

(c) reporting substantial differences in scores between prospective follicular and luteal phases in the Calendar of Premenstrual Experiences (COPE);

(d) having regular menstrual cycles during the previous six cycles;

(e) not using hormonal or pharmacological agents;

(f) not being pregnant or lactating during the previous twelve months.

Sixteen women were excluded from participating in this study for the following reasons:

- seven were suffering from period pain only;
- three reported irregular periods;
- four were very mild PMS suffers, and
- two were using oral contraceptives.

After the completion of three consecutive cycles of prospective recording in a menstrual diary, thirty subjects aged 24-45 years entered the treatment phase of the study. The majority (62.5%) of the subjects reside in the Western suburbs of Melbourne. Their involvement resulted from interest stimulated by advertisements in local papers, community health centres and by a community radio station. The remaining subjects (37.5%) live in other suburbs within metropolitan Melbourne. These women were referred from several hospitals, in response to an article in " Life Wise " magazine and to an interview on SBS Radio (Mandarin language programme). All interviews were conducted at the Health Practice Unit, St Albans Campus, at Victoria University of Technology.

4.2 Instrument

The Calendar of Premenstrual Experiences (COPE) scale with minor changes (changed mood liability to mood swing; changed poor flushes to hot flushes) has been used throughout this study for a prospective recording of symptoms, in order to establish the presence and the severity of PMS and to identity changes of these symptoms at the end of the study. The validity and reliability of COPE were created and assessed by Mortola *et al* (1990) from the

Department of Reproductive Medicine, School of Medicine, University of California, administering it throughout two consecutive ovulation cycles to thirty-six rigidly screened women with PMS, as well as to eighteen controls. A research results showed that the COPE luteal phase score distinguished PMS women from controls correctly in 104 out of 108 cycles, with only a 2.8% false-negative rate and no false positives (Mortola *et al* 1990).

Concurrent validity has been established by correlating specific items from the COPE Scale with similar items on the profile of Mood States Scale (Mortola *et* al, 1990). Mortola *et al* (1990) concluded that the COPE instrument is a valid, reliable and practical PMS inventory, which can be used in clinical practice and some research procedures.

In this study, daily symptom experience was recorded by each participant for three consecutive menstrual cycles (before, during and after the treatments) in a "Menstrual Diary" (**appendix 1**), which defines the most commonly reported symptoms of PMS, including 12 common behavioural symptoms and 10 physical symptoms. The participants were also required to record any other symptoms experienced during the cycle which were not listed in the "Menstrual Diary". Each day the participants rated their menstrual cycle-related symptoms in order to define their presence and severity. A scale of 0 to 3 was used (**appendix 2**), where 0 indicated that the symptom was not present; 1 indicated that the symptom was noticeable but did not impair activity; 2 indicated that the symptom interfered with the ability to function, and, 3 indicated incapacitation because of the symptom.

A follicular phase score was established by summing the total points on days 3-9 of the menstrual cycle. A luteal phase score was done by summing the total

points on the last 7 days of the cycle. Measurements were obtained monthly throughout the course of the study for each subject. The total scores of the follicular phase symptoms and the luteal phase symptoms were used to select subjects for the study and to determine individual differences pre- and post-treatment, and to compare the pre- and post- treatment between the real acupuncture and sham acupuncture groups.

The subjects were also required to record a daily basal body temperature (BBT) as an adjunct of COPE in order to distinguish between the follicular and the luteal phases.

4.3 Setting

Subjects living in the Western metropolitan area of Melbourne attended the Health Practice Unit (HPU), St Albans Campus, Victoria University of Technology, for initial interviews and for the treatment required. An acupuncture practice centre in a Melbourne South-Eastern suburb was used for those subjects who were unable to access the HPU.

The primary focus of both health care facilities is acupuncture therapy. The Health Practice Unit is a multi-disciplinary health care facility, providing a variety of services to both the University and local communities. The HPU was established in 1994 to provide a facility for teaching, practice and research, for students and staff of the University. The health care services currently offered at the HPU are acupuncture therapy, herbal medicine, massage therapy and community group projects. It is serviced by students and staff of the Department of Health Sciences of Victoria University. There are four treatment rooms in the unit. The acupuncture centre is a private acupuncture and Chinese medicine practice with two treatment rooms,

providing acupuncture and Chinese herbal treatment. The practice was established in 1993 and serves the south-eastern metropolitan area of Melbourne.

4.4 Procedures

The procedures undertaken by all subjects in this study comprised two phases with each phase covering three consecutive menstrual cycles.

4.4.1 Phase I: Diagnostic Phase

Each participant was required to record their menstrual cycle symptoms daily for three cycles by using the Calendar of Premenstrual Experiences (COPE) as a tool for the prospective confirmation of the diagnosis of PMS. Before giving the COPE instrument to the participants, formal interviews were arranged for each of the participants who were provided with a plain language description of the study (**Appendix 3**). During the interview, the researcher, a practitioner of Chinese medicine, firstly provided a profile of his personal and academic background (**Appendix 3**), and then briefly explained the aim and the procedures of the study. After the interview, the women were asked to further consider whether they wanted to participate into this study. If they wanted to participate, they were asked to contact the researcher by phone to arrange for their first appointment. Upon consent to participate, the women were asked to complete a personal information sheet (**Appendix 4**) which included:
a). general information, b). history of menstruation, c). retrospective history of PMS and the symptoms for the past six months, d). general health history. Accordingly, a tentative diagnosis of PMS for each participant was made.

After the interview, each participant was given a "Data Records" booklet (**Appendix 6**) which contained: 1). a preface, which briefly explained the

necessity of maintaining records of personal menstrual experiences for three months before commencing treatment, 2). instructions, on how to record daily symptom experiences accurately, and 3). forms for the menstrual diary, on which symptoms experienced were to be recorded. The researcher also explained the meaning of each symptom that was listed in the "Menstrual Diary" (**Appendix 1**).

The researcher met with every participant at the end of each menstrual cycle during the three month pre-treatment phase in order to undertake a preliminary review of their records and to discuss their progress and concerns. When the participant completed three menstrual cycles of recording, the luteal phase and the follicular phase scores were calculated by the researcher in order to establish a diagnosis of premenstrual syndrome according to the criteria used in this study.

The Diagnosis of PMS was based on the following criteria:

1. the luteal phase score had to be at least twice that of the follicular phase score;
2. the luteal phase score had to be at least 42;
3. the follicular phase score had to be less than 40. [NB: A follicular phase score of more than 40 suggested a disorder other than PMS. In well-selected populations, women with PMS alone do not achieve higher follicular phase scores on this inventory, as described by Mortola (1992)].

Thirty women met the above criteria and were selected into this study. In order to place them into different TCM pattern groups, all the subjects underwent a thorough TCM diagnostic assessment. The assessment included the four TCM classic diagnostic approaches. They are:

1. looking: to observe the systemic and regional changes through the person's appearance, manner, emotions, spirit(*shen*), facial colour, skin, tongue and secretions;
2. listening and smelling: voice, respiration, body odour etc.
3. asking: to gain information about the onset and progress of the complaint, present symptoms, associated symptoms with the complaint, and other conditions relevant conditions. Ten TCM classical questions were asked.
4. palpation and pulse taking: to detect the pathological changes by feeling the pulse and palpating the skin, head, neck abdomen and acupuncture points.

A TCM diagnostic sheet was designed by the researcher (**appendix 5**) and was used to determine individual's pattern of disharmony for every subject. The TCM diagnosis for each woman was verified by an independent TCM practitioner.

4.4.2 Phase II: Treatment Phase

Four women withdraw halfway through the treatment phase. Twenty-six subjects received treatments for three consecutive menstrual cycles.

4.4.2.1 Subject Groups

The subjects were grouped according to age and then the TCM patterns. The subjects within each age and TCM pattern group were then randomly assigned to either the real acupuncture group or the sham acupuncture group. The first subject in each pattern group was placed in the real acupuncture group, the second one was placed in the sham acupuncture group and the third one was placed into the real acupuncture group again (**Chart 1,2**). Three TCM

patterns of disharmony were distinguished within the twenty six subjects according to TCM differential diagnosis (**Table 2**).

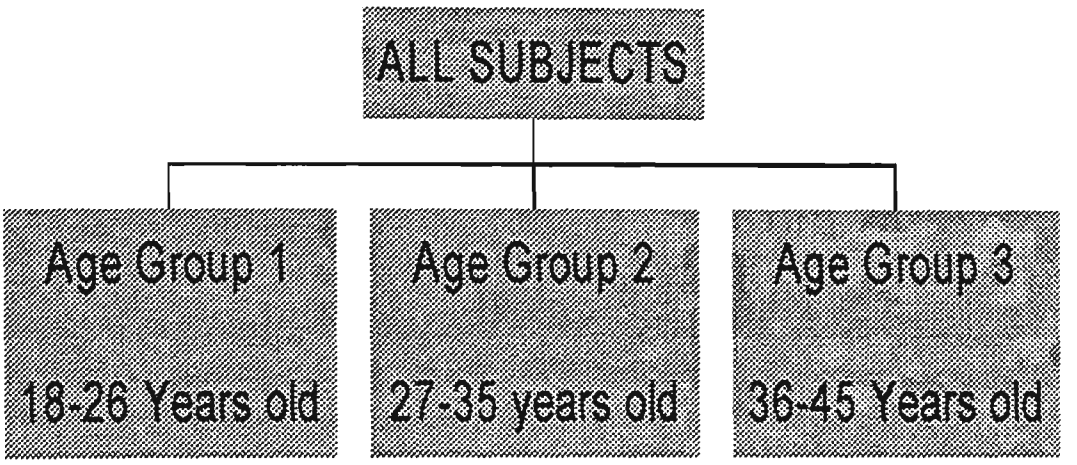


Chart 1: Subject groups according to age (arbitrary division)

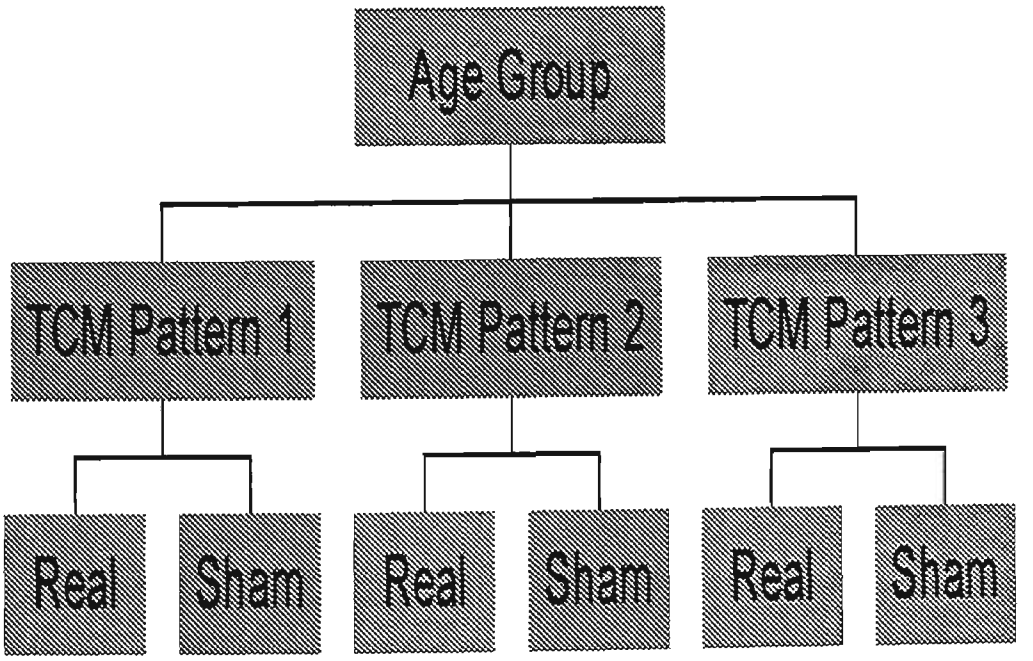


Chart 2: Subject groups according to TCM pattern

Table 2. TCM Patterns of Disharmony and Clinical Manifestations

PATTERNS	MAIN CLINICAL MANIFESTATIONS
1. Liver Qi Stagnation (*Gan QI Yu Jie*)	irritability, expressed anger, mood swings, tension, anxiety, crying easily, breast tenderness, abdominal bloating.
2. Liver Qi Stagnation, (*Gan QI Yu Jie*) Heart & Spleen Qi Deficiency (*Xin Pi Liang Xu*)	depression, mood swings, anxiety, heart palpitations, insomnia, swelling, food craving, changes of appetite, diarrhoea.
3. Liver Qi Stagnation, (*Gan QI Yu Jie*) and "discord between the heart and kidney"[1]* (*Xin Shen Bu Jiao*)	anxiety, feeling of isolation, depression, mood swings, crying easily, dream-disturbed sleep or insomnia, dizziness, heart palpitations, hot flushes.

[1]* According to the TCM theory of five elements (*wu xing*), the *xin* (heart meridian system) is seen as analogous to fire because the heart is like an energy station which brings warmth to the body; the kidney is analogous to *water* because it mainly involves water metabolism. The heart, located in the upper part of the body sends warmth to the lower part of the body while the kidney sends body fluid (*yin*) to the upper part of the body and therefore prevents the *fire* (heart) from becoming over active. The heart and kidney balance each other, each assisting and checking the action of the other. The disruption of this relationship is often referred to as "discord between the heart and kidney".

a) Real Acupuncture Group (RAG),

Subjects assigned to the Real Acupuncture Group (RAG) were given acupuncture therapy in accordance with TCM principles and differential diagnosis. The treatment principles were determined according to the three TCM Patterns:

1. The treatment principle for Pattern 1 was to soothe the liver and move the stagnated liver *qi*. Major points used were:

- Liver 3--is the *Yuan* point of the liver meridian which is very powerful to regulate liver function. Liver 3 is also *Shu* point and Earth point of the meridian which has the effect of moving and soothing liver qi flowing along the meridian, and harmonise Earth (spleen/stomach) and Wood (liver/gall bladder).
- Large Intestine 4--is the *Yuan* point of the large intestine meridian which is often used together with Liver 3 (four gates of the body) to encourage and promote the free flow of the qi along the whole system. The combination of Liver 3 and Large Intestine 4 has a strong calming effect in both physically and emotionally.
- Spleen 6--is the Meeting point of three meridians (spleen, liver and kidney) which has the effect of "one stone kill three birds". Spleen 6 is often used to strengthen the transporting and transforming function of the Spleen and to eliminate dampness and fluid retention.
- Gall Bladder 40--*Yuan* point of the Gall Bladder meridian, is used here to support the Liver meridian and enhance the effect of Liver 3 to further promote the free flow of qi throughout the system.
- Ren 3--is a Connecting point with the spleen, liver and kidney meridians where the *Yuan qi* gatherings and transports to the system especially to the reproductive organs. As the front *Mu* point of the

Bladder meridian, Ren 3 has a strong effect of clearing dampness and fluid retention.

2. The treatment principle for Pattern 2 was to soothe the liver, to tonify the heart and to strengthen the spleen. Major acupuncture points used were:

- Liver 13--is one of the Eight Influential points for the *zang* organs. It is an important point for the harmonising of all internal *zang* organs, especially in between the spleen and the liver since this point is also a front Mu point of the spleen..
- Large Intestine 4--as the *Yuan* point of the large intestine meridian, it is used here to remove the stagnated *qi* and to clear the mind and head. It also regulates the function of the Large Intestine and then helps to control the symptoms of diarrhoea or constipation.
- Spleen 6--is used here to strengthen the transporting and transforming function of the Spleen and to enhance the production of qi and blood to nourish the Heart. It also has the effect of eliminating dampness and fluid retention.
- Stomach 36--is the Earth point in the Earth meridian, therefore it has a very strong effect of strengthen the Earth organs (spleen and stomach). It is used here not only to manage all of the digestive system's symptoms, but also to support Spleen 6 to enhance the production of qi and blood.
- Heart 7--is the *Yuan* point of the Heart meridian, so it is often used to regulate the function of the Heart. Because it is also the *Shu* (transporting) point of the meridian where in controlling the Heart qi in and out, it is so called the "Gate of the spirit".

- Ren 17--is the front Mu point of the Pericardium meridian which helps the normal function of the Heart. More important is that this point is one of the *Eight Influential Points* for qi, so it has a very strong effect in promoting the free flow of qi in the whole body especially in the chest region. Therefore, it is very powerful to eliminate heart palpitations, anxiety, breasts tenderness, fatigue etc..
- Pericardium 6--is named the "inner Gate" of the body, it means this point is an important pathway towards to the internal organs. It is powerful in regulating the function of thoracic and abdominal organs especially the Heart, Lung and Stomach. It is used here in combining with Ren 17 to enhance the total effect.

3. The treatment principle for Pattern 3 was to soothe the liver, to nourish the kidneys and to calm the spirit. Major acupuncture points used were:

- Liver 3-- is the *Yuan* point of the liver meridian which is very powerful to regulate liver function. Liver 3 is also *Shu* point of the meridian that encourages the free flow of the qi along the meridian. Liver 3 is used here for the stagnated liver qi.
- Kidney 3--is the *Yuan* point of the Kidney meridian which has a strong tonify effect and nourishes *Yin*. It is also the *Shu* point of the meridian, so, it always transports the Kidney *Yin* (water) up to the body to balance the *Fire* (which is the nature of the Heart), therefore harmonises the relationship between these two organs. Kidney 3 has been used classically to regulate the *Chong* and *Ren* meridians, and these two meridians are strongly related to the reproductive system especially in women.

- Heart 7--is the *Yuan* point of the Heart meridian, is used here to harmonise the Heart and calm the *shen* (spirit). This point is also a transporting point of the Heart meridian, combined with Kidney 3 (transporting point of the Kidney meridian) would enhance the relationship between the *Water* and the *Fire*.
- Spleen 6-- as the Meeting point of three meridians (spleen, liver and kidney), Spleen 6 is used here to strengthen the function of these three meridians. It would also enhance the production of *qi* and blood to nourish the Heart and the Kidney.
- Du 20--is a extremely powerful point in governing the mind and calming the spirit, so it is used here to manage the emotional and behaviour symptoms. Du 20 is also a meeting point of Du meridian with the Liver meridian and all six *Yang* meridians, it would be very useful here to ease the Liver and lifting up energy.

The location of the points are described below and is also shown in diagrams 2-7.

1. Liver 3 is located on the dorsum of the foot, in the depression distal to the metatarsal bones.
2. Large Intestine 4 is on the dorsum of the hand, between the 1st and the 2nd metacarpal bones, in the middle of and slightly closer to the 2nd metacarpal bone.
3. Liver 13 (Liv 13) is located at the free end of the eleventh rib.
4. Gall Bladder 34 (GB 34) is in the depression anterior and inferior to the small head of the fibula.
5. Ren 3 is located on the anterior midline of the abdomen, 4 *cun* below the umbilicus.

6. Ren 17 is on the anterior midline of the abdomen, at the level with the fourth intercostal space.
7. Spleen 6 (Sp 6) is on the posterior border of the medial aspect of the tibia, 3 *cun* directly above the tip of the medial malleolus.
8. Stomach 36 (St 36) is located 3 *cun* below the lateral knee eye (St 35), one finger width lateral to the anterior crest of the tibia.
9. Heart 7 (Ht 7) is on the palmar side of the wrist, at the ulnar end of the transverse crease, in the depression on the radial side of the tendon of the ulnar flexor muscle of the wrist.
10. Pericardium 6 (P 6) is located at 2 *cun* above the transverse crease of the wrist, between the tendon of m. Palmaris longus and m. Flexor radialis.
11. Kidney 3 (kid 3) is in the depression between the tip of the medial malleolus and the achilles tendon.

b) Sham Acupuncture Group (SAG)

Subjects assigned to the Sham Acupuncture Group (SAG) were needled in areas not recognised as acupuncture points. The same number of points per subject was used in both the sham and real groups. The points used on the subjects in the real group with the matching sham points used on the subjects in the sham group are shown in Table 3. The location of the sham acupuncture points (SAP) is shown in diagrams 2-7.

The principle for the selection of sham acupuncture point was as the following:

1. Areas off the twelve primary meridians.
2. Areas off the eight extra meridians.
3. Approximately 20-30 mm from the real points.
4. Areas off the twelve divergent meridians.

5. Areas away from the recognised extra points.
6. Areas away from the joints where the meridian *qi* often accumulating.

Table 3. Real and Sham Acupuncture Points

REAL ACUPUNCTURE POINTS (RAP)	**SHAM ACUPUNCTURE POINTS (SAP)**
Liver 3 (Liv 3)	SAP No.1
Liver 13 (Liv 13)	SAP No. 2
Gall Bladder 34 (GB 34)	SAP No. 3
Ren 3	SAP No. 4
Ren 17	SAP No. 5
Spleen 6 (Sp 6)	SAP No. 6
Stomach 36 (St 36)	SAP No. 7
Heart 7 (Ht 7)	SAP No. 8
Pericardium 6 (P 6)	SAP No. 9
Kidney 3 (kid 3)	SAP No. 10
Large Intestine 4 (LI 4)	SAP No. 11

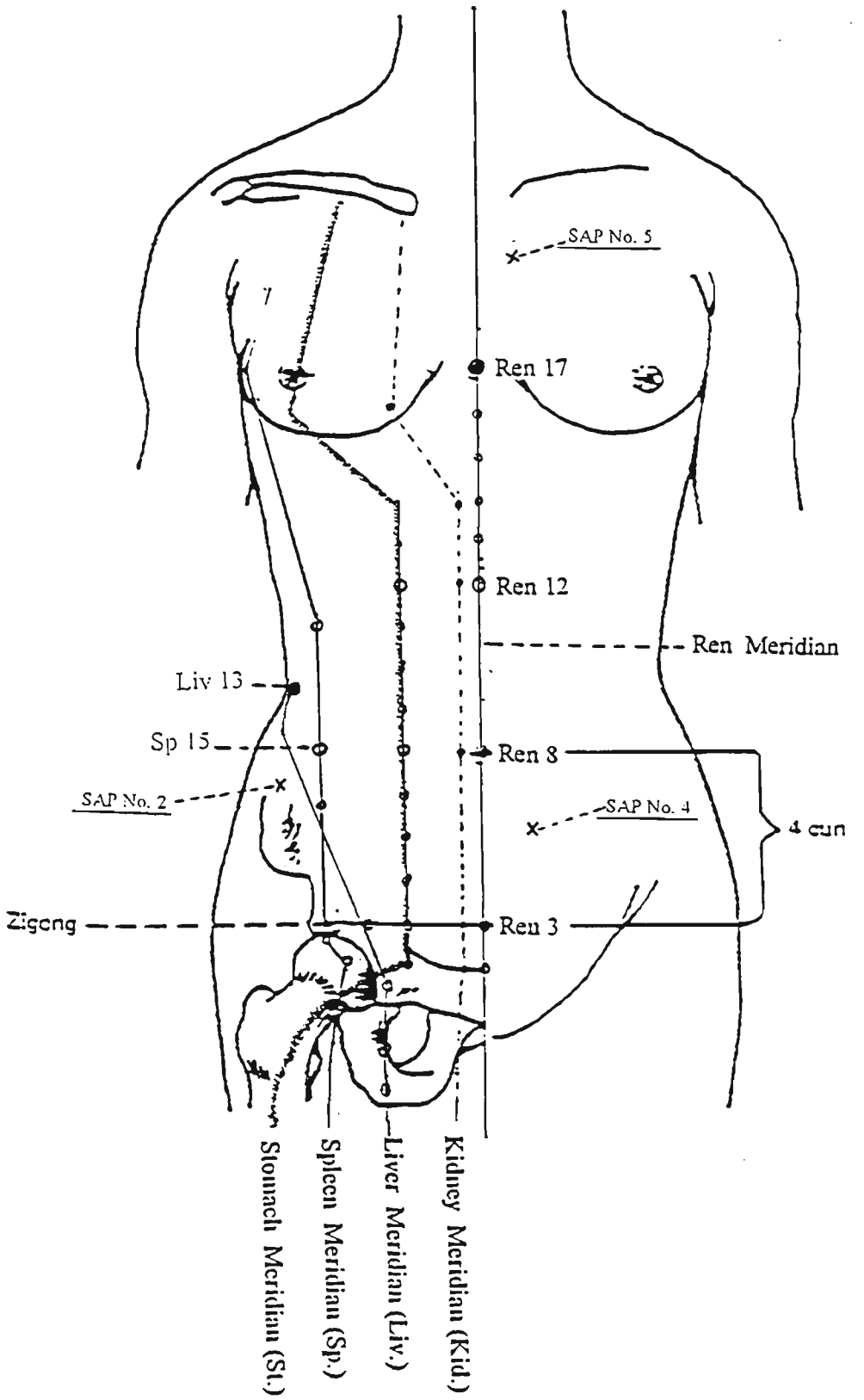


Diagram 2 Real & Sham Acupuncture Points on Chest and Abdomen

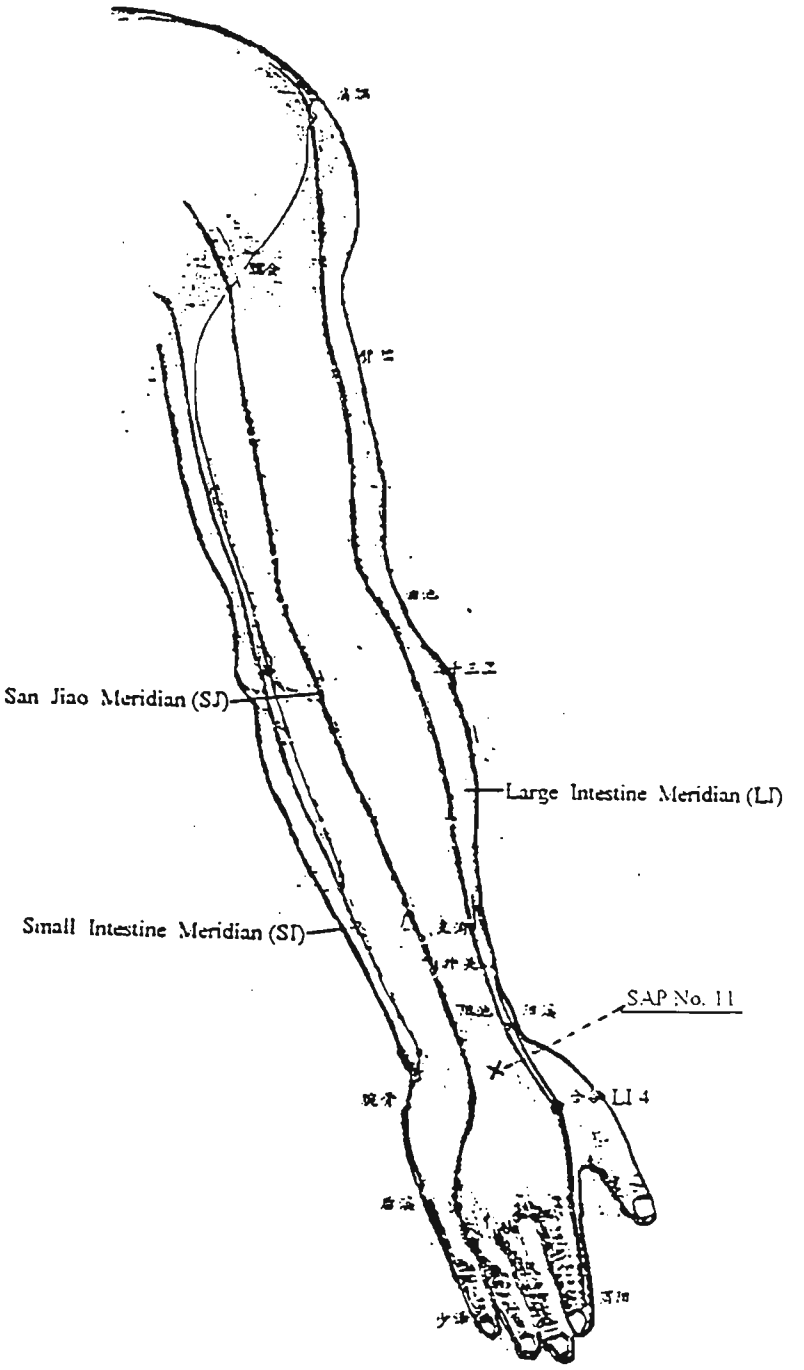


Diagram 3 Real & Sham Acupuncture Points on the Posterior Aspect of Upper Limb

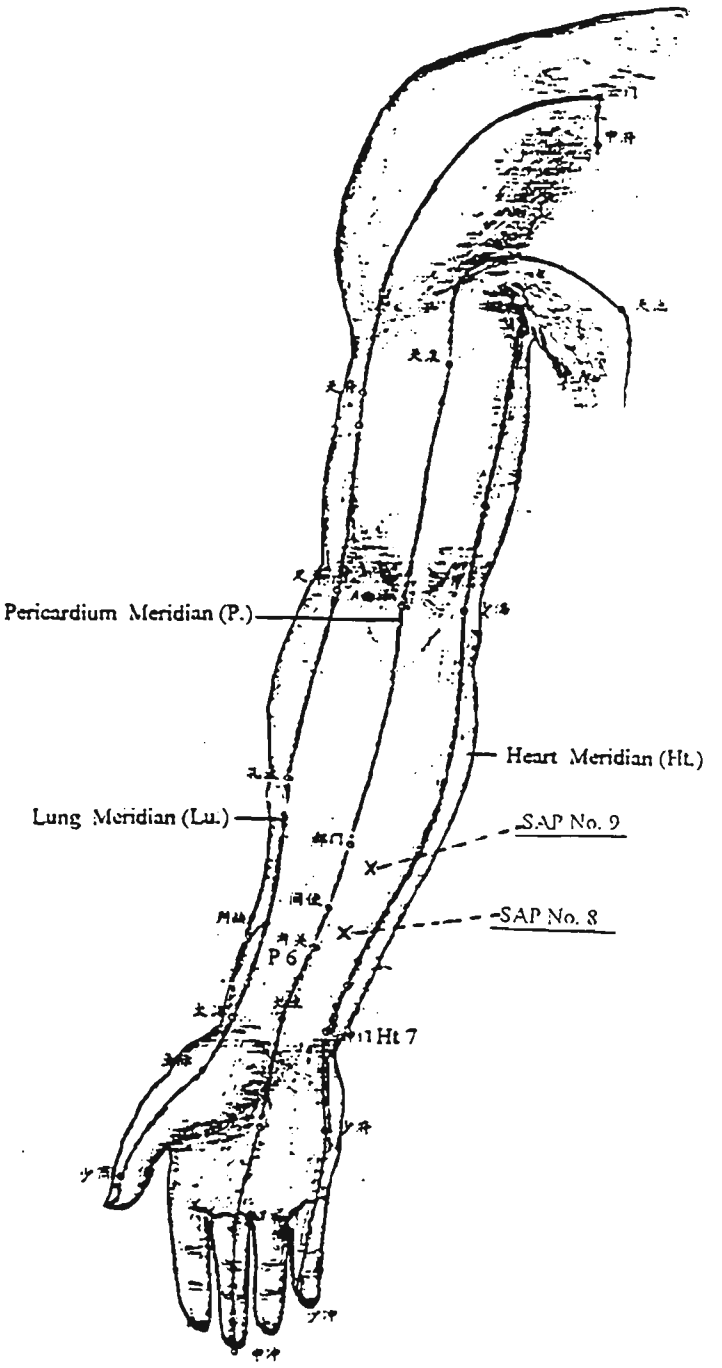


Diagram 4 Real & Sham Acupuncture Points on the Anterior Aspect of Upper Limb

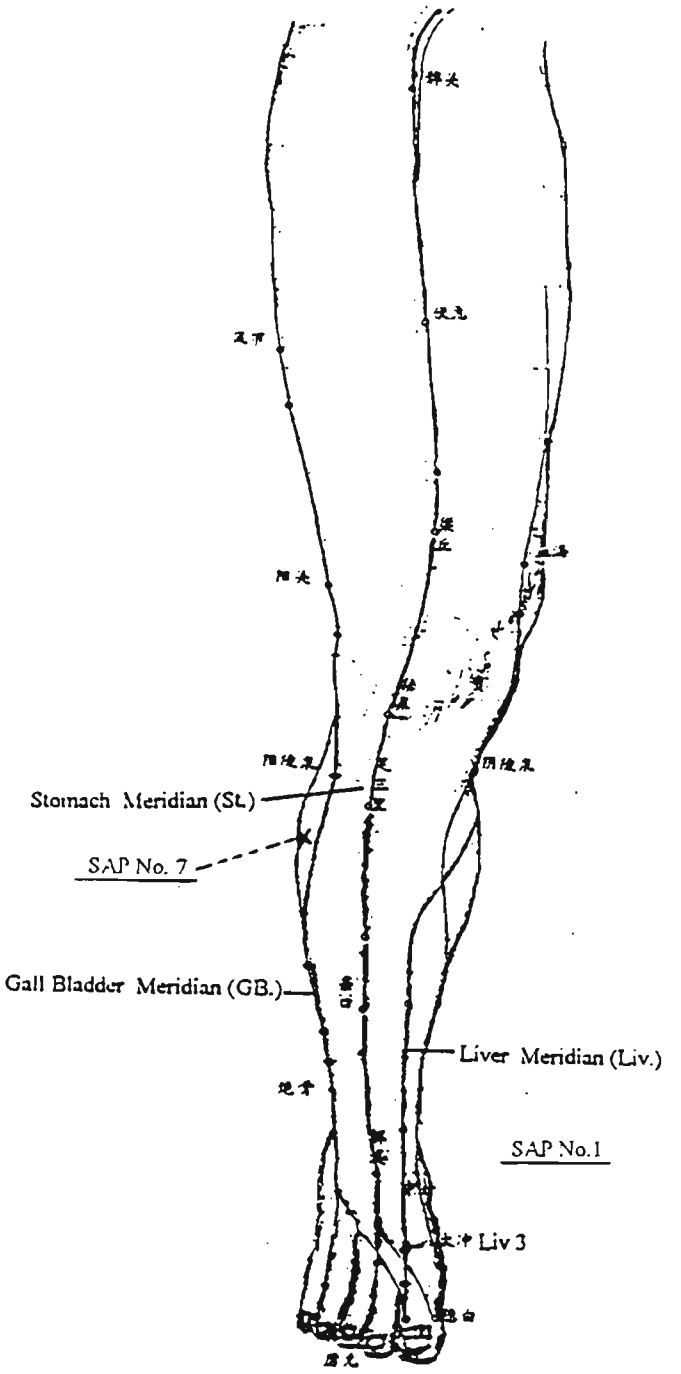


Diagram 5 Real & Sham Acupuncture points on the Anterior Aspect of Lower Limb

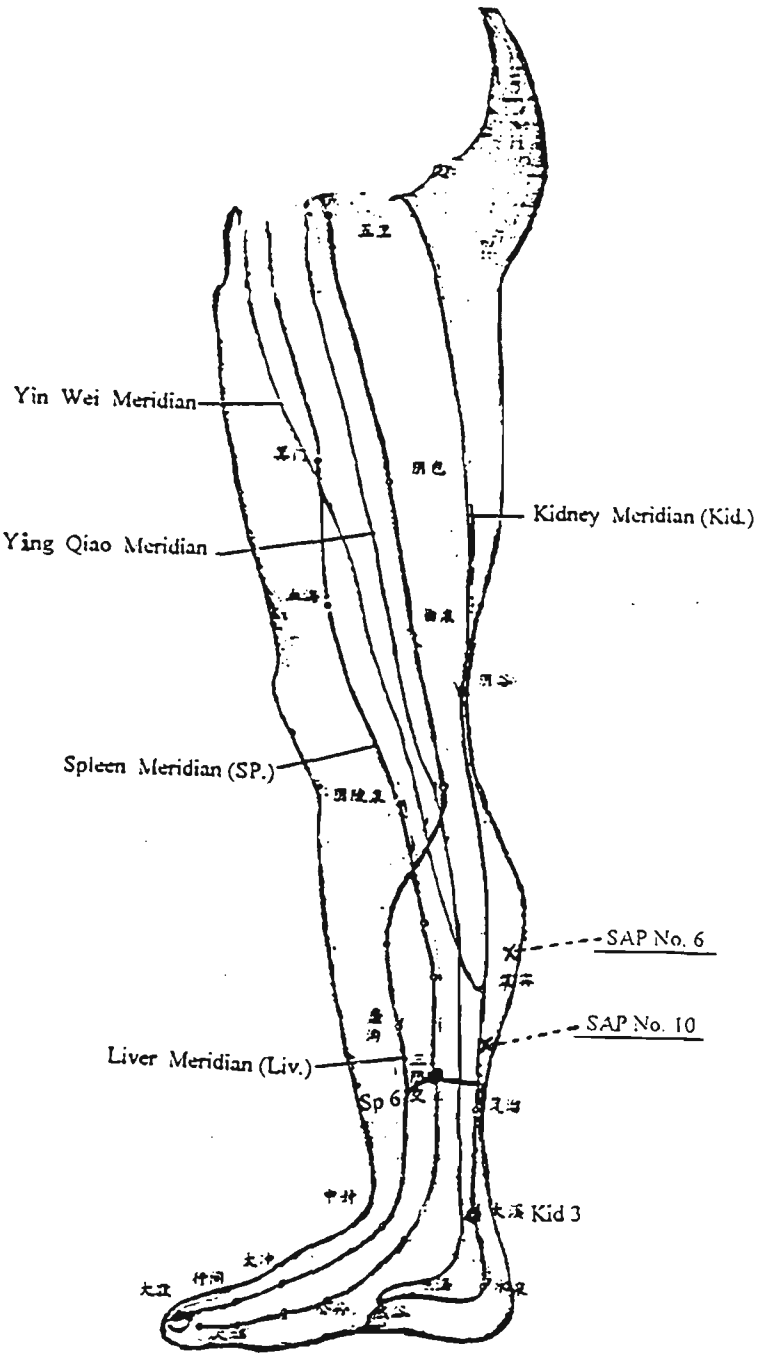


Diagram 6 Real & Sham Acupuncture Points on the Medial Aspect of Lower Limb

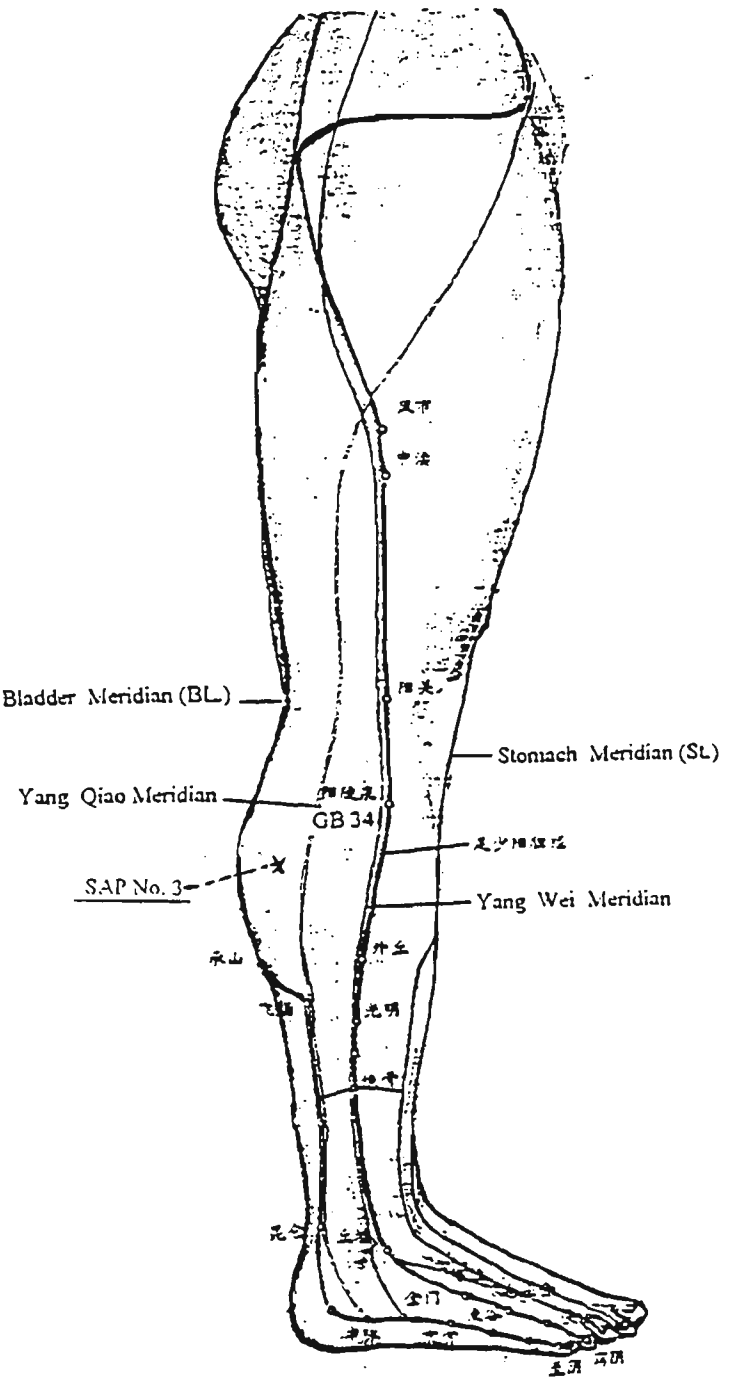


Diagram 7 Real & Sham Acupuncture Points on the Lateral Side of Lower Limb

4.4.2.2 Treatment

Treatment was provided twice a week by the researcher, except during cycle days 5-12 (the symptom-free interval) for both groups. During each treatment, subjects were asked to lie down and expose the areas to be needled.

The subjects within each pattern group were requested to present for the treatments at particular times of the day and at particular intervals, since TCM recognises daily cyclical rhythms within the organism. Please note, subjects in both the real acupuncture group and the sham acupuncture group were treated in the same way in order to maintain the blind nature of the trial.

4.4.2.3 Needles and Needling Methods:

The same style, brand and size needles were used for both the real and the sham groups, and the same needling techniques (skin preparation, needle manipulation etc.) were used on subjects in each pattern group (**Table 4**).

Table 4. Needles and needling method

Brand:	Hwato
Size:	#30 (Diameter: 0.30mm), 1 *cun* (25.00mm) and 1.5 *cun* (40.00mm)
Style:	Chinese disposable without tube
Needling angle:	Perpendicularly and/or obliquely
Needling depth:	0.3 *cun* to 1.5 *cun*
Form of manipulation:	Uniform reinforcing-reducing method.
Retaining time:	30 minutes

4.4.3 Phase III: Follow-up Phase:

Each subject was encouraged to maintain the "Menstrual Diary" for further three menstrual cycles after finishing the treatment phase.

4.5 Ethical Considerations

A plain-language description of the study was provided to every woman at the initial interview. The description paper includes the following information:

1. The background of the researcher.
2. A brief introduction to acupuncture.
3. The epidemiology of PMS.
4. The aim of the study.
5. The population and the treatment process of the study.
6. The potential side-effects of acupuncture.
7. The confidentiality and the anonymity of the research.

The above information was orally explained by the researcher. The sham and real acupuncture was clearly described and every participant was told that they could withdraw from this study at any time without prejudice. Informed consent was obtained from all subjects.

All records were stored securely and confidentially and only available to the researcher and the supervisors.

There was an agreement that at the completion of the study, subjects who were in the SAG, would be offered a complimentary course of real acupuncture therapy.

CHAPTER 5 : RESULTS AND FINDINGS

5.1 Data Analysis

Thirty women entered this study. Four subjects withdrew from the study:

- one because of a motor cycle accident,
- one was too sensitive to needling,
- two others because they felt that there was "not much difference" before and after the treatments.

The remaining twenty six subjects completed the whole treatment phase and their results were used for statistical analysis.

5.1.1 Demographic Analysis

Demographic analysis revealed that twenty one subjects were married or living in de facto relationships. Five subjects were single and living with their families. Thirteen subjects had given birth. Nineteen were of European background and seven were Asian. Twenty one of the subjects were employed outside the home and five were housewives. Six drank small amount (1-3 glasses per week) of alcohol regularly. The mean age of the subjects in the treatment group was 34 years (SD $\pm$6.5) and in the sham acupuncture group, it was 35.38 years (SD $\pm$6.7). There was no statistically significant difference ($p = 0.599 > 0.05$) between these two groups according to age (**Table 5**).

Table 5. Mean age in the real & the sham acupuncture groups

	Mean	SD
Treatment group	34.00	$\pm$6.5
Sham group	35.38	$\pm$6.7

Five subjects had previously been treated with pharmaceutical agents with no success, seven had tried evening primrose oil, seven had tried vitamin B6 and two others had had naturopathic treatment, but they all said that they did not experience much relief of their symptoms.

5.1.2 Statistical Analysis

The pre- and post-treatment luteal phase scores were calculated both in the treatment group and in the sham acupuncture group by adding the scores of last seven days prior to menstruation (totally six months). The statistical analyses of data were performed by using these scores, through one-way repeated measures analysis of variance, and two-tailed t-tests.

There was no significant difference between the treatment and the sham acupuncture groups in the total pre-treatment scores ($p>0.05$).

5.1.3 Results and Findings

The difference between pre- and post-treatment in the treatment group was statistically significant ($p<0.05$). There was no significant difference between pre- and post-treatment in the sham acupuncture group ($p>0.05$).

Table 6. Mean values of total score pre- and post-treatment

	Real	Sham
Pre-treatment	$\bar{x}$	$\bar{x}$
	150.15	115.15
Post-treatment	$\bar{x}$	$\bar{x}$
	63.60	114.10

Chart 3. Shows the differences between the total luteal phase scores from the first cycle to the sixth cycle in the treatment group and the sham acupuncture group.

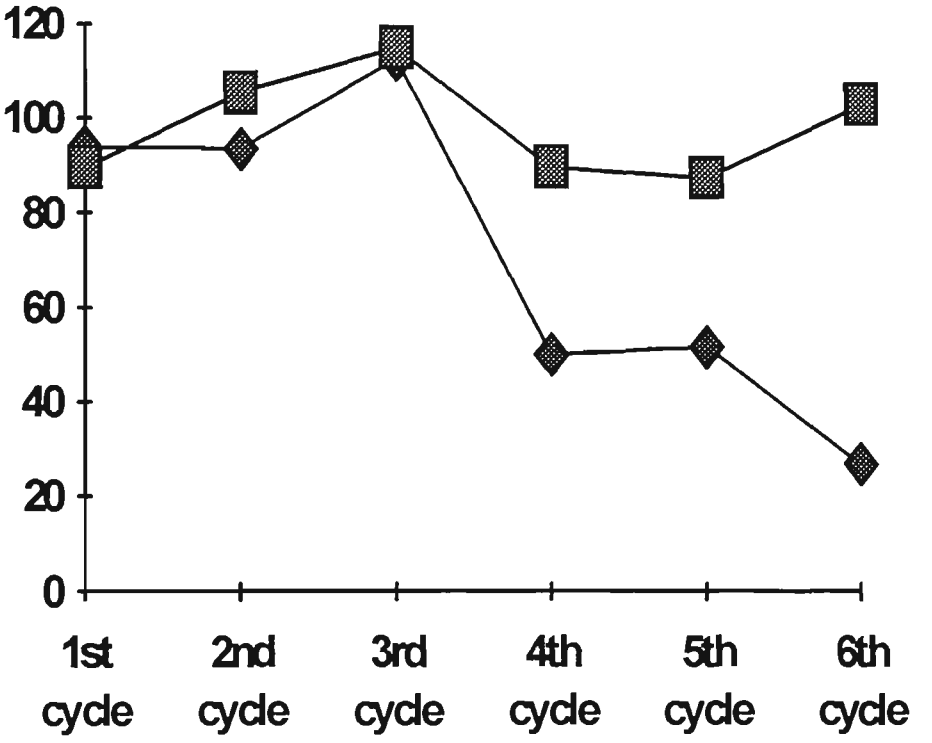


Chart 3. Total luteal phase scores (means) of each cycle in the treatment (big square) & the sham groups (small rhomb).

Table 7 depicts the differences between the symptoms reported during the first three menstrual cycles and during the last three cycles.

Table 7. Severity of relevant presenting symptoms

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

*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

5.2 Follow up evaluation

Only three subjects (all from the treatment group) completed the three months' follow up "Menstrual Diary". Accordingly this information was not used in data analysis.

CHAPTER 6 : DISCUSSION AND RECOMMENDATIONS

6.1 General Discussion

6.1.1. Relief of the Symptoms

This study demonstrated that acupuncture is effective in providing substantial relief for women experiencing PMS, especially with respect to the affective (behavioural) symptoms, such as irritability, anxiety, mood swings, over-sensitivity and expressed anger, and some relief of the somatic symptoms such as abdominal bloating and breast tenderness (see Table 7).

Affective symptoms were more severe than somatic symptoms in this study (see Table 7). Most of the subjects reported that somatic symptoms were easier to cope with than affective symptoms. The affective symptoms were also the main reason given for disruptions in the women's normal life. Some of the subjects reported that during particular times of the month other family members were becoming victims, in other words, they were also PMS sufferers.

All affective symptoms except depression responded better to the treatment than somatic symptoms (see Table 7). However, affective symptoms reoccured more readily than somatic symptoms. Somatic symptoms such as swollen extremities, abdominal bloating, breast tenderness responded very well to acupuncture, but acne responded much more slowly. Four subjects reported, that they lost weight after completing the three-month course of treatment.

Depression was one of the most difficult symptoms to resolve. One subject reported, that the symptom got even worse after the treatment. In contrast with irritability and expressed anger, which are caused by *gan* (liver meridian system) *qi* stagnation, the cause of depression is more likely to be *xin qi* deficiency or discord between the *xin* (heart meridian system)and the *shen* (kidney meridian system). Accordingly, if the acupuncture point Liver 3, commonly used in removing the stagnation from the *gan* (liver) meridian, is selected, it will sedate liver and weaken the power of the mother to feed the son (according to TCM theory of five phases, the *gan* is the mother of the *xin*). This may in turn make the *xin* (heart) *qi* even weaker and may be the reason, why depression responded so slowly to the treatment. When the *gan* (liver) *qi* is stagnated (with symptoms such as irritability, expressed anger) and *xin* (heart) *qi* deficiency or discord between the *xin* and the *shen* (with symptoms such as depression, insomnia, palpitations) appear at same time, the TCM treatment principle is to soothe the *gan* (liver) *qi* as well as to tonify the *xin* (heart) and to nourish the *shen* (kidney). From the principle of acupuncture point selection, in this situation, Liver 13 and Liver 8 may have been better choice than liver 3.

6.1.2 The Importance of TCM Aetiology

While women are increasingly seeking therapeutic help for PMS, a lack of understanding of its aetiology means that treatment focuses on the symptoms rather than on the underlying cause. Despite multiple theories being proposed and considerable research under taken, the aetiology of PMS still remains an enigma. The cause of PMS from a TCM point of view is clear. Rather than provide symptomatic treatment, TCM focuses on the underlying cause. To understand the underlying cause from a TCM point of view, we may simply divide the symptoms presented in this study into three groups (see Table 8).

Table 8. Symptoms of PMS and its TCM Pattern of Disharmony

Group	Symptoms	TCM Disharmony
Group 1	Irritability, expressed anger, mood swings, emotional over-sensitivity, crying easily, breast tenderness, bloating, etc.	Liver *qi* stagnation (*Gan qi yu jie*)
Group 2	Depression, anxiety, feeling of isolation, forgetfulness, heart palpitations, dizziness, etc.	Heart *qi* deficiency (*Xin qi xu*) and/or discord between the Heart and Kidney (*Xin shen bu jiao*)
Group 3	Swelling, food craving, gastrointestinal symptoms.	Spleen *qi* deficiency (*Pi qi xu*)

*clearly, from Table 8 it can be seen, that the function of the *gan* (liver meridian system) plays a very important role in the TCM aetiology of PMS. Since the *gan* is responsible for the ascent, descent and harmony of *qi* of the whole body, the smooth flow of the *gan qi* forms an important link in the circulation of blood and body fluids. In TCM, the *gan* is responsible for spreading and regulating *qi* and *xue* (blood and its functions). Pathological changes to the *gan* in females usually results in emotional changes, changes to the digestive function and obstruction to the flow of *qi*.

It is very clear that the majority of the symptoms related to PMS are connected with the *gan's* (liver) function in maintaining the smooth flow of *qi*. When the *gan* fails to maintain the smooth flow of *qi*, symptoms of the stagnation of liver *qi*, such as irritability, expressed anger, mood swings, crying easily, anxiety, breast tenderness, abdominal bloating, menstrual pain in the lower abdomen or the lower back, clot discharge, fluid retention, headache, insomnia or fatigue may occur. According to TCM concept of differentiation of the syndrome, removal of the stagnation or the blockage from the *gan* system and regulation and restoration of the function of the *gan* in maintaining the free flow of the *qi* should be the treatment principle for PMS, especially for the most common pattern of PMS.

Even though the *xin* (heart meridian system), *pi* (spleen meridian system), and the *shen* (kidney meridian system) are also involved in the TCM aetiology of PMS, according to this study, the *gan* (liver meridian system) plays the most important role.

6.1.3 PMS and Dysmenorrhoea

Twenty two of the twenty six subjects in this study were suffering from period pain as well as PMS. Seventeen of them experienced severe pain (with the rating score 0-10 used in this study, for period pain score greater than 6 was considered as severe). It was very interesting to note, that with the alleviation of PMS, the severity of period pain was also reduced. Even though the aetiology of PMS and period pain may be different from Western medicine point of view, they are very similar in the TCM. Thus according to TCM theory, the main causes of dysmenorrhoea and PMS are often the same, ie *gan* (liver) *qi* stagnation. In TCM, there is an important treatment principle called *same diseases different treatment and different diseases same treatment*. When the principle of differentiation of syndromes is used to guide clinical practice, several different patterns (syndromes) may be found in the same disease; by extension, the same syndrome may appear in a variety of diseases in the course of their development.

This observation leads to two maxims of clinical relevance: *"applying different methods of treatment to the same disease"* and *"treating different diseases with the same method"*. For example, a Chinese herbal formula *Xiao Chai Hu Tang* has been used in many different diseases with very good results (eg. in chronic hepatitis, biliary cystitis, acute pancreatitis, gastric ulcer, duodenal ulcer, premenstrual syndrome, pyelonephritis, hypertension, Meniere's syndrome), and the hypertension can be treated with different Chinese herbal formulae such as *Liu Wei Di Huang Tang, Ling Yang Gou Teng Tang, Long Dan Xie Gan Tang , Tian Ma Gou Teng Yin* etc., according to different patterns (or syndromes), which may be involved in its aetiology (Chen *et al* 1988; Chen 1989; Yan 1992).

6.1.4 Research Methodology

Sham acupuncture has been commonly used as a placebo in many controlled acupuncture trials (Gaw *et al*, 1975, Godfrey *et al* 1978, Mendelson *et al*, 1983; Margolin *et al*, 1993). However, Vincent (1989) claimed, that needling the non-classical sites can not be assumed to be a placebo, because some researchers reported, that stimulation at many different sites, whether or not they be classical acupuncture points, may produce therapeutic benefits. Neurophysiological research has demonstrated that any noxious stimulus will result in endorphin release through a neurophysiological mechanism. This phenomena is termed as Diffuse Noxious Inhibitory Control (DNIC). Needling and in particular needle manipulation in both the Real Acupuncture Group (RAG) and the Sham Acupuncture Group (SAG) may have brought DNIC into effect particularly in relation to pain relief. The fact that pain relief was substantially greater in the RAG indicates that pain relief resulting from Real Acupuncture cannot be solely attributed to DNIC (Li *et al* 1987, Price *et al*, 1988; WHO 1994, Xu *et al*, 1995).

Moreover, according to Takeshige (1983, 1985), real acupuncture points produce a different type of analgesia compared with non-acupuncture points. The Western biomedical mechanisms by which acupuncture treats internal diseases and disorders such as asthma, irritable bowel syndrome etc. are unclear. Current neurophysiological knowledge can only be used to explain some immediate effects of acupuncture and not the whole range of effects. However, both the neurophysiological research findings and controlled clinical trials have provided sufficient evidence to distinguish the effects of real acupuncture points from the sham points (Meng *et al*, 1984; Takeshige 1985; Li *et al*, 1987; Vincent 1989; Deluze *et al*, 1992;).

Mock TENS (Transcutaneous Electrical Nerve Stimulation) was introduced as a control into acupuncture trials in early 1980s (Macdonald *et al*, 1983; Lewith *et al*, 1983; Dowson *et al*, 1985). In this procedure, mock TENS is used in the usual way, but no electrical current actually passes between the electrodes. Thus, the mock TENS may even compromise the single blind trial, because mock TENS does not induce any electrical sensation like the normal TENS does. Nevertheless, Petrie and his colleague (1985) agued that sham TENS may offer a valid placebo condition for controlled studies, if the sham TENS is combined with strong visual and verbal suggestion.

In recent years, minimal acupuncture was suggested as a better form of sham acupuncture by Vincent and his colleague (1986). In this form, sham acupuncture points are placed away from classical points and needles are inserted at depth of only 1-2 mm, with very mild stimulation. This procedure minimises the specific effects of the needling, while its psychological impact is still maintained. However, it may be argued that minimal acupuncture is inadequate, as it does not mimic the the sensation of being needled at real acupuncture points.

The controlled trial is the final arbiter for the efficacy evaluation of a therapy. Although in any clinical research, double-blind trials are considered to be the preferred method, this approach is questionable, when applied to acupuncture (Lewith *et al*, 1993). Unlike other methodologies, an acupuncture trial cannot be double-blind, if the research is to be conducted by a qualified acupuncturist or Chinese medical practitioner. Godfrey *et al* (1978) suggested that an experienced acupuncturist marks the acupuncture sites on the subject, who then is treated by a technician trained merely in needling technique. However, it is impossible for the technician to produce the same quality of treatment as the acupuncturist would. Therefore, most researchers now recognise that acupuncture trials need to be single-blind. Nevertheless, some sigle-blind acupuncture trials were described incorrectly as double-blind studies in the past.(Vincent, 1989, Lewith, 1993).

6.1.5 Sample Size and the Measurements

Despite the small sample size of this study, sufficient data was generated to allow appropriate statistical analysis. Fortunately, more than twenty symptoms were observed and used to measure the outcome of this study. This is an advantage in clinical trials of PMS compared with some other menstrual-related conditions, such as dysmenorrhoea, where only one symptom can be observed. This is why a small sample size produced reliable information and adequate statistical power for data analysis.

6.1.6 Placebo Effects

Because there is no standard treatment for PMS, that can be used as a control, a placebo treatment was used for the control group in this study. Symptom scores (mean value) were reduced by 23% within the sham acupuncture group (SAG) in the first two treatment cycles, while the scores were reduced by 55% within the real acupuncture group (RAG). However, during the last treatment cycle, the symptom

scores were reduced by only 10% within the SAG, while there was 76% reduction of their severity within the RAG (see **Chart 6**). At the completion of the treatment phase, four out of thirteen (30.7%) subjects in the sham acupuncture group reported some noticeable improvements in some of the affective symptoms, while eleven out of thirteen (85%) reported significant improvement in the treatment group. However, statistically significant placebo effects were not found in this study.

6.2 Limitations and Recommendations

Sufficient sample size is always needed to provide an adequate statistical power, especially, if sham acupuncture is used as a control. Twenty six subjects is a small size for a clinical trial, even though statistically it was an adequate sample size for this study. However, a study involving a larger sample size would be more valuable.

In a clinical trial, the therapist may affect the patient's response. In order to minimise and limit that effect, it is necessary to standardise treatment including the clinical setting, interview process, size and number of needles used, and needling technique, in both the RAG and the SAG.

Follow up is recommended in all clinical trials. As this study required three months of prospective recording in a menstrual diary and then another three months treatment phase. With daily symptoms recording, most of the subjects were tired of recording their signs and symptoms by the completion of the treatment phase. This is why only three subjects completed the follow up procedure. It was a significant weakness of the study. After a course of acupuncture treatment, the therapeutic effect is often observed to continue for a period of time. Follow up assessment is recommended in any future studies.

From a TCM perspective, apart from acupuncture, regular exercise is recommended to prevent PMS, as it encourages the free flow of *gan* (liver) *qi*. Alcohol and caffeine-containing beverages should be avoided, since they may cause *gan qi* stagnation. Salt and sugar should be avoided in the premenstrual phase, as they can cause fluid retention which can block the free flow of *gan qi*.

CHAPTER 7 :CONCLUSIONS & IMPLICATIONS

7.1 Conclusions

Acupuncture is effective in treating premenstrual syndrome (PMS), especially in providing substantial relief from the affective symptoms of PMS.

It is important to acknowledge that premenstrual syndrome is a complex clinical condition with a large number of possible manifestations and its aetiology remains controversial. Therefore, a broad range of therapeutic options may be chosen by both the patient and the practitioner.

Affective symptoms of PMS resolved quickly, while somatic symptoms resolved more slowly. However, over time, affective symptoms returned more quickly than somatic symptoms.

The function of the *gan* (liver meridian system) plays a very important role in the TCM aetiology of PMS. Since the *gan* is responsible for the ascent, descent and harmony of *qi* of the whole body, the smooth flow of the *gan qi* forms an important link in the circulation of blood and body fluids. Pathological changes to the *gan* in females usually results in emotional changes, changes to the digestive function and obstruction to the flow of *qi*. Even though the *xin* (heart meridian system), *pi* (spleen meridian system), and the *shen* (kidney meridian system) are also involved in the TCM aetiology of PMS, according to this study, the *gan* (liver meridian system) plays the most important role.

Liver qi stagnation is the most common pattern disharmony of PMS. Resolving *gan* (liver) *qi* stasis was necessary in all three TCM pattern groups, therefore, it was the major treatment principle in treating premenstrual syndrome in this study.

Rather than provide symptomatic treatment, TCM focuses on the underlying cause. The holistic concept and the *Bian Zheng Shi Zhi* (treatment based on the pattern differential diagnosis) principle are the most important parts of the fundamental construction of TCM framework.. They have been highly considered and well applied through out this study.

In performing acupuncture in clinical trials, *De Qi* sensation is essential to the quality of the treatment, especially to the real acupuncture points while most sham acupuncture points do not often have such sensations.

In this study, sham acupuncture effect has once more been demonstrated different from the real acupuncture effect while it has been demonstrated in many other studies. Therefore, the sham comparison is a reliable and feasible form of control condition for acupuncture clinical trials.

7.2 Implication

From a Western medicine perspective the signs and symptoms of PMS are not well understood, but the TCM framework provides an understanding of both the commonness and uniqueness of PMS.

Whereas modern Western medical science has tended to focus on understanding illness from an organic perspective, TCM takes a more holistic and systematic perspective. Accordingly, TCM may be able to be looked to, to provide a more coherent understanding of the dysfunctional aspects of illness.

The TCM treatment principle for gan qi stasis, the most common pattern of disharmony in PMS should be to remove gan qi stasis and ensure the free flow of qi and xue.

Sham acupuncture can be used as a valid control for acupuncture clinical trials, however the sham points should be carefully selected and the needling techniques should also be comparable to those used on the real acupuncture points.

APPENDICES

Appendix 1: Menstrual Diary

MENSTRUAL DIARY

PATIENT NO.:

DAY OF CYCLE	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
MORNING TEMPERATURE																																		
DATE																																		
MENSTRUATION																																		
SYMPTOMS																																		
FATIGUE																																		
IRRITABILITY																																		
BLOATING																																		
ANXIETY/TENSION																																		
BREAST TENDERNESS																																		
MOOD LIABILITY																																		
DEPRESSION																																		
FOOD CRAVING																																		
ACNE																																		
INCREASED APPETITE																																		
OVER-SENSITIVITY																																		
SWELLING																																		
EXPRESSED ANGER																																		
CRYING EASILY																																		
ISOLATION																																		
HEADACHE																																		
FORGETFULNESS																																		
*G.I. SYMPTOMS																																		
POOR FLASHES																																		
HEART PALPITATIONS																																		
DIZZINESS																																		
**DISTURBANCES																																		
OF CONDITIONS																																		

*G.I. = GASTROINTESTINAL

** If you experience a symptom other than those noted above, please place a "tick" on the day, then turn over sheet and note day and exact symptoms.

1

OTHER SYMPTOMS

DATES	DESCRIPTION OF SYMPTOMS

2

Appendix 2: Instructions for Menstrual Diary

INSTRUCTIONS:

PART A:

(1) Start recording on the first day of your period, which is considered day 1 of the menstrual cycle. Mark an (M) in the box labeled menstruation on the days of your menstrual flow. Rate your symptoms according to the following scale and mark in the corresponding boxs:

0: No symptom
1: Symptom is noticeable but does not impair activity.
2: Symptom interfered with the ability to function.
3: Incapacitation because of the symptom.

If you have any symptoms not listed, used the extra spaces to record them.

(2) Continue to record daily in the diary until the commencement of your next period when you should begin a new chart.

(3) Repeat this process for three menstrual cycles.

PART B:

1. Using your basal thermometer, take your temperature about the same time each day. Before rising is the best time. Do this every morning even during menstruation. Be sure not to eat, drink, or smoke before taking your temperature. Keep the thermometer at your bedside.

2. Take your temperature orally. Do not switch your method of temperature taking in the middle of a cycle. Take a reading after 5 full minutes. If you are too sleepy to read and chart your temperature before getting out of bed, or need glasses or contact lenses to see the mercury, you can read and chart your temperature later as long as the thermometer is not disturbed.

3. Record your temperature reading on your chart each day. Every time after your recording, clear the thermometer to the bottom reading.

4. Any obvious reason for a temperature variation, such s a cold, infection, insomnia, and sleeping late, should be noted on the " DISTURBANCES OF CONDITIONS" section of you chart for that day.

5. Adequate charting and interpretation of the chart are very important. Chart every day and do not rely on your memory of what the reading was yesterday or the day before.

Appendix 3: Plain-language Description of the Study

PLAIN-LANGUAGE DESCRIPTION OF THE STUDY: ACUPUNCTURE AND PREMENSTRUAL SYNDROME (PMS)

I (Deyuan Wang) am undertaking a Masters Degree in the Department of Health Science at Victoria University of Technology. I am a Doctor of Traditional Chinese Medicine having completed the five year program at the Nanjing College of Traditional Chinese Medicine in China. I would very much appreciate your consideration of participating in this project. Please read the following information about the study and feel free to ask me any questions or discuss any concerns that you may have.

INTRODUCTION:

Acupuncture as a therapy has long been indicated for premenstrual and menstrual problems. It is one of the oldest and most widespread healing methods in the world,although it has been used for thousands of years, it has only recently gained credibility in the western world.

"The view of the World Health Organisation (WHO) is that the sheer volume of evidence in favour of the ancient practice of acupuncture demands that the therapy be given major consideration by those involved in primary health care" (Boylston Aw, 1987,P115).

It has been estimated that up to 95 percent of women experience some physical or psychological symptoms in the premenstrual phase of the cycle, and 5 to 10 percent (1 million in Australia) of women experience severe, disabling premenstrual symptoms requiring treatment.(McMurchie et al, 1989, Johnson SR,1987).

This study will evaluate the effectiveness of acupuncture for treating premenstrual syndrome (PMS).

POPULATION AND TREATMENT:

About 30 volunteers (subjects) will participate in the study. Subjects will be selected on the basis of interview with the researcher and on meeting the diagnose of PMS by (1) a three months recurrence of at least one behavioural symptom and one physical symptom during the 5 days before menses which would be documented by a self-maintained dairy (attached). (2) the subjects are required to have relief of the symptoms within 4 days of the onset of menses and a symptoms-free interval lasting until at least cycle day 12. (3) the subjects must also meet the requests of the

calendar of Premenstrual Experiences Scale instrument (see "Menstrual Diary"). If the volunteer meets the above criteria, then they will be selected to participate in the main study.

Treatment will be provided twice a week except the cycle day 5-12 (symptom-free interval) by the researchers. Subjects meeting the criteria will be randomly assigned to either a control or a treatment group. Every subject has equal chance to be assigned to either group. The treatment group will be given acupuncture therapy in accordance with traditional Chinese medical principles and differential diagnosis and the control group will be needled in areas not traditionally recognised as being acupuncture points. Subjects will not know which group they are in until the completion of the project. At the completion of the study, those subjects who were in the control group will be offered real acupuncture therapy as the treatment group did.

All subjects participating in the study will continue to document their menstrual diary and morning temperature every day throughout the study.

Usually, there is no risk or side-effects with acupuncture therapy, but sometimes a mild soreness may be felt and bruising around the acupuncture points may occur during or after treatment. Occasionally a person may experience some dizziness during or after treatment and it is possible but highly unlikely that a needle may break during treatment.

The confidentiality and anonymity of the research files will be respected and only the researchers will have access to the subject's data. Participation in this study is voluntary. Informed consent will be obtained form all subjects.

At any time during the study subject may withdraw without any prejudice, subject may at ant time contact the researcher (Deyuan Wang) to discuss concerns or questions.

Contact Phone No.	365 2552	Monday — Friday	9:30 — 4:30
	365 2625	Monday	1:00 — 4:00
		Wednesday	9:00 — 12:00
		Saturday	9:00 — 4:00

Appendix 4: Confidential Information Sheet

CONFIDENTIAL SHEET

Victoria University of Technology

****
Please answer each question, if any questions are unclear please ask me (TCM Dr Deyuan Wang) for further explanation. All information provided is considered confidential.

GENERAL INFORMATION

Mrs/Miss/Ms/Surname_____

Given Names_____Date of Birth___/___/_____

Are you currently living in a relationship (married, de facto etc) ? If so, for how long_____Number of Children_____

Occupation_____Nationality_____

Address_____P/Code_____

Telephone:(Home)_____(Business)_____

HISTORY OF MENSTRUATION

(1)Age at first menses: <9yrs___9-10___11-12___13-14___15-16___17-18___>18___(2)Date(first day) of last period_____/_____/_____

Descriptions of menstruation during the previous six months:

(3)Do you menstruate at regular intervals ? Yes___No___ If yes, how frequently do you menstruate ? <24days__24-35__35-50__>50_

(4)Length of Period:<2days___2-3___4-5___6-7___8-9___>10days__

(5)Amount: scanty_____normal_____heavy_____very heavy_____

(6)Colour: reddish_____bright red_____dark red_____purple_____

(7)Nature: thin_____normal_____thick_____with clots_____

(8)Did you experience period pain during the last six cycle ? Yes___No___ If yes,how would you rate your pain (on average) ? Place an "x" on scale below:

(No pain)0 1 2 3 4 5 6 7 8 9 10(Severe pain)

(9)Have you been pregnant or lactating during the previous nine months?_____

1

PREMENSTRUAL SYMPTOMS

In the past six months which of the symptoms below did you experience every month ? Please tick.

[ ]Fatigue
[ ]Irritability
[ ]Bloating
[ ]Anxiety
[ ]Tension
[ ]Breast Tenderness
[ ]Mood Swings
[ ]Depression
[ ]Food Craving
[ ]Acne
[ ]Increased Appetite
[ ]Emotional Over-sensitivity
[ ]Swelling
[ ]Anger
[ ]Crying Easily
[ ]Feelings of Isolation
[ ]Headache
[ ]Forgetfulness
[ ]Gastrointestinal symptoms
[ ]Hot Flashes
[ ]Heart Palpitations
[ ]Dizziness
Others_____
_____

(2)Have you taken or received any treatment for these symptoms?

If so, please give details_____

_____

_____

GENERAL HEALTH HISTORY

(1)Have you suffered any gynaecological illness ? Please explain with dates_____

_____

(2)Have you suffered any psychological or emotional disorders ?

Please explain with dates_____

_____

_____

_____

(3)Have you suffered any other major illness in the past ? Please explain with dates_____

_____

_____

_____

(4)Have you ever had any operations ? Please explain with dates

_____

_____

_____

(5)List any medications you are currently taking:_____

_____

_____

_____

(6)Are you currently taking oral contraceptives ? Yes____No___

(7)Do you drink alcohol ? If so, what do you drink_____

how much per day: 1-3glasses_____3-5glasses_____>5glasses_____

(8)Do you smoke ? If so, how many cigarettes per day_____

(9)Are you happy with your work ? Yes_____No_____

(10)Are you happy with your family life ? Yes_____No_____

(11)Have you any allergies ? If so ,identify_____

(12)Have you had acupuncture before ? Yes_____No_____

Signature_____Date__/__/__

Thank you for taking the time to complete these questionnaire.

()DW/PMS.93

Appendix 5: TCM Diagnostic Sheet

TCM DIAGNOSTIC SHEET

Subject No._____

LOOKING(Wang-zhen)

Appearance: Strong_____Normal_____Weak_____
Fat_____Normal_____Thin____Skinny_____

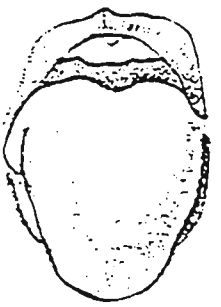
Manner & Emotions: Talkative_____Active_____Outward____
Quiet_____Passive_____Inward_____

Shen(spirt): Look and Shine of eyes_____
Facial expression_____
Posture_____
Speech_____
Responsiveness_____
Clarity of thought_____

0__1__2__3__4__5__6__7__8__9__10
(Lack of shen) (Having shen)

Facial Colour: Shiny and moist____Pink____Red____
White____Pale____Yellow____Purplish____
Other_____

Tongue:



Body_____
_____
_____

Coating_____
_____
_____

Skin_____

Secretions and Excretions_____

1

LISTENING AND SMELLING(Wen-zhen)

Voice_____ Respiration_____
Odor_____ Others_____

ASKING(Wen-zhen)

Sensations of Cold and Hot: Fear cold_____ Fear hot_____
Chill_____ Fever_____
Hot felling in palms and soles_____
Hot flushes_____ Others_____

Perspiration: Spontaneous sweating_____
Night sweating_____
Others_____

Headaches and Dizziness_____
_____

Pain: Site_____
Nature_____
Time & Duration_____

Chest and Abdomen_____
_____

Urine and Stool_____
_____

Appetite and Cravings_____
_____

Thirst_____

Tastes in the mouth_____

Sleep_____

Gynaecological Concerns:
Age at first menses_____ Date(first day) of last period_____
Amount_____ Colour_____ Nature_____
Cycle of menstruation_____ regular_____ irregular_____
Vaginal discharge_____

PALPATION AND PULSE TAKING (Qie-zhen)

Palpation: Skin_____
Head and Neck_____
Chest and Hypochondria_____
_____
Abdomen_____
Acu-points_____
_____

Pulse:

Left				Right		
Front	Middle	Rear		Front	Middle	Rear
+	+	+	Superficial	+	+	+
+	+	+	Middle	+	+	+
+	+	+	Deep	+	+	+

Description: Left_____
_____
_____

Right_____
_____
_____

DIAGNOSIS:_____
_____

Confirmed by_____

Date of Recording____/____/_____

Appendix6: "Data Records" Booklet

VICTORIA UNIVERSITY OF TECHNOLOGY (ST ABLANS CAMPUS)

DEPARTMENT OF HEALTH SCIENCES

RESEARCH STUDY

"P. M. S."

DATA RECORDS

Patient Number: _____

Thank you for agreeing to participate in this research study "**Acupuncture and Premenstrual Syndrome (PMS)**". Women have very different experiences with the biological activity of menstruation. And thus, it is necessary to review each women's experience prior to commencing participation in this study. A record of your menstruation experience needs to be kept for a three (3) month period of time. The information recorded will be reviewed by the researchers to determine whether you meet the diagnostic criteria of premenstrual syndrome being used in this study. One of the researchers will need to meet with you monthly during the three (3) month recording period of time. The purpose of the meetings is to have a preliminary review of the records and, to discuss your progress and concerns. The meetings will take approximately 30 minutes of your time.

All information in this research study, specifically this record, will be kept confidential. Your anonymity will be respected in that you will be given a patient number which is known only by you and the researchers. All records will contain only patient numbers. No other person will have access to any of the information provided by you.

Please read the instructions in this booklet and look at the recordings sheets. If you have any concerns or questions please contact one of the researchers involved in this project (David Wang or Dr Kerry Watson 365 2552).

Thank you for agreeing to participate in this study. Please BEGIN your recording with your next menstruation cycle. I will meet with you again _____ _____. Please bring this booklet with you.

Sincerely,

David Wang
Master of Health Science Student

MENSTRUAL DIARY

PATIENT NO:

DAY OF CYCLE	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
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