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NEWSLETTER

中医 Traditional Chinese Medicine



Dr. Zhu Liangchun's Way of Treating Difficult Disorders

By Wan Wenrong, Journal of Traditional Chinese Medicine, 2000; (41) 1:14-15, edited for length

The main problem with so-called difficult diseases lies in the discrimination of a complicated pattern and the ensuing difficulty in establishing a corresponding treatment method. The following key points prevent giving in to confusion when being faced with a difficult pattern and lay the foundation for a clear strategy to work with; a) Continually expanding the working knowledge of the basic theory, which permits Practitioners to; b) apply these theories with increasing flexibility in clinical practice; c) continuously evaluating the methods and techniques of pattern identification and treatment determination and d) looking for the essence of the pattern rather than getting caught up with minor aspects of the pattern. Following these key points naturally develops a Practitioner's expertise in developing the unique characteristics and advantages of Chinese herbal medicine.

This general strategy should be combined with the following specific points when treating difficult disorders:

Out of the ordinary diseases are often caused by phlegm evil. Disorders that resist treatment involve both phlegm and stasis.

Phlegm is a pathological substance; its internal cause is loss of regulation of organic function with ensuing blockage of the Qi pathways, disharmony of viscera and bowels, fluids congealing, water-damp lodging in the body, inhibited Qi transformation and consequent formation of phlegm-drool.

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Phlegm and Mental Disorders

Phlegm-drool obstructs by nature, blocking the Qi pathways and clouding the mansion of the spirit (the spirit is stored by the heart and can be said to correspond to the Western concept of "mind"). As a consequence there is no free flow in the upper burner and inhibited spreading in the lower burner, which may manifest in withdrawal, mania, or epilepsy. If this is a recurring or lingering problem, the tongue is purple or has stasis macules and the patient's mental-emotional symptoms worsen cyclically. These symptoms are due to phlegm with concurrent blood stasis that has developed like this: Phlegm Qi congeals and stagnates, and this Qi disease reaches the blood. Qi and blood stagnate, obstruct the orifices, and cause abnormalities of the essence-spirit ("essence-spirit" here used in the sense of the Western "mind") with symptoms that seem to resist treatment. This is why Dr. Zhu concentrates on the phlegm and blood stasis aspect when treating mental-emotional disorders. Thus, an important treatment principle of mental disorders is flushing phlegm and transforming stasis - used, of course, with skilful flexibility.

Characteristics and Manifestations of Phlegm:

- Dull, stagnant eye spirit, dark gloomy facial complexion, or dark circles around the eyes.
- Fat body, sensation of distension in hands and feet.
- Oily skin, or shiny oily complexion. In the case of phlegm fire, the cheeks tend to be red. Phlegm dampness tends to manifest as grey (ashen) and stagnant facial complexion.
- Depressed or absent-minded, or suffering from vexation, agitation and restlessness.
- Tongue is fat and enlarged, with a coating that is white and slimy, like powder, or grey slimy and thick. Pulse: Sunken, string-like, slippery, or soggy and moderate.
- Patient suffers from being easily frightened with palpitations, vexation, insomnia, or loss of consciousness, twitching, or mental-emotional abnormalities.

These characteristics of phlegm disorders are closely connected to the symptoms of mental disorders. Not all of the above symptoms need to be present, one or two are enough to use phlegm treatment principles.

Regarding the treatment of phlegm-rheum, Dr. Zhu has gained valuable insight from Jiang Baosu's Wen Zhao Yi An and based on this put forward the principle: When treating phlegm one must treat blood, when blood is quickened then phlegm can be transformed.

Suitable Formulas and Medicinals

Dr. Zhu has often used Wang Qingren's Kuang Dian Meng Xing Tang with variations to treat periodic mental disorders. **Dosage:** One dose daily, taken continuously over one month, after which the symptoms should show improvement. Continued administration for another month should control further periodic outbreaks.

Ingredients: Tao Ren [Persica], Hong Hua [Carthamus], Mu Tong [Caulis Akebiae], Chi Shao [Red Peony] quicken blood and free the flow of the network vessels, eliminate stasis and clear the spirit, Chai Hu [Bupleurum], Qing Pi [Blue Citrus], Xiang Fu [Cyperus], Yuan Zhi [Polygala] course the liver and rectify Qi, free the flow of the network vessels and open depression, Dan Shen [Salvia] and Suan Zao Ren [Zizyphus] nourish blood and quiet the spirit, enrich Yin and downbear fire. These medicinals are assisted by Ci Shi [Magnetitum] to calm the heart and quiet the spirit as well as preventing Chai Hu [Bupleurum] from upbearing and lifting excessively. Fu Ling [Hoelen] strengthens the spleen and transforms dampness, calms the heart and quiets the spirit. This prescription quickens the blood and transforms stasis, and at the same time nourishes the heart and quiets the spirit.

When treating an enduring disease, think of the following factors: Vacuity, stasis, the disease having entered the network vessels, and the disease having reached the kidneys

Often, impediment tends to be treated based on joint swelling and pain, using the treatment methods dispelling wind, dissipating cold, and drying dampness. This approach does not always work, especially in the case of insensitive impediment (characterised by numbness). One has to consider that the patient's Yang Qi is already vacuous which permits disease evils to easily lodge in the channels and network vessels. These evils obstruct Qi and blood, which then congest and stagnate in the channels and vessels. These may sink and enter the bone marrow, fixed like glue and become hard to move. Phlegm and stasis congeal and inhibit free flow, resulting in swelling and pain that recur repeatedly. Therefore this condition has two aspects, vacuity of right and repletion of evil. The pathological changes are located in the bones which are governed by the kidney. Thus boosting the kidneys and strengthening the bones is the correct treatment method to treat the root of this disorder, and only treating the root gives the desired results.

In fact Dr. Zhu finds that in various difficult disorders, although treatment based on pattern differentiation may involve several bowels and viscera, patients do tend to present with many signs of kidney Yang vacuity. Dr. Zhu often supplements the kidney using a formula he composed himself called Pei Bu Shen Yang Tang (Banking and Supplementing Kidney Yang Decoction). Ingredients: Yin Yang Huo [Epimedium] 15g, Xian Mao [Curculigo] 10g, Gou Qi Zi [Lycium Fruit] 10g, Zi He Che [Placenta Hominis] 6g, Gan Cao [Licorice] 5g.

Case History: A small boy called Lin, one year old, was first examined on March 11th 1999. The accompanying guardian explained that the child had suffered from diarrhoea for one month, manifesting as five to six stools per day, the stool was watery in appearance. Western medical treatment had yielded no results. These days the symptoms had become worse and were accompanied by a listless spirit, lack of warmth in the extremities, and a noticeably sunken fontanel. Stool examination revealed ++ fatty

substance and ++ pus cells. Traditional Chinese Medicine (TCM) pattern differentiation was spleen and kidney Yang vacuity. Treatment consisted of supplementing kidney Yang, fortifying the spleen and stopping diarrhoea. Formula used: Dr. Zhu's Pei Bu Shen Yang Tang adding Bu Gu Zhi [Psoralea], Yi Zhi Ren [Alpinia], Lu Jiao Shuang [Cornu Degelatinum Cervi], Chao Bai Zhu [Atractylodes White] 10g each, decocted in water. After taking the medicine for two days the diarrhoea stopped. The child passed normal stool twice a day. After taking the medicine for four days, the boy's spirit improved, his eyes had spirit, and the fontanel was less sunken. A repeat examination revealed that his stool was normal and the boy was healthy.

If the symptoms of the upper are of a different nature than the symptoms of the lower, treatment should start with a focus on the symptoms of the lower. If the symptoms of the exterior seem to suggest a different pattern than the symptoms of the interior, treatment should set out with attending to the symptoms of the interior

A difficult disorder is called difficult because of its many changes and transformations, and because of its complexity. During pattern discrimination, besides grasping the major conflict, one also has to clearly discriminate between true symptoms and false symptoms. Only then is it possible, in the event of contradictory symptoms, to discriminate the correct pattern and establish a clear treatment plan with clearly defined steps.

Example: During the kidney stage of chronic nephritis, on the one hand there are often symptoms associated with Yang Qi vacuity such as lassitude of spirit and aching lumbus, weak and wilting legs, and lack of appetite. On the other hand there are symptoms of Yin vacuity and Yang hyperactivity e.g. vertigo and feeling of distension in the head, tendency to high blood pressure, and vexation and agitation. In this situation of symptoms of the upper and lower seemingly contradicting each other, one must treat with a clear focus while not losing sight of the other symptoms. The focus of the treatment is warming the kidneys and supporting Yang, thereby treating the lower as priority. This main treatment is assisted by enriching Yin to subdue Yang.

Importance of the right dosage of Chinese medicinals and formulae

As the predecessors say: "The secret of Chinese medicine that is not usually passed on is the art of the right dosage", and indeed the right dosage is a matter of experience. In clinical reality, even if pattern discrimination and the treatment strategy are correct, but the dosage of the medicinals is not right (too light or too strong or not in right combination) this will strongly influence the effectiveness. The art of the right dosage is inseparable from the doctor's level of experience.

Example: When Dr. Zhu uses Yi Mu Cao [Leonorus] to treat high blood pressure he calls to our attention that Yi Mu Cao [Leonorus] has a marked effect on clearing

the liver and downbearing counter-flow, and achieves excellent results with postartum hypertension, but only if the dosage is at least 60g. To this effect Yi Mu Jiang Ya Tang was created. The ingredients are Yi Mu Cao [Leonorus] 60g, Du Zhong [Eucommia] 12g, Sang Ji Sheng [Loranthuss] 20g, Gan Cao [Licorice] 5g. If cases of severe headache, add Xia Ku Cao [Prunella] 12g, Gou Teng [Gambir] 20g, Sheng Bai Shao [Uncooked White Peony] 12g, Sheng Mu Li [Uncooked Oyster Shell] 30g. If there is marked Yin damage, add Nu Zhen Zi [Ligustrum] 12g, Shi Hu [Dendrobium] 15g, and Sheng Di Huang [Raw Rehmannia] 15g.

Dr. Zhu also uses Yi Mu Cao [Leonorus] to treat ascites in cirrhosis of the liver. Symptoms include enlarged abdomen and blue veins along the abdominal wall when there is abdominal distension. Yi Mu Cao [Leonorus] is used in quantities of 120g and added to the base formula. This should alleviate the bloating and eliminate ascites.

Another example of right dosage and combination is Dr. Zhu's use of Xian Cao [Siegesbeckia] 100g in combination with Dang Gui [Angelica Sinensis] 30g to treat wind-damp as seen in rheumatoid arthritis.

Formulas and medicinals for specific conditions can be combined with treatment based on pattern identification

Pattern discrimination forms the core of Chinese medicine, but TCM also differentiates diseases. Dr. Zhu has integrated TCM with the disease differentiation of Western medicine to create many empirical formulas. A good example for such a creation is Wen Shen Li Niao Fang (Warms the Kidneys and Disinhibit Urination Formula). The formula contains Huang Qi [Astragalus], Shu Di Huang [Cooked Rehmannia], Shan Yao [Dioscorea], Shan Zhu Yu [Cornus], Liu Ji Nu [Herba Artemisia Anomalae], Hu Po [Succinum], Chen Xiang [Lignum Aquilariae], and Wang Bu Liu Xing [Semen Vaccariae Segetalis]. The formula warms the kidneys and disinhibits urination. It was designed for prostatic enlargement hypertrophy. This condition is usually seen in elderly patients. At their advanced age, both Yin and Yang tend to be damaged, and kidney Qi is vacuous. Qi transformation does not move properly leading to stasis and turbidity. Therefore, the pattern consists of a root vacuity and tip repletion. If the Practitioner sees inhibited urination and treats it with strong prescriptions that blandly seep and disinhibit urine, not only does he not hit the mark, but he will also damage both Yin and Yang. Dr. Zhu identified the main disease mechanisms as kidney Qi insufficiency with Qi vacuity and blood stasis. For this purpose he uses Huang Qi [Astragalus] and Liu Ji Nu [Herba Artemisia Anomalae] to mutually assist each other in boosting Qi and transforming stasis. Shu Di Huang [Cooked Rehmannia], Shan Yao [Dioscorea] and Shan Zhu Yu [Cornus] supplement kidney essence; Hu Po [Succinum] transforms stasis and frees urination. Chen Xiang [Lignum Aquilariae] moves Qi stagnation in the lower burner and Wang Bu Liu Xing [Semen Vaccariae Segetalis] opens the urinary bladder Qi blockage. If used with the appropriate variations according to the individual pattern, this formula achieves remarkable results.

中医基础 TCM Principles

Articles appearing under the heading "TCM Principles" are suitable for graduates of the **Sun Ten Self Study Course** and carry footnotes referring to content explained in the course. The articles are ideal to review your studies and further your knowledge in a particular area of TCM.

TCM Female Physiology, Pathology and Treatment

By Dagmar Riley.

Physiology and Pathology

The distinguishing characteristics of female physiology in TCM are largely determined by menstruation and gestation, and healthy menstruation and gestation both depend on the abundance and correct flow of blood. Understanding how the different viscera contribute to the abundance and healthy flow of blood in the body is important in the diagnosis and treatment of female disorders.

The Spleen Manages the Blood and Participates in the Formation of Qi and Blood

Blood is formed from food essence extracted by the spleen and stomach. This is why it is important that everybody, especially women, maintain a healthy nutritious diet. Unfortunately, it is often women who skip meals in order to diet or nibble on a sandwich and salad while men tend to eat proper warm meals. Female patients benefit immensely from being taught simple but effective guidelines on how to maintain a diet that strengthens the spleen. A basic "stomach and spleen diet" is made up of fresh food that is cooked (neither cold nor raw, so the popular combination sandwich and salad is out!) and not extreme in flavor (not too spicy, salty etc.). All uncooked foods such as salads, yoghurt and sandwiches are classified as cold foods, including cold drinks. Raw foods do not present a problem if eaten together with a warm meal, but the excessive consumption of cold foods leads to sluggish digestion (for further information please refer to the article "When the Herbs Don't Do Anything - the Importance of Strengthening the Spleen", Sun Ten Newsletter, March/April 2005 edition). An impairment of the spleen's function of movement and transformation of food essence manifests in signs of Qi and blood vacuity, such as pale complexion, low energy, fluid retention, scanty and pale menstrual flow, and it may contribute to amenorrhea, late menstruation, and infertility etc.



"A basic 'stomach and spleen diet' is made up of fresh food that is cooked (neither cold nor raw)..."

The spleen also manages the blood, which means that it controls the flow of blood in the vessels and prevents blood from spilling out of the vessels. One of the functions of Qi is to contain the liquid substances of the body (including blood, sweat and sperm), and so the spleen "manages the blood" with the aid of spleen Qi. Abnormal bleeding can also be caused by other factors than spleen Qi vacuity (spleen not governing blood) such as blood heat, blood stasis or trauma. Differentiation is usually simple and requires observation of accompanying symptoms. Taking menorrhagia as an example, heavy menstrual bleeding with the accompanying heat symptoms bright red or dark red menstrual flow, feverishness, thirst, restlessness, anxiety, dark urine, a red tongue and a rapid pulse would be attributed to blood heat. Heavy menstrual bleeding with the accompanying Qi vacuity symptoms pale menstrual flow, fatigue, shortness of breath, pale complexion, abdominal distension, loose stools, anxiety, palpitations, a pale tongue and a thready and weak pulse points to abnormal bleeding due to the spleen not managing the blood. Bleeding due to blood stasis would manifest with accompanying blood stasis signs such as dark menstrual flow with clots, dysmenorrhea, abdominal pain exacerbated by pressure and alleviated with the passing of menstrual clots, a purple tongue and a wiry and choppy pulse.

The Liver Stores Blood and Governs Free Coursing

The liver function of storing blood has a direct impact on the two extraordinary vessels (Chong Mai and Ren Mai) that regulate menstruation.

The liver also governs free coursing, meaning that it ensures the free flow of Qi and blood, unobstructed mental and emotional activity, the unobstructed secretion of bile, and the smooth function of the spleen's moving and transformation. A disturbance of this function can cause Qi stagnation which can possibly lead to blood stagnation. In women this tends to manifest as irregular

or painful menstruation, pain and distension in the breast before menstruation, emotional frustration and depression etc.

Liver Qi stagnation is also likely to overwhelm the spleen and interfere with its function of moving and transforming food essence with consequential blood vacuity. A common scenario leading to this pattern would be a woman suffering some kind of mental or emotional stress with irregular eating habits or frequent dieting. Stress inhibits the free flow of mental and emotional activity, which impairs the liver's function of free coursing and leads to liver Qi stagnation. The spleen, already weakened by dietary irregularities, is overwhelmed by the stagnating liver. The result is Qi stagnation (impaired free coursing of the liver), and blood vacuity (impaired movement and transportation of food essence by the spleen). Blood vacuity in turn affects the liver function of storing blood and the direct relationship to the two extraordinary vessels that regulate menstruation. This extremely common clinical picture manifests in combined symptoms of liver Qi stasis, blood vacuity and spleen Qi vacuity e.g. menstrual irregularities such as dysmenorrhoea, irregular menstrual cycle, pre-menstrual breast distension, scanty menstruation, amenorrhoea, and fatigue, light sleep, depression, irritability and headache. This symptoms picture fits the formula Xiao Yao San [Bupleurum & Dang Gui Formula] or, in case of accompanying heat signs such as thirst, flushing and night sweats, Jia Wei Xiao Yao San [Bupleurum & Peony Formula] fits best.

“A common scenario leading to this pattern would be a woman suffering some kind of mental or emotional stress with irregular eating habits or frequent dieting. Stress inhibits the free flow of mental and emotional activity, which impairs the liver's function of free coursing and leads to liver Qi stagnation.”

The Heart Governs the Blood and Vessels

The heart moves the blood in the vessels, ensuring proper blood circulation. The heart also stores the spirit, governing mental vitality and consciousness. If this function is healthy, it manifests as clear thinking, balanced emotions, good memory and sound sleep. If however, a woman experiences emotional turmoil or shock, this can affect menstruation and fertility.

The Kidney Stores Essence

The abundance of kidney essence reflects the reproductive capacity. Infertility, though there are many causes, always involves kidney essence vacuity in some way.

“Jia Wei Xiao Yao San is indicated in the extremely common clinical picture of liver Qi stagnation with spleen Qi vacuity and blood vacuity. It soothes the liver and resolves depression, strengthens the spleen and supplements blood, regulates menstruation, clears heat and cools blood.”

Formulae

a) The Liver Stores Blood and Governs Free Coursing

***Jia Wei Xiao Yao San* [Bupleurum & Peony Combination]**

Jia Wei Xiao Yao San is indicated in the extremely common clinical picture of liver Qi stagnation with spleen Qi vacuity and blood vacuity. It soothes the liver and resolves depression, strengthens the spleen and supplements blood, regulates menstruation, clears heat and cools blood. Traditional indications include irritability, depression, headache, fatigue, light sleep, and thirst combined with any of the following: Dysmenorrhoea, irregular menstrual cycle, pre-menstrual breast distension, scanty menstruation, and amenorrhoea.

Jia Wei Xiao Yao San has been found to lower oestrogen levels¹, thus making it effective in treating oestrogen excess disorders.

b) Blood Stagnation

***Gui Zhi Fu Ling Tang* [Cinnamon & Hoelen Combination]**

Gui Zhi Fu Ling Tang is indicated in cases of blood stagnation mainly in the lower jiao (lower abdomen) manifesting as masses and/or pain upon palpation in the lower abdomen. This can be accompanied by irregular menstruation, amenorrhoea, abnormal uterine bleeding, and dark clotted menstrual flow. The tongue is often cyan or with purple spots. Based on the traditional indications, the formula is often used in cases of endometriosis, pelvic inflammatory disease, uterine fibroids, ovarian cysts, polycystic ovarian syndrome (PCOS), hysteromyoma, insufficient post-partum uterine involution, retained placenta, dysmenorrhoea, amenorrhoea, dysfunctional uterine bleeding, irregular menstruation, leucorrhoea, infertility, or climacteric disorders (menopausal syndrome).

In modern clinical studies, Gui Zhi Fu Ling Tang has been found to reduce blood-stream oestrogen levels², making it useful in the treatment of oestrogen-excess disorders. Another study has found Gui Zhi Fu Ling Tang to stop the growth of uterine fibroids without affecting the menstrual cycle or bringing about weight gain.³



“Ba Zhen Tang supplements both blood (liver) and Qi (spleen). The formation of blood depends on spleen Qi.”

c) The Spleen Participates in the Formation of Qi and Blood

Ba Zhen Tang [Dang Gui & Ginseng Eight Combination]

Ba Zhen Tang supplements both blood (liver) and Qi (spleen). The formation of blood depends on spleen Qi. This is why, when treating blood vacuity, it is important to add Qi supplementing medicinals as is the case in this formula. Traditional indications include fatigue, loose stools, pale complexion, blurred vision, muscle spasms, combined with any of the following: Amenorrhoea, dysmenorrhoea, scanty menstruation, irregular menstruation, and spotting.

Si Wu Tang [Dang Gui Four Combination]

Supplements and quickens blood, and regulates menstruation. It is often used as an add-on formula to reinforce blood supplementation.

d) The Spleen Manages the Blood and the Heart Governs the Blood and Vessels

Gui Pi Tang [Ginseng & Longan Combination]

Gui Pi Tang treats abnormal bleeding due to an impairment of the spleen's ability to govern blood. It supplements Qi and blood, and also nourishes the heart and calms the shen (spirit). Traditional indications include early periods, uterine bleeding and other chronic recurrent haemorrhaging, combined with fatigue, shortness of breath, pale complexion, abdominal distension, loose stools, forgetfulness, anxiety, palpitations, light sleep and dream disturbed sleep.

e) The Kidney Stores Essence

Liu Wei Di Huang Wan [Rehmannia Six Formula]

Liu Wei Di Huang Wan supplements kidney (and liver) Yin. Traditional indications include a weak lower-back/knees, thirst (especially at night), dry mouth/throat, feverishness, hot sensations in the soles and palms, night sweats, combined with any of the following: Amenorrhoea, scanty menstruation, infertility and anovulation.

Liu Wei Di Huang Wan is the base formula for most kidney Yin and Yang supplementation formulas. Adding Rou Gui [Cinnamon] to Liu Wei Di Huang Wan [Rehmannia Six Formula] can be added in cases of kidney Yang vacuity with the symptoms: Lumbago, weak and/or painful lumbus and knees, cold lower back and loins, cold extremities, pale complexion, fatigue, oedema, low libido, thin profuse vaginal discharge in combination with any of the following: Amenorrhoea, scanty menstruation and infertility.

From the Sun Ten Quality Control Desk

Investigation of the Extraction Yield of Cinnamaldehyde from Cinnamon Containing Herbal Formulae

Shuenn-jiji Sheu, Yuh-pan Chen and Hong-yen Hsu, Modern Drug Weekly of Taiwan 2002; (2020),4

A large amount of cinnamaldehyde is lost during the process of manufacturing scientifically prepared herbal formulae if they are decocted in the open air, and then concentrated at room or higher temperature under reduced pressure. A number of commercial products have this problem, and the so-called scientific preparations of these formulae may have severe quality defects if their decoction and concentration processes are not improved.

“A large amount of cinnamaldehyde is lost during the process of manufacturing scientifically prepared herbal formulae if they are decocted in the open air, and then concentrated at room or higher temperature under reduced pressure.”

Sun Ten uses equipment that enables recovery of the volatile oils during decoction of the herbs, with the collected volatile oils later evenly blended into the dried powder or granules of the herb extract. Sun Ten also uses spray-drying in order to effectively reduce the loss of these active constituents.

References available upon request.

中西医结合 Integrated Traditional and Western Medicine

Pilot Study Comparing the Clinical Effects of Sun Ten's Jia Wei Xiao Yao San [Bupleurum & Peony Combination] and a Continuous Combined Hormone Replacement Therapy in Post-Menopausal Women with Climacteric Symptoms

L.-C. Chen et al. / Sun Ten Journal 2004 March, pp. 84-90

Introduction: Most post-menopausal women may experience a variety of symptoms that are caused by changes in oestrogen and progesterone levels. The potential symptoms include: Hot flashes and skin flushing, night sweats, insomnia, mood swings including irritability, depression, anxiety, irregular menstrual periods or spotting of blood in between periods and vaginal dryness.

While hormone replacement therapy (HRT) is highly effective at relieving menopausal symptoms and may provide protection against certain conditions (such as osteoporosis), the results of a major study called the 'Women's Health Initiative' led physicians to revise their recommendations regarding HRT. The study began in the fall of 1997 and was scheduled to be completed in 2005. However, researchers halted the study midway on May 31, 2002 because they felt that the health risks for participants taking HRT outweighed the possible benefits of HRT. This created a renewed interest in the use of safe and efficacious alternative medicines, such as the TCM formula Jia Wei Xiao Yao San [Bupleurum & Peony Combination].

Jia Wei Xiao Yao San consists of Dang Gui [Angelica Sinensis], Bai Shao [Peony], Bo He [Mentha], Chai Hu [Bupleurum], Sheng Jiang [Ginger], Gan Cao [Licorice], Fu Ling [Hoelen], Bai Zhu [Atractylodes], Shan Zhi Zi [Gardenia] and Mu Dan Pi [Moutan]. It soothes the liver and resolves depression, strengthens the spleen and supplements blood, regulates menstruation, clears heat and cools blood. The traditional indications for Jia Wei Xiao Yao San cover symptoms of liver Qi stasis leading to fire, blood vacuity and spleen vacuity, including: Depression, irritability, short-temperedness, headache, insomnia, dizziness, palpitations, thirst, flushing, low-grade fever, night sweats, dysmenorrhoea, premenstrual breast distension or oedema, irregular menstruation, amenorrhoea or excessive menstrual flow and fatigue. These symptoms overlap largely with the symptoms experienced by post-menopausal women.

The study: A randomised, controlled pilot study was performed to evaluate the clinical effects of Jia Wei Xiao Yao San [Bupleurum & Peony Combination] (JWXYS) compared to continuous combined hormone replacement therapy, on quality of life in non-hysterectomised post-menopausal women.

The trial compared the effect of a 16 weeks treatment with JWXYS (supplied by Sun Ten Pharmaceutical Co., Taipei, Taiwan) or HRT in post-menopausal women with climacteric symptoms. The Greene Climacteric Scale (see Table 1) was used to assess the clinical effects at baseline and after 16 weeks of treatment with either JWXYS or HRT. This scale independently measures psychological, somatic and vasomotor symptoms; each symptom is rated by the subject according to its severity using a four point rating scale. The physiological parameters, such as follicle-stimulating hormone and estradiol levels, were also recorded at the same time points.



Results:

- Both JWXYS and HRT induced a significant reduction of prevalence and severity of menopausal symptoms.
- Both JWXYS and HRT showed significant reductions of psychological (anxiety, depression) and somatic symptom scores on the Greene Climacteric Scale.
- Significant changes of mean scores in FSH and E2 were found with HRT treatment.
- JWXYS caused less unusual vaginal bleeding or spotting episodes and absence of breast tenderness during the study period. The low frequency of breast tenderness with JWXYS compared with oestrogen-containing HRT suggests that women complaining of breast tenderness while on conventional HRT might consider switching to JWXYS.
- The beneficial effects of JWXYS were not mediated by hormone replacement-like effects: The improvements in climacteric symptoms of JWXYS were not mediated by oestrogenic effects, because no changes were seen in the E2 and FSH levels. This is consistent with the finding that breast tenderness was less frequent with JWXYS than with HRT, which might be related to the relatively high E2 levels with the latter.

Clinical Parameters Before and After 16-Weeks Treatment with JWXYS or HRT

	JWXYS (n=24)			HRT (n = 14)		
	Baseline	After 16 Weeks	Mean Change	Baseline	After 16 Weeks	Mean Change
FSH; IU/l	63.34 (37.22)	71.52 (32.64)	8.18 (30.37)	72.14 (32.61)	20.59 (13.21)	-51.55 (41.49) *
E ₂ ; pg/ml	51.80 (38.19)	49.75 (22.63)	-2.05 (30.95)	42.23 (25.32)	101.25 (81.71)	58.02 (93.44) *
Blood Urea Nitrogen (BUN; mg/dl)	13.77 (3.29)	13.64 (3.30)	-0.14 (2.62)	14.38 (2.14)	13.92 (1.93)	-0.46 (1.33)
Creatinine (Cr.; mg/dl)	0.85 (0.10)	0.86 (0.15)	0.02 (0.14)	0.93 (0.09)	0.89 (0.12)	-0.04 (0.09)
Alanineaminotransferase(ALT;u/l)	19.95 (9.20)	21.91 (10.84)	1.95 (5.24)	19.57 (5.65)	16.36 (5.23)	-3.21 (7.39)
Fasting Blood Sugar (FBS; mg/dl)	86.73 (9.17)	87.73 (10.66)	1.00 (17.17)	93.14 (8.40)	91.57 (2.53)	-1.57 (6.95)
Total Cholesterol (TC; mg/dl)	197.14 (18.12)	203.50 (14.09)	6.36 (17.92)	199.07 (26.37)	189.21 (22.37)	-9.86 (22.19)
Triglyceride (TG; mg/dl)	74.36 (27.42)	73.64 (19.76)	-0.73 (25.81)	143.57(136.17)	159.43(128.80)	15.86 (42.09)

Data are presented as the mean values (S.D.).

* $P < 0.05$ (paired t -test for the evolution within the treatment group).

Quality of Life as Assessed by the Greene Climacteric Scale Before and After 16-Weeks Treatment with JWXYS or HRT

	JWXYS (n=24)			HRT (n = 14)			Differences Between Groups
	Baseline	After 16 Weeks	Mean Change	Baseline	After 16 Weeks	Mean Change	
Total Score	16.58 (5.27)	7.92 (3.35)	-8.67 (2.51) *	14.00 (8.77)	3.57 (1.65)	-10.43 (7.33) *	NS
Primary Endpoint							
Psychological	7.67 (3.27)	3.08 (2.19)	-4.58 (1.89) *	5.00 (4.93)	0.57 (0.76)	-4.43 (4.47) *	NS
Anxiety	5.25 (2.64)	2.08 (1.74)	-3.17 (2.08) *	2.71 (3.22)	0.57 (0.76)	-2.14 (2.63) *	NS
Depression	2.42 (1.84)	1.00 (1.32)	-1.42 (1.35) *	2.29 (2.27)	0.00 (0.00)	-2.29 (2.27) *	NS
Somatic	5.42 (2.55)	2.50 (1.79)	-2.92 (2.15) *	5.43 (3.18)	1.43 (0.51)	-4.00 (2.94) *	NS
Vasomotor	2.33 (1.74)	1.25 (1.11)	-1.08 (1.14) *	1.29 (2.27)	0.14 (0.36)	-1.14 (2.18)	NS
Sexual Dysfunction	1.17 (1.17)	1.08 (1.14)	-0.08 (0.28)	1.86 (1.29)	1.43 (0.94)	-0.43 (0.51) *	$P < 0.05$

Data are presented as the mean values (S.D.). NS: Not Significant.

* $P < 0.01$ (paired t -test for the evolution within the treatment group).

The present study is the first controlled trial to compare the clinical effects of the traditional Chinese herbal prescription JiaWei XiaoYao San (Bupleurum and Peony Combination) (JWXYS), and an oestrogen-progestogen combined HRT on climacteric symptoms in non-hysterectomised post-menopausal women. The results obtained in this pilot study suggested that JWXYS might offer effective relief in climacteric symptoms and that the beneficial effects might not be mediated by hormone replacement-like effects, as the FSH and E₂ levels were not affected by the treatment. Moreover, JWXYS showed good compliance and safety without oestrogenic effects and metabolic alterations. Generally, the preliminary results suggested that JWXYS was a safe and efficacious therapy and might be an alternative choice for relief of climacteric symptoms in post-menopausal women who refuse or have contraindications for HRT.

Table 1: The Greene Climacteric Scale

Symptoms	Not at all (Score 0)	A little (Score 1)	Quite a bit (Score 2)	Extremely (Score 3)	Symptoms	Not at all (Score 0)	A little (Score 1)	Quite a bit (Score 2)	Extremely (Score 3)
1. Heart beating quickly or strongly					12. Feeling dizzy or faint				
2. Feeling tense or nervous					13. Pressure or tightness in head or body				
3. Difficulty in sleeping					14. Parts of body feel numb or tingling				
4. Excitable					15. Headaches				
5. Attacks of panic					16. Muscle and joint pains				
6. Difficulty in concentrating					17. Loss of feeling in hands or feet				
7. Feeling tired or lacking energy					18. Breathing difficulties				
8. Loss of interest in most things					19. Hot flushes				
9. Feeling unhappy or depressed					20. Sweating at night				
10. Crying spells					21. Loss of interest in sex				
11. Irritability									