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2nd WFCMS International Congress of Traditional Medicine held in Paris

世界中医药学会联合会第二届国际传统医药大会在巴黎召开

The second WFCMS International Congress of Traditional Medicine was successfully held from 30 September to 2 October 2005 in Paris, France. The congress was undertaken by Pan European Federation of TCM Societies, Pan European Federation of Consultants in TCM and French Union of TCM Professionals.

Chair and vice chairs of WFCMS in the opening ceremony of the 2nd WFCMS International Congress

More than 700 delegates from 34 countries attended the congress. The congress covered a wide range of topics in Chinese medicine. The congress received over 200 thesis’s, 85 of which were selected to be presented to the congress.

The 3rd International Conference of Traditional Medicine is to be held in September 2006 in Toronto, Canada.

PEFOTS 2nd General Assembly held in Paris

全欧洲中医药学会联合会第二届会员大会在巴黎召开并选举产生第二届理事会和专业委员会成员

The second General Assembly of the Pan European Federation of TCM Societies (PEFOTS) was held in Paris on 29 September 2005. Delegates from PEFOTS member states attended the General Assembly.

The General Assembly was presided over by PEFOTS vice chairman Ramon Calduch of Spain. Bernadette Ward, Director of the Acupuncture Foundation of Ireland, gave her presentation "TCM education in Europe: The core TCM curriculum and the ECTS system of credits". The presentation was well received and sparked much discussion in the audiences.

PEFOTS President Zhilin Dong presents the working report to the general assembly. During the tenure of the last PEFOTS board, PEFOTS has successfully organized International TCM conferences in Barcelona, Lisbon and Manchester; launched and published European Journal of Traditional Chinese Medicine; joined the World Federation of Chinese Medicine Societies (WFCMS) and holds WFCMS vice presidency; participated in the implementation of EU Traditional Herbal Medicinal Products Directive, and Response to MHRA Consultation; participated in the European Forum for Complementary and Alternative Medicine (EFCAM) which is now an Interested Party of the Herbal Medicinal Products Committee (HMPC) of the European Medicines Agency (EMEA); and established relations with South American TCM organizations in South American countries. The General Assembly fully endorsed the work of the Board.

After agreeing on the nomination and election methods of the new board members, the General Assembly elected the new board. Mr. Zhilin Dong of the Netherlands was unanimously re-elected as Chairman of PEFOTS. The complete list of the members of the new PEFOTS Board and 7 Working Committees can be found below.

PEFOTS Board members and the delegates then listened to the presentation by the Lithuanian delegate which applied to host the next PEFOTS International TCM Conference. The Board decided that the next PEFOTS International Conference is to be held from 26 to 28 May 2006 in Vilnius, Lithuania.
2nd PEFOTS BOARD

President: Zhilin Dong (The Netherlands)
Vice-President: Carlo M. Giovanardi (Italy)
Ramon M. Calduch (Spain)
Guo-Guang Zhu (Finland)
Pedro Choy (Portugal)
Andrea Bijaoui (France)
Francois Marquer (France)
Jianping Wang (Germany)

Secretary General: Hui Jun Shen (UK)
Board members: Bernadette Ward (Ireland)
Andrea Bijaoui (France)
Francois Marquer (France)
Jianping Wang (Germany)

2nd PEFOTS Working Committees

Legislation:
Chairman: Carlo M. Giovanardi (Italy)
Members: Ramon M. Calduch (Spain)
Pedro Choy (Portugal)
Zhilin Dong (Netherlands)
Guo-Guang Zhu (Finland)
Francois Marquer (France)
Huijun Shen (UK)
Jianping Wang (Germany)

Education:
Chairman: Bernadette Ward (Ireland)
Members: Donghui Chen (Denmark)
Jose Choy (Portugal)
Federico Marmori (France)
Guilio Picozzi (Italy)
Weixiang Wang (Netherlands)
Jidong Wu (UK)

Acupuncture:
Chairman: Mingzhao Cheng (UK)
Members: H. van Brero (Netherlands)
Jin Liu (Germany)
Sotte Lucio (Italy)
Marc Mezard (France)
Vitalijus Naumavicius (Lituania)

Chinese Herbs:
Chairman: You-Ping Zhu (Netherlands)
Members: Zhen Chen (Hungary)
Gabriela Gil (Portugal)
G. Rotolo (Italy)
Herve Verbanck (Belgium)
Guo-Guang Zhu (Finland)
PEFOTS Education Committee meeting in Dublin
全欧洲中医药学会联合会教育专业委员会召开第一次会议

The PEFOTS Education Committee met in Dublin on February 23rd 2006.

Ms. Bernadette Ward, chair of the Education Committee, made a presentation on the Bologna agreement and the ECTS system of academic credits. She presented her design of the TCM core curriculum, which had been submitted to the Irish Department for Health.

Producing a TCM core curriculum, acceptable to western students, which had been quantified and designed on the basis of ECTS (European Credit Transfer System) credits will be one of the main tasks of the Education Committee. PEFOTS should also establish an accreditation commission within Europe.

The meeting discussed the detail of the curriculum, differences in programmes, teaching and examination systems, the difficulties of standardisation between languages. It was agreed to use the ECTS of academic measuring and crediting as a model within PEFOTS.
Germany granted the first traditional herbal medicinal product registration

German has granted the first traditional herbal medicinal product registration in the EU since the Directive on Traditional Herbal Medicinal Products came into force in April 2004. The registered traditional medicine is in liquid form consisting of 13 active herbal substances. Many of the ingredients such as ginger, clove flower, galangal, black pepper, nutmeg, dried bitter-orange, cinnamon bark and cardamom fruit are also used in TCM.

British Pharmacopoeia to include Chinese herbs

The British Pharmacopoeia Commission has initiated the development of new monographs for Chinese herbs. Known manufacturers have been invited to co-operate with the British Pharmacopoeia Secretariat in the development of these monographs for publication. The Chinese herbs proposed to be included in the British Pharmacopoeia are:

Bai Shao Yao (Paeoniae alba radix), Bai Zhu (Atractylodis macrocephalae), Ban Xia (Pinelliae rhizoma preparata), Chai Hu (Bupleuri radix), Chen Pi (Citri reticulatae pericarpium), Chuan Xiong (Ligustici wallichii rhizoma), Dan Shen (Salviae miltorrhizae radix), Fu Ling (Poria cocon), Gan Cao (Glycyrrhiza radix), Gou Qi Zi (Lycii chinensis Fructus), He Shou Wu (Polygoni multiflori radix), Huang Qi (Astragali radix), Huang Qin (Scutellariae radix), Mu Dan Pi (Moutan radicis cortex), Shan Yao (Dioscoreae radix), Shen Di Huang (Rehmanniae glutinosa radix), Suan Zao Ren (Ziziphi spinosae semen), Yi Yi Ren (Coicis semen).

Draft of traditional medicines model released in the US

According to the American Herbal Products Association (AHPA), nine national organizations working together as the Traditional Medicines (TM) Congress have released the first public draft of “A Proposed Regulatory Model for Traditional Medicines: Guiding Assumptions and Key Components.” This comprehensive document presents ideas for a new model for the regulation of traditional medicines in the U.S., and will now be subject to an open review process by interested individuals and organizations.

China bans the sales of herbs of Aristolochia origin

China’s State Food and Drug Administration (SFDA) issued a decree on 5 August 2004 to withdraw the pharmacopoeia monographs of two herbs of Aristolochia origin, i.e. Guang Fang Ji (Radix Aristolochiae Fangchi) and Qing Mu Xiang (Radix Aristolochiae). As from 30 September 2004, all herbal formula and herbal products containing Guang Fang Ji must be replace by Fang Ji (Radix Stephanotae Tetrandrae), Qing Mu Xiang must be replaced by Tu Mu Xiang (Radix Inulae).

Warnings must be printed on the leaflets and packages of the products that contain the following four herbs of Aristolochia origin, Ma Dou Ling (Fructus Aristolochiae), Xun Gu Feng (Herba Aristolochiae Mollissimae), Tian Xian Teng (Herba Aristolochiae) and Zhu Sha Lian (Radix Aristolochiae Kaempferi). Contents of the warnings include (1) This product contains Aristolochia herbs that contains aristolochic acid, which can cause damages to the kidneys; (2) This products is a prescription only medicine that can only be purchased with a prescription of a medical doctor. It should be used under prescribed conditions.

The genesis of this model goes back to 2004 when AHPA joined eight other organizations to exchange ideas about the future of traditional medicines in the U.S. These discussions culminated in the formation of the TM Congress. In seeking to emphasize both the value of traditional medicines and the responsibilities that are associated with their use, it was agreed that: The goal of the Traditional Medicines Congress is to benefit public health by ensuring access to traditional medicines in a manner that provides a reasonable expectation of public safety.

“The current legal framework for dietary supplements provides significant options for consumer healthcare choices,” noted AHPA President Michael McGuffin. “And while some goods that have long been used as traditional medicines fit neatly into this framework, the therapeutic uses of these are restricted and many are entirely excluded. The model proposed here would completely protect the current law, while developing a new option that will benefit marketers who want to sell traditional medicines and practitioners and consumers who want to use them.” Anyone with an interest in traditional medicines is now invited to review the draft document that the TM Congress has developed. A Proposed Regulatory Model for Traditional Medicines is posted online at AHPA’s website, www.ahpa.org. The deadline for comments is March 31st.
the supervision of medical professionals. Kidney functions should be monitored when using this product and it should be immediately discontinued when abnormal kidney functions are detected; (3) It should be used with caution for children and seniors. It is contraindicated for pregnant women, infants and those with kidney problems.

Another herb Guan Mu Tong (Caulis Aristolochiae Manshuriensis) had been withdrawn in 2003 and was replaced by Mu Tong (Caulis Akebiae).

**Chinese Pharmacopoeia 2005**

The 8th edition of the Pharmacopoeia of the People’s Republic of China, or more commonly known as Chinese Pharmacopoeia 2005, came into effect on 1 July 2005. There are major revisions in this edition of the Chinese Pharmacopoeia.

Three herbs derived from Aristolochia species, i.e. Guan Mu Tong (Caulis Aristolochiae Manshuriensis), Guang Fang Ji (radix Aristolochiae Fangchi) and Qing Mu Xiang (Radix Aristolochiae) are withdrawn. To replace Guan Mu Tong, Mu Tong (Caulis Akebia) which is believed to be the original source of Mu Tong, is restated in this new edition as the legitimate source of Mu Tong. Caulis Akebia also replaces Caulis Aristolochiae Manshuriensis in formulas such as Long Dan Xie Gan Wan that used to contain Guang Mu Tong.

In another interesting development, a western herb, i.e. St. John’s Wort is included in this edition of the Chinese Pharmacopoeia under the entry of Herba Hyperici Perforati (Guanyejinsitao). However, no TCM temperature and taste properties are given to this herb, nor is channel tropism.

There are also considerable revisions and improvements to the General Notices, Requirements of Monographs, General Requirements for Preparations in Appendices and new testing methods. The contents of Appendices are revised to large extent in comply with international standards for drug quality control. Furthermore, stylistic rules and layout, wording, units, and symbols are also standardized.


The increase in the number of monographs in Chinese Pharmacopoeia 2005 is obvious which contains up to 3214 monographs of drugs, with 525 new admissions in total. Volume I contains 1146 monographs, with 154 new admissions and 453 revised monographs. Volume II deals with 1967 monographs, with 327 new admissions and 522 revised monographs. Volume III contains 101 monographs, with 44 new admissions and 57 revised ones. The monographs in Appendices common to all the three volumes are presented in each volume respectively in a harmonized and unified form.
**Research Highlights**

**Chinese herb cuts alcohol consumption**

The Chinese herb Kudzu, or Ge Gen (Puerariae Radix) appears to be able to reduce alcohol consumption in heavy drinkers. Those who were given the herb extract in capsule form for seven days prior to a drinking session cut their alcohol consumption by almost 50% compared to controls given a placebo. Not only did they consume fewer beers, but they took more and fewer sips and therefore consumed the beer more slowly.

In a report published by the journal, Alcoholism: Clinical & Experimental Research, scientists have found that the extracts from the herb kudzu may be effective in reducing alcohol consumption. The study performed at McLean Hospital gave subjects either kudzu extract or a placebo for seven days and allowed them the chance to drink as much of their favorite beer as they wanted. Subjects were in their twenties and generally consumed three to four drinks a day. Results from four 90-minute sessions showed a decrease in the overall consumption and sip volume with an increase in time to finish the beer. After administering the kudzu or placebo the beer was weighed sip by sip to give a complete analysis of consumption. Researchers were unsure how the kudzu affected consumption but presumed that the extract somehow increased the effects of the alcohol and blood alcohol levels. No side effects were reported. Kudzu could prove to be a safe and effective way to decrease alcohol cravings and consumption in alcoholics.

In 2003, a Harvard lab found kudzu's inhibitory effects on alcohol consumption in rats and hamsters and recently completed the follow-up human study. Plans are to find a way to safely manufacture a drug for use as a supplement to alcoholism therapies.


**Acupuncture may treat chronic headaches**

The October issue of the journal Headache has published a study that found that supplementing medical management with acupuncture may result in improvements in frequency and pain intensity of headaches.

Researchers at the University of North Carolina at Chapel Hill School of Medicine were lead by Dr. Wunian Chen, an instructor in the department of family medicine trained in the use of traditional Chinese acupuncture. A randomized, controlled trial of 74 patients with chronic daily headache (CDH) compared medical management provided by neurologists to medical management plus ten acupuncture treatments. Daily pain severity and headache-related quality of life (QoL) were measured.

Medical management plus acupuncture resulted in an improvement of three points on the Headache Impact Test and eight or more points on Short Form 36 Health Survey. After six weeks, patients receiving acupuncture were 3.7 times more likely to have less headaches.

The International Headache Society criteria for chronic tension-type headache are headaches on 15 or more days a month (180 days per year), for at least six months. It is estimated that 4-7 percent of Americans suffer with chronic headaches.


**Acupuncture for pregnancy depression**

Pharmaceutical medication is largely unsuitable for depression during pregnancy and therefore any non-pharmaceutical alternative is potentially of great value. In a study carried out at Stanford University, 61 women with major depressive disorder were randomly assigned to receive one of three treatments: (i). Individually tailored true acupuncture designed to treat their depression, (ii). True acupuncture but with points not chosen to treat the depression, and (iii). Massage treatment (included to provide a control for attention, physical contact, relaxation and respite from daily stress). Acute phase treatment was given for twelve sessions over eight weeks, with continued treatment throughout pregnancy for those who responded. As far as possible the acupuncture treatment was double-blinded, with the treatment to be given by a treating acupuncturist determined by a different (assessing) acupuncturist. The assessment, treatment design, needle insertion, and needle stimulation were all standardised. Response rates at the end of the acute phase were 68.8% in the depression specific acupuncture, 47.4% in the non depression-specific acupuncture, and 31.6% in the massage group. The study also showed that successful treatment of depression during pregnancy offers protection from postpartum depression.
Acupuncture helps facial pain
针灸缓解面痛
Twenty-five patients suffering from orofacial pain (myofascial pain 15, tempomandibular joint synovitis 5, fibromyalgia 2, neuropathic pain 2, trigeminal neuralgia 1) were assessed for pain before and after treatment by acupuncture. All patients were treated at Hegu L.I.-4, with further points needled according to individual presentation. Patients received a mean of 3.8 treatments each. All experience a reduction in pain after treatment, with mean value pain scores dropping from 5.28 to 2.26 over the study period, a significant reduction.

Cinnamon for diabetes
肉桂和糖尿病
Researchers have found that Cinnamon can help increase insulin sensitivity and therefore may be a potential treatment for diabetes. The active ingredient in cinnamon hydroxycalcone affects insulin receptors to help promote glucose uptake into cells and promote glycojen synthesis. In a December 2003 Diabetes Care study (1), cinnamon was found to improve glucose and lipids in people with diabetes. Sixty patients with type 2 diabetes who were taking a sulfonylurea (glyburide) were given doses of cinnamon or a placebo for 40 days. Fasting blood glucose declined by 18 to 29 percent after 40 days and 20 days after stopping use fasting glucose was still lower than at baseline. Also in December 2003 a rat study found that cinnamon extract improved insulin action via increasing glucose uptake in vivo through enhancing the insulin-signaling pathway in skeletal muscle (2). In 2004, researchers at a USDA center in Maryland reported that polyphenols in cinnamon potentiate insulin action making them beneficial in the control of glucose intolerance and diabetes (3). Researchers have also found that cinnamon extracts can prevent the development of insulin resistance at least in part by enhancing insulin signaling and possibly via the NO pathway in skeletal muscle (4). German researchers found earlier this year that cassia extract (a species of cinnamon) has a direct antidiabetic potency as evidenced by an insulin release from INS-1 cells (5).

Cinnamon is a spice often used in food, beverages, chewing gums, toothpastes, mouthwash, liniments, nasal sprays and suntan lotions. Although cinnamon bark and flowers have been used medicinally in Asia for thousands of years. Cinnamon has been used for type 2 diabetes, gastrointestinal problems, diarrhea, infections, the common cold, menopausal symptoms, rheumatic conditions, hypertension, angina and kidney disorders. Although there are no serious side effects reported, blood glucose levels should be monitored in diabetic patients when taking supplemental doses. Medication adjustments may be necessary.

American Ginseng may prevent colds
西洋参可以以防感冒
A study published in the October issue of the Canadian Medical Association Journal has found that taking ginseng supplements may reduce the number of colds experienced. Researchers at the University of Alberta conducted a randomized, double-blind, placebo controlled study on 323 participants at the onset of the influenza season in November 2003. All subjects had reported a history of at least 2 colds in the previous year. People were given two 200mg capsules of North American ginseng extract or a placebo to be taken after breakfast each day for four months.

The ginseng supplements were tested for batch-to-batch consistency to contain 80 percent poly-furanosyl-pyranosyl-saccharides and 10 percent protein from North American ginseng. Colds were measured on reports filled out by participants once a day documenting the severity of symptoms (sore throat, runny nose, sneeze, nasal congestion, malaise, fever, headache, hoarseness, earaches and cough) on a four-point scale. A two-day symptom score greater than 14 met modified Jackson criteria for a cold. Results for the 130 who received and used their ginseng supplements found that the mean number of Jackson-verified colds per person was less in the ginseng group than in the placebo group. Also the proportion of subjects with recurrent Jackson-verified colds during the four months and overall symptom scores were significantly lower in the ginseng group.

Ginseng has long been associated with helping ward off influenza and the common cold but there is little clinical evidence to support its use. Further studies must be done to validate these results, because although the study was properly randomized it was paid for by CV Technologies Inc, the manufacturer, of the popular Canadian cold medication, Cold-fx®.

Source: Predy GN et al. Efficacy of an extract of North American ginseng containing poly-furanosyl-pyranosyl-saccharides for preventing upper respiratory tract infections: a randomized controlled trial. CMAJ 2005;173(9)IV.
**Xiao Yao Wan and bipolar depression**

逍遥丸辅助治疗两极型抑郁症有效

In a double-blind, placebo-controlled randomised controlled trial, the efficacy of i. Carbamazepine (CBZ), ii, CBZ plus the Chinese herbal medicine Free and Easy Wanderer (Xiao Yao Wan), and iii. Placebo, was compared in the treatment of 124 bipolar depressed and 111 manic patients over a twelve week period. CBZ plus Xiao Yao Wan produced significantly better outcomes on three measures of depression at four and eight weeks and significantly greater clinical response rate in depressed subjects (84.8% versus 63.8%), but no such benefit was found in manic subjects. There was a lesser incidence of dizziness and fatigue in the combination therapy compared to CBZ monotherapy. These results suggest that adjuvant Xiao Yao Wan has additive beneficial effects in bipolar patients, particularly for those in depressive phase.


**Chinese herbs and asthma**

中药治疗哮喘

ASHMI, or anti-asthma herbal medicine intervention, a Chinese preparation comprised of three herbs (a simplification of a fourteen-herb formula used to treat asthma in Chinese hospitals) was found to be almost as effective as prednisone in a comparative study, with none of the negative affects on adrenal function associated with the prednisone. Each ASHMI capsule contained 0.3 g dried aqueous extract. The total daily dose of 12 capsules (3.6 g) is equivalent to extracts of a mixture of the raw herbs Ling Zhi (Ganoderma) 20 g, Ku Shen (Radix Sophorae Flavescentis) 9 g, and Gan Cao (Radix Glycyrrhizae) 3 g.

It is the first time a controlled study has shown Chinese herbal medicine proving as effective as a corticosteroid for aiding asthma patients. The study was conducted on over 90 patients who were given either oral ASHMI, prednisone, or a placebo.

After four weeks, both the ASHMI and prednisone groups showed significant lung function improvement. There was a slight, but still measurable, greater improvement in the prednisone group. ASHMI, however, unlike prednisone, also has the benefit of having no negative effects on adrenal function.


**Laser acupuncture for depression**

激光针灸治疗轻中度抑郁症

In a double-blind randomized controlled trial, active laser acupuncture was found to be significantly more effective for the treatment of mild to moderate depression (at twelve weeks from trial onset) compared to sham laser acupuncture. In this trial, the practitioner did not know during treatment whether the laser device was active or not and was asked not to communicate with the patient other than a first greeting. Treatment was given twice a week for four weeks, then weekly for four weeks. The principal points used were Qimen LIV-14 (right), Jiuiwei REN-15, Juque REN-14, Shenmen HE-7, Ququan LIV-8 (left). Additional points were used in cases where anxiety scores were high, (mainly Yingu KID-10).

Laser acupuncture is non-invasive and therefore free of infection risk. Laser acupuncture is well tolerated with transient fatigue as the most common adverse effect. The technique is relatively easily learned by community based general practitioners. Laser acupuncture is worth further investigation as a treatment for mild to moderate depression in primary care.


**Acupuncture is a more effective and less costly treatment for patients with chronic low back pain**

针灸治疗慢性腰痛既有效又经济

Objective: To test whether patients with persistent non-specific low back pain, when offered access to traditional acupuncture care alongside conventional primary care, gained more long-term relief from pain than those offered conventional care only, for equal or less cost. Safety and acceptability of acupuncture care to patients, and the heterogeneity of outcomes were also tested.

Design: A pragmatic, two parallel group, randomised controlled trial. Patients in the experimental arm were offered the option of referral to the acupuncture service comprising six acupuncturists. The control group received usual care from their general practitioner (GP). Eligible patients were randomised in a ratio of 2:1 to the offer of acupuncture to allow between-acupuncturist effects to be tested.

Setting: Three non-NHS acupuncture clinics, with referrals from 39 GPs working in 16 practices in York, UK.
Participants: Patients aged 18-65 years with non-specific low back pain of 4-52 weeks’ duration, assessed as suitable for primary care management by their general practitioner.

Interventions: The trial protocol allowed up to ten individualised acupuncture treatments per patient. The acupuncturist determined the content and the number of treatments according to patient need.

Main outcome measures: The Short Form 36 (SF-36) Bodily Pain dimension (range 0-100 points), assessed at baseline, and 3, 12 and 24 months. The study was powered to detect a 10-point difference between groups at 12 months post-randomisation. Cost-utility analysis was conducted at 24 months using the EuroQoL 5 Dimensions (EQ-5D) and a preference-based single index measure derived from the SF-36 (SF-6D). Secondary outcomes included the McGill Present Pain Index (PPI), Oswestry Pain Disability Index (ODI), all other SF-36 dimensions, medication use, pain-free months in the past year, worry about back pain, satisfaction with care received, and safety and acceptability of acupuncture care.

Results: A total of 159 patients were in the ‘acupuncture offer’ arm and 80 in the ‘usual care’ arm. All 159 patients randomised to the offer of acupuncture care chose to receive acupuncture treatment, and received an average of eight acupuncture treatments within the trial. Analysis of covariance, adjusting for baseline score, found an intervention effect of 5.6 points on the SF-36 Pain dimension [95% confidence interval (CI) -1.3 to 12.5] in favour of the acupuncture group at 12 months, and 8 points (95% CI 0.7 to 15.3) at 24 months. No evidence of heterogeneity of effect was found for the different acupuncturists. Patients receiving acupuncture care did not report any serious or life-threatening events. No significant treatment effect was found for any of the SF-36 dimensions other than Pain, or for the PPI or the ODI. Patients receiving acupuncture care reported a significantly greater reduction in worry about their back pain at 12 and 24 months compared with the usual care group. At 24 months, the acupuncture care group was significantly more likely to report 12 months pain free and less likely to report the use of medication for pain relief. The acupuncture service was found to be cost-effective at 24 months; the estimated cost per quality-adjusted (QALY) was 4241 pounds sterling (95% CI 191 pounds sterling to 28,026 pounds sterling) using the SF-6D scoring algorithm based on responses to the SF-36, and 3598 pounds sterling (95% CI 189 pounds sterling to 22,035 pounds sterling) using the EQ-5D health status instrument. The NHS costs were greater in the acupuncture care group than in the usual care group. However, the additional resource use was less than the costs of the acupuncture treatment itself, suggesting that some usual care resource use was offset.

Conclusions: Traditional acupuncture care delivered in a primary care setting was safe and acceptable to patients with non-specific low back pain. Acupuncture care and usual care were both associated with clinically significant improvement at 12- and 24-month follow-up. Acupuncture care was significantly more effective in reducing bodily pain than usual care at 24-month follow-up. No benefits relating to function or disability were identified. GP referral to a service providing traditional acupuncture care offers a cost-effective intervention for reducing low back pain over a 2-year period. Further research is needed to examine many aspects of this treatment including its impact compared with other possible short-term packages of care (such as massage, chiropractic or physiotherapy), various aspects of cost-effectiveness, value to patients and implementation protocols.

Source:

**CAM reduces sick leave**

针灸等补充医学疗法减少慢性病患者因病缺勤时间

A study by researchers at the University of Duisburg-Essen in Germany found that complementary and alternative medicine (CAM) reduces the sick leave of chronically ill patients with non-life-threatening chronic diseases such as back pain, migraine, skin diseases, allergies that has not been improved with conventional therapies. Sick-leave per year of 441 chronically ill patients at work increased from 22 days to 31 days within three years prior to intervention, and decreased to 24 days in the second year of treatment, sustaining at this level in the following two years.

Patients involved in this study received the following CAM therapies: acupuncture, electric acupuncture, neuraltherapy, homoeopathy, colon therapy, manual therapy, reflexzone therapy, orthomolecular medicine, isotherapy, symbiosis regulation. Patients were treated on average with three different therapy modalities, with acupuncture, homoeopathy, oxygen therapy, and neuraltherapy as the most often used. As this is an uncontrolled observational study efficacy of any specific CAM treatment can not be proven. However, the results might indicate an general effectiveness of CAM in
primary care. Future studies should identify the most suitable patients for CAM practices, the most appropriate and safe treatments, which will help to properly position complementary and alternative medicine in the modern health care system.

Source:

US NCCAM funds TCM research Centers
美国政府资助建立中医药研究中心

The National Center for Complementary and Alternative Medicine (NCCAM) of the US has recently awarded grants to several research centers of Chinese medicine.

The Center for Arthritis and Traditional Chinese Medicine at the University of Maryland in Baltimore received funds to study traditional Chinese medicine approaches, including acupuncture and herbal remedies and their effects on arthritis. The center will conduct a clinical trial of HLXL, an 11-herb Chinese formula, on osteoarthritis of the knee; animal studies will test acupuncture’s ability to relieve inflammatory pain and the use of HLXL on autoimmune arthritis.

Center for Chinese Herbal Therapy at New York’s Mount Sinai School of Medicine will determine the mechanism of action, active components, and efficacy of a three-herb formula, ASHMI, in the treatment of allergic asthma. Additional studies will look at how the herbs might work and will identify the active components.

Functional Bowel Disorders in Chinese Medicine - Multiple centers will compose a group to study Functional Bowel Disorders in Chinese Medicine. The University of Maryland, Chinese University of Hong Kong, University of Illinois and the University of Western Sydney (Australia) will conduct multidisciplinary research on traditional Chinese medicine (TCM). The group will determine the effects of acupuncture and herbal preparations in irritable bowel system (IBS) sufferers. This collaboration will conduct research on TCM practices - acupuncture and herbs - for the treatment of irritable bowel syndrome (IBS). Researchers will study the effects of acupuncture and a TCM herbal preparation in an animal model of IBS. They will also conduct a preliminary study of the herbal preparation in people with IBS.

NCCAM also announced another international center, which is being funded by the National Cancer Institute: International Center of Traditional Chinese Medicine for Cancer. The University of Texas M.D. Anderson Cancer Center in Houston will team with Fudan University Cancer Hospital in Shanghai (China) to conduct preclinical and clinical studies of herbal formulations, acupuncture and Qi Gong. The research focus is studies of TCM approaches - herbs, acupuncture, and Qi Gong - for cancer, its symptoms, and treatment-related side effects.
Often referred to as hay fever, allergic rhinitis is a non-effective, inflammatory disease of the nasal airways and conjunctiva caused by acquired reactivity to an exogenous allergen, ranging from pollen and dust to animal dander, but most commonly grass pollen. The most common form of allergic rhinitis is seasonal allergic rhinitis, which typically occurs at the same time each year when certain plants are in bloom. Symptoms may vary ranging from running eyes and nose, sneezing and sore lips and nose, red eyes, glandular swelling and skin reaction to itching and general soft tissue swelling. Allergic rhinitis can be a recurrent depressing condition, interfering with many aspects of the patients’ lives; for example, students suffering from hay fever may attain lower academic performance during critical study years, with lifelong consequences.

The four basic steps in the management of hay fever are:
• Control or removal of allergens and irritants, wherever possible. Avoidance of irritants, such as cigarette smoke, helps to reduce symptoms;
• Prescription of antihistamines. As histamine is a crucial mediator of the allergic response, particularly the immediate response, antihistamines form the mainstay of treatment in hay fever;
• Application of corticosteroid sprays which do not treat acute symptoms, but are effective prophylaxis;
• Immunotherapy or desensitization which involves regular injections of the allergens responsible for the patient’s symptoms.

Acupuncture and herbal remedies have been used to combat symptoms similar to allergic rhinitis successfully for centuries.

TCM PATTERN DIFFERENTIATION AND TREATMENT OF ALLERGIC RHINITIS

1. Deficiency cold of lung Qi
Main symptoms of the pattern include extreme itching in the nasal cavity, continuous sneezing, running nose, nasal congestion and hyposmia. Patients with deficiency cold of lung Qi are often aversion to cold and are prone to catch colds. They are also likely to exhibit lassitude, weak voice, or spontaneous sweating, pale face, tongue light red with thin and whitish coating, and fine and weak pulse.

Treatment principle for this pattern of allergic rhinitis is to warm and supplement the lung, and to dispel wind and cold.
The formula for this pattern of allergic rhinitis is the modified Wen Fei Zhi Liu Dan (温肺止流丹加减). The composition of the modified formula is Ren Shen (Radix Ginseng) or Dang Shen (Radix Codonopsis) 9g, Huang Qi (Radix Astragali) 12g, Wu Wei Zi (Fructus Schizandrae) 9g, He Zi (Fructus Chebulae) 6g, Xi Xin (Herba Asari) 3g, Fang Feng (Radix Saposhnikoviae) 9g, Jie Geng (Radix Platycodi) 9g, Zhi Gan Cao (Radix Glycyrrhizae Preparata) 6g.

For those with excessive amount of watery nasal discharge, add Qian Shi (Semen Euryales) 10g and Wu Mei (Fructus Mume) 10g. For those with coughs and not so much phlegm, add Ban Xia (Rhizoma Pinelliae Preparata) 12g and Fu Ling (Poria) 15g.

2. Lung and spleen Qi deficiency
Main symptoms of the pattern include nasal congestion and distension, nasal discharge clear or sticky white, hyposmia, inferior nasal concha mucosa swelling, whitish or grayish, or exhibiting polypoid change. The symptoms are recurrent, and can be accompanied by heavy headedness, dizziness, short of breath, fatigued cumbersome limbs and poor appetite. Patients with this pattern exhibit pale tongue with white coating, dental impressions on the margins of the tongue, and soggy and weak pulse.

Treatment principle for this pattern of allergic rhinitis is to strengthen the spleen and replenish Qi, and to invigorate the lung and constrain lung Qi. The formula for this pattern of allergic rhinitis is the modified Bu Zhong Yi Qi Tang (补中益气汤加减) consisting of Huang Qi (Radix Astragali) 15g, Bai Zhu (Rhizoma Atractylodis Macrocephalae) 9g, Dang Shen (Radix Codonopsis) 9g, Gan Cao (Radix Glycyrrhizae) 9g, Chen Pi (Pericarpium Citri Reticulatae) 9g, Sheng Ma (Rhizoma Cimicifugae) 6g, Chai Hu (Radix Bupleuri) 6g, Dang Gui (Radix Angelicae Sinensis) 9g, He Zi (Fructus Chebulae) 6g, Wu Wei Zi (Fructus Schizandrae) 9g, Ze Xie (Rhizoma Alismatidis) 9g, Xin Yi (Flos Magnoliae) 9g, Bai Zhi (Radix Angelicae Dahuricae) 9g, Xi Xin (Herba Asari) 3g.

For those with excessive amount of nasal discharge, add Qian Shi (Semen Euryales) 15g. For those with coughs and much phlegm, add Bai Qian (Radix Peucedani), Ku Xing Ren (Semen Armeniacae Amarum) 9g. To stop sneeze, add Chan Tu (Periostracum Cicade) 6g and Di Long (Pheretima) 12g.

For children, it is more appropriate to prescribe Shen Ling Bai Zhu San for allergic rhinitis of lung and spleen Qi deficiency pattern.

3. Kidney deficiency due to enduring illness
This pattern often presents as perennial allergic rhinitis with main symptoms of nose itching, continuous sneeze and watery nasal discharge, nasal mucosa whitish and swelling.

Treatment principle for this pattern of allergic rhinitis is to warm the kidney and invigorate Yang, and to reinforce the kidney to promote Qi absorption. The herbal formula for this pattern is composed of Ren Shen (Radix Ginseng) or Dang Shen (Radix Codonopsis) 9g, Huang Qi (Radix Astragali) 12g, Wu Wei Zi (Fructus Schizandrae) 9g, Xi Xin (Herba Asari) 3g, Jing Jie (Herba Schizonepetae) 9g, Jie Geng (Radix Platycodi) 9g, Zhi Gan Cao (Radix Glycyrrhizae Preparata) 6g, He Tao Ren (Semen Juglandis) 12g, Fu Peng Zi (Fructus Rubi) 9g, Jin Yin Zi (Fructus Rosae Laevigatae) 9g, Ge Jie (Gecko) 5g.

4. Heat stagnation in the lung
Patients with this pattern of allergic rhinitis, when having hot meals or encountering heat (hot air, steam, etc.), have nose distension and congestion, itching in the nose, frequent sneezing, clear nose discharge, swelling of inferior turbinate. Patients of this pattern do not have obvious systemic symptoms. Some have coughs, throat itching, dry mouth and aversion to heat. Pulses are stringlike or slippery and stringlike. Patients' tongues are red with white tongue coating.

Treatment principle for this pattern of allergic rhinitis is to diffuse inhibited lung Qi with herbs of mild actions. The formula for this pattern of allergic rhinitis is the modified Xin Yi Qing Fei Yin (辛夷清肺饮加减) consisting of Sheng Shi Gao (Gypsum Fibrosum) 20-30g, Zhi Mu (Rhizoma Anemarrheneae) 9g, Zhi Zi (Fructus Gardeniae) 9g, Huang Qin (Radix Scutellariae) 9g, Pi Pa Ye (Folium Eriobotryae) 9g, Sheng Ma (Rhizoma Cimicifugae) 6g, Bai He (Bulbus Lilli) 9g, Mai Dong (Radix Ophiopogonis) 9g, Gan Cao (Radix Glycyrrhizae) 6g, Bo He (Herba Menthae) 3g, Lian Qiao (Fructus Forsythiae) 9g.

Add Bai Zhi (Radix Angelicae Dahuricae) 9g and Man Jing Zi (Fructus Viticis) 9g for those with headache. For those with coughs and much phlegm, add Gua Lou (Fructus Trichosanthis) 15g, Qian Hu (Radix Peucedani) 9g and Ku Xing Ren (Semen Armeniacae Amarum) 9g.

CHINESE HERBAL PATENTS FOR ALLERGIC RHINITIS

Bi Min Gan Wan (鼻敏感丸)
Consisting of Xin Yi (Flos Magnoliae), Cang Er Zi (Fructus Xanthii), Jing Jie (Herba Schizonepetae), Zhi Mu (Rhizoma
Anemarrhenae), Ye Ju Hua (Flos Chrysanthemi Indici), Gan Cao (Radix Glycyrrhizae), Lian Qiao (Fructus Forsythiae), Bai Zhi (Radix Angelicae Dahuricae), Fang Feng (Radix Saposhnikoviae), Wu Wei Zi (Fructus Schisandrae Chinensis) and Jie Geng (Radix Platycodi). Bi Min Gan Wan is used to treat allergic rhinitis and hayfever with symptoms of itching in the nose, nasal distension and congestion, frequent sneezing, watery nasal discharge, accompanied by lassitude, spontaneous sweating, pale tongue with thin and white tongue coating and weak pulse.

**Bi Yan Pian (鼻炎片)**

The original composition of Bi Yan Pian as appeared in the Chinese Pharmacopoeia include Cang Er Zi (Fructus Xanthii), Xin Yi (Flos Magnoliae), Fang Feng (Radix Saposhnikoviae), Lian Qiao (Fructus Forsythiae), Ye Ju Hua (Flos Chrysanthemi Indici), Wu Wei Zi (Fructus Schisandrae Chinensis), Jie Geng (Radix Platycodi), Bai Zhi (Radix Angelicae Dahuricae), Zhi Mu (Rhizoma Anemarrhenae), Jing Jie (Herba Schizonepetae), Gan Cao (Radix Glycyrrhizae), Huang Bai (Cortex Phellodendri), Ma Huang (Herba Ephedra) and Xi Xin (Herba Asari). Due to safety concerns, Ma Huang and Xi Xin are not legally available in Europe. Therefore Bi Yan Pian on the European market is devoid of Ma Huang and Xi Xin, making it virtually the same in composition as Bi Min Gan Wan. Thus it has similar indications to those of Bi Min Gan Wan.

**Cang Er Zi Pian (苍耳子片)**

Cang Er Zi Pian is composed of Cang Er Zi (Fructus Xanthii), Bai Zhi (Radix Angelicae Dahuricae), Xin Yi (Flos Magnoliae), Bo He (Herba Menthae) and is used for allergic and perennial rhinitis, acute and chronic sinusitis with symptoms of nasal congestion, persistent nasal discharge, frontal headache, dizziness. Patients tongue coating is thin white, or yellow coating in the middle of the tongue, with floating pulse.

Research found that a modified Cang Er Zi Pian formula Shi-Bi-Lin is able to inhibit the cytokines of interleukin 4 (IL-4) and tumor necrosis factor alpha (TNFα). It also modestly affect IL-6 release from the human mast cell line (HMC-1), indicating that the modified formula could modulate the mast cell-mediated hypersensitivity reaction in allergy. Inhibition of mast cell-derived IL-4 and TNFα might explain the efficacy of this formula in treating allergic disease (Zhao et al., 2005).

**Yu Ping Feng Pian (玉屏风片)**

Yu Ping Feng Pian (also known as Gyokuheifu-san in Japan), made from the classical herbal formula Yu Ping Feng San, or Jade Screen Powder, consists of Huang Qi (Radix Astragali), Bai Zhu (Rhizoma Atractylodis Macrocephalae) and Fang Feng (Radix Saposhnikoviae). It strengthens the defensive Qi and surface resistance, and stops excessive sweating. Traditionally it is used for spontaneous sweating, aversion to wind, and pallor, and prone to catch cold due to insufficient surface resistance. More recently, the formula has come to be recommended as a preventive remedy for seasonal allergic rhinitis (hay fever) as well as a treatment for allergic reactions (both sinus congestion and skin rashes). It is also used to prevent illness, such as during the winter cold/flu season. It is especially useful for those who have weak body resistance and are easy to catch colds.

Research found that oral treatment with Yu Ping Feng Pian (Gyokuheifu-san) has preventive and curative effects in allergic rhinitis induced by Japanese cedar pollen in guinea pigs. Yu Ping Feng Pian significantly suppressed the frequency of sneezing induced by pollen and tended to reduce nose-scratching behavior in guinea pigs both during the sensitization period (prevention) and the pollen inhalation period (treatment) (Makino et al., 2004). Yu Ping Feng Pian also consolidates the resistance of nasal mucosa to prevent the invasion of exopathogen, and suppresses the pathogen-specific antibodies (Makino et al., 2005). Yu Ping Feng Pian may also inhibit the development and severity of asthma (Fang et al., 2005).

**References**


Effect of acupuncture in the treatment of seasonal allergic rhinitis: a randomized controlled clinical trial


The clinical efficacy and safety of acupuncture in the treatment of Seasonal Allergic Rhinitis (SAR) was evaluated by employing a two-phase crossover single-blind clinical trial. Thirty subjects were randomly assigned to two groups with 17 and 13 subjects respectively and treated with real or sham acupuncture (three times per week) for four consecutive weeks and then a crossover for treatments for a further four weeks without a washout period. The administration of real acupuncture treatment was guided by a syndrome differentiation according to Chinese Medicine Theory. Subjects were assessed by various criteria before, during and after the treatments. Outcome measures included subjective symptom scores using a five-point scale (FPS), relief medication scores (RMS) and adverse effect records. Twenty-six (26) subjects completed the study. There was a significant improvement in FPS (nasal and non-nasal symptoms) between the two types of acupuncture treatments. No significant differences were shown in RMS between the real acupuncture treatment group and the sham acupuncture treatment group. No side effects were observed for both groups. The results indicate that acupuncture is an effective and safe alternative treatment for the management of SAR.

Acupuncture and Chinese herbal medicine in the treatment of patients with seasonal allergic rhinitis: a randomized-controlled clinical trial


Background: Patients with allergic rhinitis (AR) increasingly use complementary medicine. The aim of this study was to determine whether traditional Chinese therapy is efficacious in patients suffering from seasonal AR.

Methods: Fifty-two patients between the ages of 20 and 58 who had typical symptoms of seasonal AR were assigned randomly and in a blinded fashion to (i) an active treatment group which received a semi-standardized treatment of acupuncture and Chinese herbal medicine, and (ii) a control group which received acupuncture applied to non-acupuncture points in addition to a non-specific Chinese herbal formula. All patients received acupuncture treatment once per week and the respective Chinese herbal formula as a decoction three times daily for a total of 6 weeks. Assessments were performed before, during, and 1 week after treatment. The change in severity of hay fever symptoms was the primary outcome measured on a visual analogue scale (VAS).

Results: Compared with patients in the control group, patients in the active treatment group showed a significant after-treatment improvement on the VAS (p=0.006) and Rhinitis Quality of Life Questionnaire (p=0.015). Improvement on the Global Assessment of Change Scale was noted in 85% of active treatment group participants vs 40% in the control group (p=0.048). No differences between the two groups could be detected with the Allergic Rhinitis Symptom Questionnaire. Both treatments were well-tolerated.

Conclusions: The results of this study suggest that traditional Chinese therapy may be an efficacious and safe treatment option for patients with seasonal AR.

A double-blind, randomized, placebo-controlled trial of acupuncture for the treatment of childhood persistent allergic rhinitis


Objective: To compare active acupuncture with sham acupuncture for the treatment of persistent allergic rhinitis among children.

Methods: Subjects with persistent allergic rhinitis were recruited from the pediatric outpatient clinic. They were randomized to receive either active acupuncture or sham acupuncture. Main outcome measures included daily rhinitis scores, symptom-free days, visual analog scale scores for immediate effects of acupuncture, daily relief medication scores, blood eosinophil counts, serum IgE levels, nasal eo-
sinophil counts, patients’ and parents’ preferences for treatment modalities, and adverse effects.

Results: Eighty-five patients were recruited from the pediatric outpatient clinic at Kwong Wah Hospital, in Hong Kong. Thirteen patients withdrew before randomization; 35 patients (mean age: 11.7 +/- 3.2 years) were randomized to receive active acupuncture for 8 weeks, and 37 patients (mean age: 11 +/- 3.8 years) were randomized to receive sham acupuncture for 8 weeks. Acupuncture was performed twice per week for both groups. Both the assessing pediatricians and the patients were blinded. There were significantly lower daily rhinitis scores and more symptom-free days for the group receiving active acupuncture, during both the treatment and follow-up periods. The visual analog scale scores for immediate improvement after acupuncture were also significantly better for the active acupuncture group. There was no significant difference in the following outcome measures between the active and sham acupuncture groups: daily relief medication scores, blood eosinophil counts, serum IgE levels, and nasal eosinophil counts, except for the IgE levels before and 2 months after acupuncture in the sham acupuncture group. No severe adverse effects were encountered. Numbness, headache, and dizziness were found in both the active and sham acupuncture groups, with no difference in incidence, and the effects were self-limiting.

Conclusions: This study showed that active acupuncture was more effective than sham acupuncture in decreasing the symptom scores for persistent allergic rhinitis and increasing the symptom-free days. No serious adverse effect was identified. A large-scale study is required to confirm the safety of acupuncture for children.

Treatment for seasonal allergic rhinitis by Chinese herbal medicine: a randomized placebo controlled trial
中药治疗花粉过敏症的随机安慰剂对照临床试验


Context: Chinese herbal medicine (CHM) is widely used to treat seasonal allergic rhinitis (SAR), however, evidence of efficacy is lacking. OBJECTIVE: To evaluate the efficacy of a Chinese herbal formulation for the treatment of SAR.

Design: Randomized, double blind, placebo controlled trial.
levels of specific immunoglobin E (IgE) were used to compare the effect of treatment. For one allergen, mugwort, a greater reduction in levels of specific IgE ($p=0.019, 0.039$) and skin test reaction ($p=0.004$) was seen in the group receiving active acupuncture compared to the group receiving sham acupuncture. However, this finding might be an artifact. No differences in clinical symptoms were seen between active versus sham acupuncture, thus the conclusion being that the effect of acupuncture on allergic rhinitis should be further evaluated in larger randomized studies.

**Effect of acupuncture on allergic rhinitis: clinical and laboratory evaluations**


Of 22 subjects with allergic rhinitis who received a series of 6 acupuncture treatments, 11 (50%) were virtually symptom-free by the end of the series, 8 (36%) experienced a moderate reduction in symptoms, and 3 (14%) received no significant relief. Clinical assessment of symptoms was made on a 6-point scale before the first treatment and before each subsequent session. Laboratory tests included absolute blood eosinophils, percentage of nasal eosinophils, and radioimmunoassay of serum IgE, performed before the first treatment, at the end of the series, and 2 months later. A significant decrease in subjective clinical rating of symptoms correlated with a concurrent drop in absolute numbers of blood eosinophils and percentage of nasal eosinophils. IgE levels decreased in 64% of the subjects by completion of treatment and in 76% at 2-month follow-up.

**Protective effect of acupuncture on allergen provoked rhinitis**


A study of the protective effect of an acupuncture therapy against a nasal allergen-provoked rhinitis was undertaken on patients suffering from seasonal allergic rhinitis. The effects of a specific acupuncture therapy (‘verum’) were compared with those of a non-specific acupuncture therapy (‘placebo’). The allergen-provocation was carried out in the “Vienna Provocation Chamber” (VCC) (Horak, 1987). 24 patients suffering from seasonal allergic rhinitis were allocated at random either to Group B and given a specific (“verum”) acupuncture therapy or to Group A and given a non-specific (“placebo”) acupuncture therapy. A nasal allergen-provocation was carried out before onset and after completion of 9 treatments. The objective and subjective results of the allergen-provocation in the VCC were not able to verify a protective effect of the acupuncture therapy. The “Diary of Complaints (Symptoms)” which the participants had to keep over the 2 months following the treatment showed a definite reduction of the subjective complaints in the verum group during the second month. The range of scatter was too great for a statistically significant result.

**Efficacy, chemistry and pharmacology of Chinese herbal medicine for allergic rhinitis**


An extensive literature search identified six randomized controlled clinical trials in which the efficacy of Chinese herbal medicine had been investigated for the treatment of allergic rhinitis. Although four of these trials had methodological flaws, the therapeutic outcomes of all six have been reviewed. One of two trials considered to be of high quality was concerned with the treatment of seasonal allergic rhinitis and the other with perennial allergic rhinitis. It is considered that all six studies demonstrated various degrees of alleviation of the symptoms of allergic rhinitis. No serious side effects were reported in any of the trials. A number of the herbs in the Chinese herbal formulae used in the trials, and/or their constituent compounds have been reported to possess anti-allergic, anti-inflammatory or immune modulation activity. Such actions include inhibition of the release or action of mast cell mediators such as histamine, inhibition of inflammation induced by chemical agents, and modulation of serum IgE levels or of lymphocyte and/or macrophage activity. An aqueous, unresolved extract of the herbal formula used in one of the six trials has been reported to exhibit a range of pharmacological actions relevant to the treatment of allergic rhinitis. Essential oils, lignans, flavonoids and sapo-nins are chemical classes that are frequently represented in individual herbs of the six Chinese herbal formulae used in the trials. The chemical structures characterising these classes of compound and the pharmacological actions of these and other constituents of the herbs, relevant to allergic rhinitis, have been reviewed.
INTRODUCTION

In the past menstrual pain in women was often thought to be psychosomatic. We now understand that menstrual pain is real. It has been recognised that gynaecological diseases/disorders such as endometriosis, dysmenorrhea, menorrhagia, and pelvic inflammatory diseases are not minor problems for women affected. They often affect women's quality of life and even reduce their productivity in general. Sufferers deserve appropriate medical consideration.

In conventional western medicine, gynaecological disorders/conditions are often treated with surgery, hormones, non-steroidal anti-inflammatory drugs (NSAID), antibiotics and so on. Though the efficacy of these treatments is rapid and widely accepted, there are many potential side effects such as nausea and vomiting related to surgery/anaesthetics; sexual problems after hysterectomy; skin rash or digestive problems related to drugs, or more seriously liver, kidney, and heart impairment related to some drugs, especially when taken for an extended period. Furthermore, some women may not respond to these treatments. The goal of any treatment is to relieve symptoms as well as to improve and restore the patient’s general health, and to improve their quality of life. This may be achieved by integration of complementary or alternative therapy such as TCM into conventional medicine.

Treatment of gynaecological disorders with traditional Chinese medicine - scientific research and clinical studies

In China, there is a long history of treating gynaecological disorders/conditions with TCM. In modern times, the integrated medical care of combining conventional western medicine with TCM has been safely provided by doctors as part of their routine medical practice in China and other Asian countries and part of the western world. Thousands of case reports showing the efficacy of TCM in the treatment of dysmenorrhea and other symptoms/conditions associated with menstruation, polycystic ovarian syndromes, endometriosis, vaginal discharge, and many more. Recent scientific research studies have demonstrated that TCM including acupuncture and herbal medicine is effective in relieving some of the symptoms related to gynaecological disorders/conditions and may provide a safe and effective complementary or alternative to conventional medicine.

Dysmenorrhea is painful menstruation of uterine origin. It is usually divided into two types: primary dysmenorrhea (with no detectable pathology and more common in adolescent women) and secondary dysmenorrhea (frequently associated with a pelvic pathology, such as endometriosis). It is a very common gynaecological complaint with a significantly negative effect on a woman’s quality of life. Acupuncture and Chinese herbal medicine has been successfully used to treat painful menstruation. Tsenov (1996) treated 48 dysmenorrhea patients with acupuncture, 24 patients with primary dysmenorrhea responded very well after one course of 2-4 sessions; 24 women with secondary dysmenorrhea responded well after two courses of treatment. In a recent clinical trial, Habek, et al. (2003) reported that within 1
year of acupuncture treatment the menstural pain disappeared in 93.3% of patients with primary dysmenorrhea and only 3.7% in the placebo group. It is known that dysmenorrhea is directly related to elevated levels of PGF2α, a potent myometrial stimulant and vasoconstrictor. Chinese herbal medicine was reported to significantly inhibit the production of prostaglandins by human myometrial cells in vitro (Shibata, et al., 1996). Furthermore, a Chinese herbal formula (Wen-Jing Tang) was found to directly suppress spontaneous contractions and prostaglandins F2α-induced contractions of rat uterine smooth muscle in vitro, which may be the main mechanisms by which it controls menstrual pain (Hsu et al., 2003). In a double-blind study, patients were treated with either herbal medicine (Tokishakuyaku-san, or Dongui Shaoyao San) or placebo during 2 menstrual cycles and were followed for 2 additional cycles. A significant alleviation of menstrual pain was observed in the herbal medicine group but not in the placebo group (Kotani et al., 1997).

Endometriosis is a disease in which the lining of the uterus (endometrium) is found outside of the uterus (ovaries, fallopian tubes, bladder, and bowel, etc). The common symptoms of endometriosis are cramping menstrual pain that may worsen with time, extremely heavy menstrual flow, diarrhea or painful bowel movements, especially prior to and during periods, and painful sexual intercourse. It is the main cause of secondary dysmenorrhea and can cause infertility. Symptoms related to endometriosis may not come all at once, but can seriously affect a woman’s life. As with dysmenorrhea, TCM has been shown to relieve symptoms related to endometriosis (Tsenov 1996; Kotani et al., 1997; Hsu et al., 2003). In a retrospective case study, interviews were held with 47 young patients who had received acupuncture for migraine headache, endometriosis, etc. Patients had a median of 8 treatments within 3 months. Acupuncture therapies included needle insertion (98%), heat/moxa (85%), magnets (26%), and cupping (26%). Most patients and parents rated the therapy as pleasant (67% children/60% parents), and most (70% children/59% parents) felt the treatment had helped their symptoms; only 1 said that treatment made symptoms worse (Kemper et al., 2000).

Pre-menstrual syndrome (PMS) or pre-menstrual tension (PMT) is a pattern of symptoms that some women experience in the days or weeks before their menstrual periods. For many women these symptoms are most noticeable a few days before their period starts and usually disappear when the menstrual period begins. The symptoms of PMS or PMT vary, but commonly include headache, breast tender-ness, acne, fatigue, disturbed sleep, bloating, constipation or diarrhea, appetite changes, anxiety or depression, irritability, and mood swings. Some women experience more severe symptoms which seriously affect their daily activities. Clinical studies have demonstrated that acupuncture and herbal medicine are effective in treating some of the symptoms associated with PMS or PMT (Chou 2005; Hu 1998; Xu 2005; Roemheld-Hamm 2005). Habek, et al. (2002) reported the successful use of acupuncture. PMS symptoms, such as anxiety, mastalgia, insomnia, nausea and gastrointestinal disorders, headaches and migraines, stopped after 2 to 4 sessions. After systemic study of related publication, it was concluded in Hardy’s review that, based on the available evidence, evening primrose oil and chastetree berry may be reasonable treatment alternatives for some patients with PMS. Dong Gui (Angelica sinensis) may have some efficacy for PMS when used in traditional Chinese multiple-herb formulas (Hardy 2000).

Polycystic ovary syndrome (PCOS) is a chronic medical condition where multiple cysts appear in the ovaries. Hormone imbalance can arise causing problems with ovulation and fertility. Symptoms of PCOS include irregular or no periods, acne, obesity and excess hair growth. TCM has been shown in many clinical studies to restore regular menstruation, relieve symptoms, and induce ovulation in PCOS patients (Yu 2004; Stener-Victorin et al., 2000; Hou et al., 2000). To evaluate whether electro-acupuncture (EA) could affect oligo-/anovulation and related endocrine and neuroendocrine parameters in women with PCOS, twenty-four women with PCOS and oligo-/amenorrhea were included in a non-randomized, longitudinal, prospective study. The study period was defined as the period extending from 3 months before the first EA treatment to 3 months after the last EA treatment (10-14 treatments altogether), a total of 8-9 months. Nine women (38%) experienced a good effect, showed increased rates of regular ovulations. These women also demonstrated significantly lower levels of body-mass index (BMI), serum testosterone concentration, serum testosterone/sex hormone binding globulin (SHBG) ratio and serum basal insulin concentration and significantly higher levels of serum SHBG than those who did not respond to EA. It was concluded that repeated EA treatments induced regular ovulations in PCOS with oligo-/amenorrhea (Stener-Victorin, et al. 2000). Hou, et al. (2000) compared the effects of a common Chinese herbal formula (Tiangui Fang) with metformin in PCOS patients. They found that both metformin and the Chinese herbal formula reduced the high serum levels of insulin in patients and induced regular ovulation.
Furthermore, the herbal formula showed a better efficacy than metformin.

In a recent review, Rangel, et al. (2005) examined the results of the clinical application of systemic medicine (based on herbs and other natural remedies) in chronic degenerative diseases through retrospective studies carried out at the Adaptogenic Medical Centres and other hospitals located in Venezuela and Puerto Rico. The results were extremely encouraging. Thirty-five patients with PCOS were included in a retrospective, multicentre, descriptive 2 year long study. The systemic medicine improved pelvic pain in all 20 symptomatic patients, menstrual disorders (amenorrhea, oligomenorrhea, dysmenorrhea, menorrhagia, menometrorrhagia,) in all 22 symptomatic patients, weakness and headache in all 17 symptomatic patients, and acne and hirsutism in 8 out of 9 (89%) symptomatic patients. Pelvic ultrasound scans revealed that 29 patients (82.8%) experienced a total disappearance of ovarian cysts, whereas 6 patients (17.2%) showed decrease in cyst size. Quality of Life (QoL) improved in all patients. Tolerance to treatment was outstanding (100%).

Irregular menstruation Clinical studies have shown that one of the main indications for acupuncture and herbal treatment was dysfunctional uterine bleeding (Yu et al., 1989; Zhang 1994; Yu 2004). Four hundred and five patients with irregular menstruation were enrolled in a recent study, and treated with Chinese herbal formulae (Ma et al., 2003). Chinese herbal medicine (Keishi-bukuryo-gan/ Guizhi Fuling Wan and Shakuyaku-kanzo-to/Shaoyao Gancao Capsule) was further reported to treat abnormal uterine bleeding caused by intrauterine devices (IUD) with a 90.3% effectiveness rate, significantly higher than the rate (43.5%) in a control group (Ren et al., 2004).

Uterine fibroids (also called leiomyomas, fibromyomas, or myomas) are benign (non-cancerous) growths of the uterus. Three out of four women have uterine fibroids, but most women are unaware of their existence as most fibroids are asymptomatic. However, some women with fibroids experience abnormal uterine bleeding, pressure on adjacent organs (such as bladder), pain, infertility, or a palpable abdominal pelvic mass and they may require treatment. Fibroid-associated symptoms have been found to be relieved by acupuncture (Yan, et al 1994). To investigate the direct effect of herbal medicine on smooth muscle cells, a Chinese herb (Ban Zhi Lian or Scutellaria barbata, commonly used as an anti-inflammatory and anti-tumour agent) was studied in an in vitro experiment. It was found that the herbal medicine significantly reduced human myometrial and leiomyomal smooth muscle cell numbers in culture, arrested cell proliferation, and also induced cell apoptosis (Kim et al., 2005). Clinical trials showed relief of fibroid-related symptoms after TCM treatment as well as a reduction in size of fibroids. One hundred and twenty cases of uterine fibroids were treated with Chinese herbal medicine Kangfu Xiaozheng or Guizhi Fuling. Patients in both treatment groups showed a shrinking of fibroids (confirmed by ultrasound scan) and an improvement of symptoms such as irregular menstruation and pain in the waist and abdomen. The total effectiveness rate achieved was 95.83% and 82.00% respectively in the two treatment groups (Sang, 2004). In a pilot study 37 menstruating women with palpable uterine fibroids were recruited and matched with controls who were enrolled in conventional treatment. The treatment program consisted of weekly traditional Chinese medicine, body therapy (somatic therapy, bodywork), and guided imagery. Treatment lasted as long as 6 months. Fibroids shrank or stopped growing in 22 patients among the treatment group and 3 among the control group (p<0.01). Symptoms of fibroids responded equally well to the therapies. All measures of patient satisfaction were significantly higher among the treatment group compared to those receiving conventional care (Mehl-Madrona 2002). The effects of a long-term intranasal administration of each of the gonadotropin-releasing hormone analogs (buserelin and nafarelin) on uterine fibroids after conservative treatment using Chinese herbal medicines (Keishi-bukuryo-gan/ Guizhi Fuling Wan and Shakuyaku-kanzo-to/Shaoyao Gancao Tang) were investigated in 30 perimenopausal women with fibroids. Hypermenorrhea and/or dysmenorrhea as a chief complaint was moderately improved by the treatment using Chinese herbal medicines in more than 60% of the patients with less than fist-sized fibroids, but not those with larger fibroids. Continuous treatment using analogs produced a long-term reduction in fibroids. The results indicate that long-term treatment using Chinese herbal medicines and gonadotropin-releasing hormone analogs for the management of uterine fibroids could be beneficial for patients a few years before menopause (Sakamoto et al., 1998). At the May 2005 American College for Advancement in Medicine Conference, Dr Warshowsky reviewed an integrative approach to the assessment and treatment of fibroid tumours and stated that patients who received an integrative approach had a mean decrease in fibroid tumour size of 0.8 cm while those in the control group had an increase in size of 1.9 cm, indicating the
importance of integrated medical care in the management of uterine fibroids (Feig et al., 2005).

The efficacy and safety of Chinese medicine in treating vaginal discharge, pelvic inflammatory disease (PID), psychosexual problems and sexual dysfunction has been demonstrated in many clinical studies (Yu et al., 1996; Mbizvo et al., 2004; Jin 2004; Zhang et al., 2004; Xin et al., 2005; Jin 2004; Honjo et al., 2004; Aung et al., 2004).

CONCLUSIONS

TCM has a long history in the management of gynaecological patients. Although its primary basis rests on empirical evidence as well as case reports, recent clinical studies support its therapeutic modalities in gynaecology. TCM aims at relieving symptoms, restoring health (mental, spiritual, emotional, and physical), and ultimately, improving women’s quality of life.

References
INTRODUCTION

Cancer (malignant tumour, neoplasm) is a group of diseases characterized by uncontrolled growth and spread of abnormal cells. Cancer can arise in many sites of the body and is named accordingly after its organ of origin. Breast cancer is mainly diagnosed in women and it is by far the most common female cancer, accounting for around 17% of female deaths from cancer in the UK. Gynaecological cancers, including cancers of the cervix, endometrium, ovary, vagina, vulva and, rarely, the fallopian tube, are the fourth most common form of cancer among women.

Many patients with cancer experience pain, anxiety, and mood disturbances. Despite developments in surgery, chemotherapy, radiation therapy and hormonal therapy and novel immunological and biologically targeted therapies, there are limitations to their benefits in cancer treatment, especially where the disease is advanced. The three conventional treatment modalities (surgery, chemotherapy and radiation therapy) often produce side effects, and the severe side effects caused by chemotherapy often lead to dose reductions or even early discontinuation of the treatment. Furthermore, the side effects often harm a woman’s sense of self-esteem, sexuality, and ultimately affect a woman’s quality of life. Relief of cancer-related symptoms is essential in the supportive and palliative care of cancer patients. Complementary therapies such as acupuncture and herbal medicine can help when conventional treatment does not bring satisfactory relief or causes undesirable side effects. Many of these therapies are natural, holistic, less intensive and cost effective. They have become more popular over the last decade.

Treatment of breast and gynaecological cancer with traditional Chinese medicine scientific research and clinical studies

Traditional Chinese medicine (TCM) is an ancient form of medicine founded on thousands of years of experience. TCM therapies mainly include acupuncture / moxibustion and herbal medicine. The management of cancer with TCM began more than two thousand years ago. There have been thousands of case reports showing the benefits of TCM treatment in patients with cancer including gynaecological and breast cancer. Many modern clinical and experimental research studies have further demonstrated the beneficial effects of TCM treatment in cancer care.

ACUPUNCTURE

Acupuncture has been recommended by several medical professional bodies, including the American Cancer Society (ACS) for the treatment of cancer and cancer treatment-related symptoms. Pain, nausea, vomiting, breathlessness, vasomotor symptoms and limb edema have all been found to respond to acupuncture treatment. Acupuncture has also demonstrated immunomodulatory effects as well as alleviating patient’s stress through relief of symptoms.

Several randomized clinical trials have shown that acupuncture stimulation effectively relieves nausea and vomiting in cancer patients and can serve as an adjunct to stan-
standard anti-emetic medication (Dundee et al., 1987; Shen et al., 1997, 2000; McMillan et al. 1991; Pearl et al., 1999). These findings are consistent with a larger body of data supporting the efficacy of various methods of acupuncture stimulation in the control of postoperative (including scheduled gynaecological and breast surgery) nausea and vomiting (Vickers, 1996; Al-Sadi et al., 1997; Streiberger et al., 2004). Hamza et al. (1999) studied the effects of acupuncture stimulation on the postoperative opioid analgesic requirement and recovery. One hundred women undergoing major gynecological procedures with a standardized general anesthetic technique were enrolled in the study and randomly assigned to treatment or control groups. In the acupuncture treatment group, the duration of patient-controlled analgesia therapy as well as the incidence of nausea, dizziness, and itching were significantly reduced compared with the control group. They concluded that acupuncture treatment decreased postoperative opioid analgesic requirements and opioid-related side effects when utilized as an adjunct to patient-controlled analgesia after lower abdominal surgery. At the National Institutes of Health (NIH) Consensus Conference in 1998 it was concluded that clear evidence supports the efficacy of acupuncture in the control of post-operative and chemotherapy-related nausea and vomiting (NIH 1998). It is certainly reasonable to accept the use of acupuncture in conjunction with standard anti-emetics to control post-operative and chemotherapy-related nausea and vomiting.

Acupuncture has been shown to provide effective relief when conventional measures fail to control chronic pain resulting from underlying disease or from conventional treatments (surgery, chemotherapy or radiation therapy) (Singh, 1978; Mann et al., 1973; Filshie & Redman, 1985; Filshie, 1988; Alimi et al., 2000). A study by He et al. (1999) found a significant relief of post-operative pain and improvement of arm movement with acupuncture treatment in 80 mammary cancer patients after ablation and axillary lymphadenectomy. Acupuncture has also been shown to be effective for chemotherapy-induced leukenopenia, post-chemotherapy fatigue, radiation therapy-induced xerostomia, insomnia, and anxiety (Lu, 2005; Vickers, 2004). The effectiveness of acupuncture and moxibustion treatment for lymphedema following intrapelvic lymph node dissection for malignant gynecologic tumours was studied. Twenty four patients were recruited, 12 of them started acupuncture and moxibustion after the occurrence of lymphedema and the other 12 were treated as soon as possible after surgery. A successful treatment or prevention of postoperative lymphedema in the lower extremities was reported in both groups (Kanakura et al., 2002).

The immunomodulatory effect of acupuncture has also been studied (Wu et al., 1994, 1995; Liu et al., 1995; Joos, 2000). The joint study conducted by researchers and medical doctors in China showed that acupuncture can strengthen and regulate the immunity of cancer patients, and significantly lessen the side-effects of chemotherapy and radiation therapy. Moxibustion on acupuncture points can significantly increase the white blood counts of the patients with late stage cancer. Lymphocyte subgroups CD3+ and CD4+ increased significantly in patients after acupuncture treatment, accompanied by decreased level of interleukin-6 and interleukin-10 and increased level of interleukin-8 and Interleukin-2. Natural killer cells were also found increased in cancer patients after acupuncture treatment. The lymphocyte proliferation rate increased after acupuncture treatment. These findings together indicate that acupuncture has immunomodulatory effects, which suggest it can be useful in the treatment of patients with compromised immunity.

CHINESE HERBAL MEDICINE

Since the early 19th century, attempts have been made to understand the property, efficacy and safety of Chinese herbal medicine through scientific research. It was also during this time that most of the drugs used in modern medicine were developed. It is therefore not surprising that most of the scientific research into herbal medicine has attempted to isolate the active ingredients of the herbs and to understand the functions of these ingredients. Chinese herbal medicine has been shown in several clinical studies to relieve symptoms related to cancer or induced by anti-cancer treatments (including chronic pain, nausea, vomiting, fatigue, etc.) and to improve the quality of life of cancer patients (Lin et al., 1996; Liu, et al., 2003; Zhang, et al., 1996). The efficacy, safety and side-effects of mistletoe extract (sME), a commonly used Chinese herbal medicine component, was studied in a multicentric, randomized, prospective clinical trial in China (Piao, et al., 2004). Two hundred and thirty three patients with breast cancer (n=68), ovarian cancer (n=71) and non-small cell lung cancer (NSCLC, n=94) were enrolled into the study. All patients were treated with standard destructive surgery and complementary sME or placebo in conjunction with chemotherapy according to treatment protocol. Two hundred and twenty-four patients fulfilled the requirements for final analysis. The occurrence of adverse events (due to chemotherapy) was less frequent in the sME group than in the placebo group. The side-effects possibly caused by sME were local inflammatory reactions at subcutaneous injection site and fever, which were self-limiting and did not require medical intervention. Quality of life was significantly improved in

sME treated patients as determined by the questionnaires FLIC (Functional Living Index-Cancer), TCMI (Traditional Chinese Medicine Index) and KPI (Karnofsky Performance Index) compared with the placebo group. In a recent paper, Lee TK et al (2005) stated that the water-soluble extract of whole ginseng (a herbal component widely used in traditional Chinese medicine) appears to give a better protection against radiation-induced DNA damage than the isolated ginsenoside fractions. Since free radicals play an important role in radiation-induced damage, the underlying radioprotective mechanism of ginseng could be linked, either directly or indirectly, to its capability of scavenging free radicals. In addition, ginseng's radioprotective potential may be due to its immunomodulatory abilities. Ginseng appears to be a promising radioprotector for cancer patients undergoing therapeutic or preventive radiation therapy to attenuate the deleterious effects of the radiation on normal tissues.

The direct inhibitory effects of some herbal medicine on cancer cell growth have been published recently in prestigious medical research journals. Extracts of Angelica sinensis (a traditional Chinese medicine which has been widely prescribed for the treatment of gynecological diseases) showed direct anti-proliferative effect on A549, HT29, DBTRG-05MG and J5 human cancer cells in vitro. The induction of G1/S arrest and activation of apoptosis in these cancer cells were also reported (Cheng et al., 2004). A special herbal complex (Hoelen, Angelicae radix, Scutellariae radix and Glycyrrhizae radix) was found to induce apoptosis in endocrine-resistant AN3CA cells and adriamycin-resistant MCF7/ADR carcinoma cells. Suppressed telomerase activity was found to contribute to the cellular apoptosis. The results suggested that this herbal complex may be a promising candidate for the treatment of endocrine-resistant gynecologic carcinomas (Lian et al., 2003). Tanshinone IIA (a derivative of phenanthrene-quinone isolated from Danshen, a widely used Chinese herbal medicine) has been reported to have antioxidant properties, and cytotoxic activity against multiple human cancer cell lines. The inhibitory effect on human breast cancer cell proliferation was shown in vitro. Tumour mass volume reduction was observed in mice treated with Tanshinone. The inhibitory effect was possibly due to upregulation and downregulation of multiple genes involved in cell cycle regulation, cell proliferation, apoptosis, signal transduction, transcriptional regulation, angiogenesis, invasive potential and metastatic potential of cancer cells (Wang et al., 2005). Several other active components of Chinese herbal medicine such as Indirubin, Ganoderma lucidum (Reishi, Lingzhi), Chlorophyllin (CHL), Herba Scutellaria Barbatae (Ban Zhi Lian) were also reported to have anti-tumour activity both in vitro and in vivo in a variety of cancers, including breast cancer and ovarian cancer (Nam et al., 2005; Jiang et al., 2004; Chiu et al., 2003; Powell et al., 2003; Campbell et al., 2002).

CONCLUSIONS

TCM has a long history in the management of cancer (including breast and gynaecological cancer) patients. Although its primary basis rests on empirical evidence as well as case studies, more modern experimental and clinical researches support the therapeutic modalities in cancer. TCM aims at: relieving symptoms (chronic pain, constipation, bloating, depression and anxiety, etc.), minimizing side effects caused by surgery, chemotherapy and radiation therapy (nausea, vomiting, fatigue, diarrhoea and lymphedema, etc.), improving the immune system, improving sexual function, restoring health, and most importantly, improving patients’ quality of life.

References

Liu F, et al. Clinical observation on treatment of multiple bone metastatic...


Dang Gui Ku Shen Pian
当归苦参片

**Ingredients:** Dang Gui (Radix Angelicae Sinensis), Ku Shen (Radix Sophorae Flavescentis)

**Actions:** Removing heat from the blood and dispelling dampness.

**Indications:** Conditions caused by blood dryness and damp-heat such as sore of the head and face, acne, urticant rashes with exudation, and brandy nose.

**Applications:** Comedo.

Du Zhong Pian
杜仲片

**Ingredients:** Du Zhog Ye (Folium Eucommiae), Du Zhong (Cortex Eucommiae)

**Actions:** Nourishing the liver and the kidney, quieting the foetus.

**Indications:** Low back pain, flaccidity of extremities, hematuria during pregnancy, and stirring foetus due to kidney deficiency; high blood pressure.

Feng Shi Ding Pian
风湿定片

**Ingredients:** Ba Jiao Feng (Folium Alangii), Xu Chag Qing (Radix Angelicae Dahuricae), Bai Zhi (Radix Angelicae Dahuricae), Gan Cao (Radix Glycyrrhizae)

**Actions:** Promoting blood circulation to remove obstruction in the channels.

**Indications:** Rheumatic and rheumatoid arthritis, cervical rib neuralgia and sciatica.

Lei Shi Jian Fei Pian
雷氏减肥片

**Ingredients:** Jue Ming Zi (Semen Cassiae), Wu Long Cha (Folium Camelliae Fermentata), He Ye (Folium Nelumbinis), Jiao Gu Lan (Herba Gynostemmatidis), He Shou Wu (Radix Polygoni Multiflori Preparata), Mei Gui Hua (Flos Rosae Rugosae), Mo Li Hua (Flos Jasminii), Dai Dai Hua (Flos Aurantii)

**Actions:** Dissolving phlegm and dispelling dampness, reducing lipids and burning fat.

**Indications:** Overweight and obesity.

Lei Shi Wei Tai Pian
Gastro-Ease Form
雷氏渭泰片

**Ingredients:** Dang Shen (Radix Codonopsis), Bai Zhu (Rhizoma Atractylodis Macrocephalae), Chen Pi (Pericarpium Citri Reticulatae), Xiang Fu (Rhizoma Cyperi), Fu Ling (Poria), Cang Zhu (Rhizoma Atractylodis), Dou Kou (Fructus Amomi Rotundus), Mai Ya (Fructus Hordei Germinatus), Shen Qu (Massa Medicata Fermentata), Ban Xia (Rhizoma Pinelliae Preparata), Chuan Mu Xiang (Radix Vladimiriæ), Gan Cao (Radix Glycyrrhizae)

**Actions:** Rectifying Qi and fortifying the stomach, reducing inflammation and relieving pain.

**Indications:** Superficial gastritis and erosive gastritis.

Ming Mu Ye Guang Pian
Vision Form
明目夜光片

**Ingredients:** Fu Ling (Poria), Tian Dong (Radix Asperagi), Ren Shen (Radix Ginseng), Mai Dong (Radix Ophiopogonis), Sheng Di Huang (Radix Rehmanniae), Shu Di Huang (Radix Rehmanniae Preparata), Ju Hua (Flos Chrysanthemi), Fructus Lycii Chinensis (Gou Qí Zi), Niu Xi (Radix Achyranthis Bidentatae), Shan Yao (Rhizoma Dioscoreae), Hu Xing Ren (Semen Armeniacae Amarum), Yue Ji Zi (Semen Cuscutae), Zhi Shi (Fructus Aurantii Immaturus), Wu Wei Zi (Fructus Schisandrae Chinensis), Bai Ji Li (Fructus Tribuli), Gan Cao (Radix Glycyrrhizae), Fang Feng (Radix Saposhnikoviae), Chuang Xiong (Rhizoma Chuanxiong), Huang Lian (Rhizoma Coptidis), Qing Xiang Zi (Semen Celosiae)

**Actions:** Calming the liver to stop the wind, nourishing Yin and improving eyesight.

**Indications:** Visual disturbance and xerophthalmia during menopause, blurred vision in hypertensive patients of liver and kidney Yin deficiency type, senile cataract, night blindness.
**Qi Bao Mei Fa Pian**  
**Goodhair Form**  
七宝美发片

**Ingredients:** He Shou Wu (Radix Polygoni Multiflori Preparata), Gou Qi Zi (Fructus Lycii Chinensis), Fu Ling (Poria), Radix Achyranthis Bidentatae, Radix Angelicae Sinensis, Semen Cuscutae Preparata, Fructus Psoraleae Preparata  
**Actions:** Enriching the liver and the kidney, nourishing the essence and blood.  
**Indications:** Premature greying of the hair or hair loss, loose teeth, spontaneous and nocturnal emission, soreness and weakness of the lower back pain and knees.

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**Qian Lie Pian**  
**Prosta Form**  
前列片

**Ingredients:** Huang Qi (Radix Astragali), Bi Li (Receptaculum Fici Pumilae), Huang Bai (Cortex Phellodendri), Ze Lan (Herba Lycopi), Pu Gong Ying (Herba Taraxaci), Liang Tou Jian (Rhizoma Anemones Raddeanae), Che Qian Zi (Semen Plantaginis), Hu Po (Amber)  
**Actions:** Strengthening the body resistance and restoring normal functions, nourishing Yin and the kidney, and inducing diuresis.  
**Indications:** Frequent urination, urinary urgency, post-voiding dribble, and blood in the urine.  
**Applications:** Chronic prostatitis, hyperplasia of prostate, and urination difficulty due to long-term illness or weakness.

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**Xiang Lian Pian**  
**Vladimiria Coptis Form**  
香连片

**Ingredients:** Huang Lian (Rhizoma Coptidis), muxiang (Radix Vladimiriae)  
**Actions:** Clearing heat and drying dampness, promotion of the flow of Qi and relieving pain.  
**Indications:** Damp-heat dysentery, tenesmus, abdominal pain caused by diarrhoea.  
**Applications:** Acute and chronic gastroenteritis, bacillary dysentery, irritable bowel syndrome (IBS).

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**Yao Tang Pian**  
**Backease Form**  
腰通片

**Ingredients:** Nan Teng (Caulis Piperis Wallichii), Bu Gu Zhi (Fructus Psoraleae Preparata), Ji Xiang Cao (Herba Reineckiae), Xu Duan (Radix Dipsaci), Niu Xi (Radix Achyranthis Bidentatae Preparata), Shan Yao (Rhizoma Dioscoreae)  
**Actions:** Nourishing the kidney, promoting blood circulation and alleviating pain.  
**Indications:** Low back pain due to kidney deficiency, and lumbar muscle strain.

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**Xiong Gui Jiao Nang**  
**Centrangel Capsules**  
芎归胶囊

**Ingredients:** Chuan Xiong (Rhizoma Chuanxiong), Dang Gui (Radix Angelicae Sinensis), Hong Hua (Flos Carthami)  
**Actions:** Promoting blood circulation and dissolving stasis, protecting CNS from damage due to moderate anoxia.  
**Indications:** Headache, dizziness, forgetfulness and memory loss, nervous tinnitus, insomnia, depression, cerebral thrombosis, hemiparesis.  
**Applications:** Prevention and treatment of transient ischemic attack and stroke. Regular use can improve memory function and sleep.

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**Ban Xia Bai Zhu Pian**  
**Pinellia Plus Form**  
半夏白术片

**Ingredients:** Bai Zhu (Rhizoma Atractyloidis Macrocephalae), Fa Ban Xia (Rhizoma Pinelliae Preparata), Ju Hong (Exocarpium Citri Rubrum), Fu Ling (Poria), Da Zao (Fructus Jujubae), Gan Cao (Radix Glycyrrhizae), Sheng Jiang (Rhizoma Zingiberis Recens)  
**Actions:** Drying dampness and resolving phlegm, calming the liver and extinguishing wind.  
**Indications:** Accumulation of wind-phlegm manifested by dizziness, headache, oppression in the chest, nausea and vomiting.  
**Applications:** Aural vertigo or neural vertigo of wind-phlegm type.
Liuwei Dihuang Wan

S. Shi, China

Liuwei Dihuang Wan (Six-ingredient pill with rehmannia) is a classical Chinese herbal formula for “kidney-Yin deficiency syndrome” defined in Chinese medicine. Extensive pharmacological and clinical studies confirmed the traditional applications of this formula. Recent pharmacological clinical investigations focused on its antineoplastic activities, especially its inhibitory effects on esophageal epithelial hyperplasia and antagonistic action against the toxicity of cancer chemotherapeutic agents. Research also showed this formula increases the plasma estrodiol level and particularly leucocytic estrogen receptor level in menopausal women.

ORIGIN OF THE FORMULA

Liuwei Dihuang Wan was formulated by physician Qian Yi during China’s Song dynasty (960-1279 A.D.). The formula was initially introduced as a pediatric remedy as a formula for kidney-Yin deficiency in children characterized by an open anterior fontanel, lack of spirit and a shiny, pale complexion. According to Qian, the most important diagnostic procedure for children was observation, particularly assessing the vitality of the infant by appearance of the complexion and the eyes. Qian believed that in infants the internal organs are not fully developed, or fully developed but not yet strong. Thus, the infant is prone to suffer from deficiency or excess, cold or heat, or other disharmony. These disharmonies would manifest in the spirit and appearance of the child, particularly revealed by the face.

The use of Liuwei Dihuang Wan as a pediatric remedy may have been popular after the publication of Qian Yi’s medical theories and formulas, but treatment of infants is a relatively limited medical area and would not be sufficient to yield such broad appeal for the formula as is seen today. The transformation of the formula from a prescription for infants to one for the adult suffering from disorders of aging was the critical factor that made the formula one which is frequently used. By now, use of Liuwei Dihuang Wan for adults with severe Yin-deficiency syndrome had become the dominant application, overshadowing its pediatric applications.

COMPOSITION AND ANALYSIS OF THE FORMULA

Liuwei Dihuang Wan is composed of the following six herbs: Shu Di Huang (Radix Rehmanniae Preparata 24 g), Shan Yao (Rhizoma Dioscoreae 12 g), Shan Zhu Yu (Fructus Corni 12 g), Fu Ling (Poria 9 g), Mu Dan Pi (Cortex Moutan 9 g), Ze Xie (Rhizoma Alismatis 9 g).

<table>
<thead>
<tr>
<th>Table 1 The structure of Liuwei Dihuang Wan</th>
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<tr>
<td><strong>Tonifying herbs</strong></td>
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<tr>
<td>Shu Di Huang</td>
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<td>Shan Zhu Yu</td>
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<td>Shan Yao</td>
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This is an elegant combination of two groups of ingredients, each of which consists of three herbs (Table 1). The first group is comprised of tonifying herbs. The principal herb, Shu Di Huang (Radix Rehmanniae Preparata), strongly enriches kidney-Yin and essence. One of the associates, Shan Zhu Yu (Fructus Corni), nourishes the liver and restrains the leakage of essence. It performs the latter function by inhibiting the improper dispersion and drainage through the liver, thereby enabling the essence to build up in the kidneys. For this to occur, an herb with strong, essence-building functions of the principal herb must be used at the same time. The other associate, Shan Yao (Rhizoma Dioscoreae), stabilizes the essence by tonifying the spleen. To reinforce the essence and improve its function, it is necessary to ensure that the spleen (the source of postnatal essence) is functioning properly.

The second group of ingredients has a predominantly draining effect in the context of this formula. They are viewed as assistants. Ze Xie (Rhizoma Alismatis) clears and drains the overabundance of "kidney-fire". It is used here to prevent the rich, cloying properties of the principal herb from congesting the mechanisms of the kidneys, which will induce even more fire from deficiency. Mu Dan Pi (Cortex Moutan) clears and drains "liver-fire" and is used here to counterbalance the warm properties of Shan Zhu Yu. Fu Ling (Poria) is a bland herb that leaches out dampness from the spleen. It is paired with Shan Yao to strengthen the transportive functions of the spleen. This prevents the formula from clogging up the digestive process, and reinforces the spleen’s function of nourishing the body. This herb and Ze Xie work together to improve the metabolism of fluids and promote urination, thereby preventing a build-up of stagnant fluids.

INTERPRETATION OF THE FORMULA

The primary function of Liuwei Dihuang Wan is to nourish and enrich the liver and kidneys. Traditional indications of the formula include soreness and weakness in the lower back, light-headedness, vertigo, tinnitus, diminished hearing, night sweats, spontaneous and nocturnal emissions, a red tongue with little coating, and a rapid, thin pulse. The patient may also present with a variety of other symptoms due to flaring up of sthenic fire including hot palms and soles, a chronic dry and sore throat, toothache, or wasting and thirsting disorder (diabetes). This is the classic presentation of kidney- and liver-Yin deficiency.

The lower back is the abode of the kidneys, which are also associated with the bones and are responsible for generating marrow (which gives the bones their resiliency and strength). When the kidneys are weak, the marrow will become depleted and there will be a general weakness of the skeletal structure in the area of the body most closely associated with the kidneys, the lower back and legs. Kidney- and liver-Yin deficiency also means that the essence (kidneys) and blood (liver) are not flourishing and are therefore unable to nourish the upper parts of the body, primarily the sensory orifices. The eyes are nourished by the liver. Lack of nourishment manifests as light-headedness and vertigo. The ears are nourished by the kidneys. Lack of nourishment manifests as tinnitus and diminished hearing. When the Yin is deficient, it is unable to retain substances during the night, which is the time associated with Yin. This causes night sweats and nocturnal emissions. The deficient-Yin is also unable to preserve the essence, which is manifested in men as spontaneous emissions. Yin deficiency and internally generated heat is reflected in the red color of the tongue and the less-than-normal moisture (little or no coating), and also in the pulse, which holds little volume (thin) and is rapid.

Depending on the individual and the particular etiology of kidney- and liver-Yin deficiency, other problems may also occur. If the heat from deficiencies is more severe, the patient will present with hot palms and soles, a flushed face, or a dry and sore throat. If the heat transforms into fire and ascends to the teeth (which are connected with the kidneys), there will be toothache. And if kidney-Qi is also unstable, there will be wasting and thirsting disorder with copious urination.

This formula may also be used in treating such biomedically-defined disorders as neurasthenia, pulmonary tuberculosis, diabetes mellitus, hyperthyroidism, chronic nephritis, chronic glomerulonephritis, urinary tract infection, hypertension, arteriosclerosis, failure to thrive, bronchial asthma, functional uterine bleeding, scanty menstruation, anemia, rheumatism, optic neuritis, optic nerve atrophy, central retinitis, infantile dysplasia and intellectual hypoevolution (Bensky & Barolet, 1990; Zhang, 1990a; 1990b).

REFERENCES
INTRODUCTION

TCM Education in Europe, has progressed, in its various forms since the first European based training courses became available. Many of us here are actively involved in TCM education, and some of us since the first European TCM training courses.

If we look at our TCM students profile, many students are older, working, in many cases already established in their career. Some of them will have a medical or part medical background, and some of them have not. We the TCM educators must tailor our training programmes to these backgrounds, while remaining true to TCM subjects and public safety.

All of these concepts, and the flexibility necessary to achieve these results are supported by a revolutionary EU commission agreement on adult education which most of our education ministers signed in Bologna in 1999.

BOLOGNA AGREEMENT

What is the Bologna Agreement and how does it affect TCM education in Europe?

In June of 1999 EU Education Ministers from Austria, Belgium, Czech Republic, France, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Swiss Confederation and The United Kingdom, met in Bologna, Italy and agreed to establish a European Area for Higher Education, to be in place by 2010. This is called the Bologna Agreement. It will affect the way we teach our courses, measure the content, evaluate the results and achieve Credits, which are then transferable from one country to the other.

The texts for The Bologna Declaration have become the fundamental principles for development in education in many of our countries. Almost all of our countries have committed themselves and therefore us, who are the educators to the implementation of the Bologna principles, with a full implementation date of 2010.

One of the significant outcomes of the Bologna agreement was the method of credit used, called ECTS (European Credit Transfer System).

European Credit Transfer System: A Common Method of Quantifying & Grading.

ECTS has no control over course content. Acknowledges the current status of adult Education in different European Countries.

All course work quantified, in the mode of Life Long Learning. Lectures; Demonstrations: Clinics: Guided Study: Self Study; Library: Group Discussion: Course work: Practical; Academic Regardless of content.

HOW DO WE WORK IT OUT?

The Experienced Teacher will know how many hours of...
work and practice is necessary to achieve a specific course goal or outcome: Quantification based on experience of course leaders and evidenced by the outcome.

EVIDENCE OF OUTCOME
The only possible evidence is
1. Examination.
   Written or Practical against the clock.
2. Evaluation or Assessment
   Written or Practical against the clock.
3. Dissertation. Research of subject, Students own work showing research sources.

ECTS CREDITS: HOW MANY?
1 Credit = 25/30 working hours (all course work, not just contact hours)
60 Credits represent 1 years work;
3 YEAR CYCLES = 180 CREDITS= Higher Diploma or Basic Degree level.
Example ECO Acupuncture/TCM training guide = 180 credits.
Measurement: 1 Contact hour = 4 course hrs.

ECTS GRADES: A FAIR SYSTEM
The ECTS grading scale ranks the students on a statistical basis. Therefore, statistical data on student performance is a prerequisite for applying the ECTS grading system. Grades are assigned among students with a pass grade as follows:
A best 10%;
B next 25%;
C next 30%;
D next 25%;
E next 10%

MORE ON ECTS
Student workload in ECTS includes the time spent in attending lectures, seminars, independent study, preparation for, and taking of, examinations, etc..
Credits are allocated to all educational components of a study programme (such as modules, courses, placements, dissertation work, etc.) and reflect the quantity of work each component requires in relation to the total quantity of work necessary to complete a full year of study in the programme considered.
Modulating Angiogenesis: The Yin and the Yang in Ginseng
人参对血管新生的双向调节作用

Ginseng has been prized as a panacea in TCM for at least 2,000 years. Currently, it is used extensively throughout the world to improve overall energy and vitality, particularly during times of fatigue or stress. In addition to immunomodulation and neuroprotection, it has been used to treat male impotence and to normalize glucose levels after meals in diabetics. In combination with Ginkgo biloba, it also improves memory and symptoms of attention deficit-hyperactivity disorder (ADHD) in children. Intriguingly, existing literature reports both wound-healing and antitumor effects of ginseng extract through opposing activities on the vascular system. Led by Dr Tai-Ping Fan of University of Cambridge, an international team from UK, Hong Kong, the Netherlands and USA has managed to elucidate this perplexity. They merged a chemical fingerprinting approach with a deconstructional study of the effects of pure molecules from ginseng extract on angiogenesis (the formation of new blood vessels).

A mass spectrometric compositional analysis of American, Chinese and Korean, and Sanqi ginseng revealed distinct “sterol ginsenoside” fingerprints, especially in the ratio between a panaxatriol, Rg1, and a panaxadiol, Rb1, the two most prevalent constituents. Using a Matrigel implant model and reconstituting the extracts using distinct ratios of the 2 ginsenosides, they demonstrate that the dominance of Rg1 leads to angiogenesis, whereas Rb1 exerts an opposing effect. Rg1 also promoted functional neovascularization into a polymer scaffold in vivo and the proliferation of, chemoinvasion of, and tubulogenesis by endothelial cells in vitro, an effect mediated through the expression of nitric oxide synthase and the phosphatidylinositol-3 kinaseÆAkt pathway. In contrast, Rb1 inhibited the earliest step in angiogenesis, the chemoinvasion of endothelial cells.

This study was published in 2004 (Sengupta S. et al., Circulation 110:1219-1225). It explains, for the first time, the ambiguity about the effects of ginseng in vascular pathophysiology based on the existence of opposing active principles in the extract. The Cambridge team also unraveled a speciogeographic variation impinging on the compositional fingerprint that may modulate the final phenotype. This emphasizes the need for regulations standardizing herbal therapy, currently under the Dietary Supplement and Health Education Act.

Furthermore, it is proposed that panaxatriols such as Rg1 and Re could be a prototype for a novel group of nonpeptide molecules that can induce therapeutic angiogenesis, such as in chronic wounds. On the other hand, as potent inhibitors of angiogenesis, panaxadiols Rb1 and Rg3 are useful in combating malignancy and other angiogenic diseases such as diabetic retinopathy. [For further information, contact Dr TP Fan, tpf1000@cam.ac.uk].

Building Cambridge Centre of Chinese Medical Sciences
剑桥大学拟建立中医药研究中心

To celebrate the 800th Anniversary of Cambridge University in 2009, Cambridge University is planning to create a Cambridge Centre of Chinese Medical Sciences. Its aim is to provide a platform for multidisciplinary research into the cellular and molecular mechanisms of Traditional Chinese medicine (TCM). To start with, it will focus on the discovery of angiogenesis modulators from TCM. The Centre will foster strategic alliance among University Departments of Biochemistry, Biotechnology, Chemistry, Engineering, Genetics, Mathematics, Medicine, Pathology, Pharmacology and Plant Sciences. In addition, the centre plans to bring together the expertise from hospitals and research institutes (e.g. Needham Research Institute, Judge Business School) affiliated with Cambridge and other universities in UK. Significantly, its interactions with the Royal Botanical Gardens, the Chinese Academy of Sciences, the Chinese Academy of Medical Sciences, and the China Academy of Traditional Chinese Medicine will offer an unprecedented opportunity to use this unique evidence-based approach to enhance global acceptance of TCM, with a view to develop novel medicines for the prevention and treatment of chronic diseases. Currently, the centre is seeking financial support from public and private sectors for the first phase of this venture. Interested parties are welcome to contact Dr TP Fan, head of the Angiogenesis & TCM Laboratory, Department of Pharmacology, University of Cambridge, Cambridge CB2 1PD, UK. E-mail: tpf1000@cam.ac.uk.
**Scutellaria baicalensis decreases ritonavir-induced nausea**


**Background:** Protease inhibitors, particularly ritonavir, causes significant gastrointestinal disturbances such as nausea, even at low doses. This ritonavir-induced nausea could be related to its oxidative stress in the gut. Alleviation of drug-induced nausea is important in effectively increasing patients’ compliance and improving their quality of life. Conventional anti-emetic drugs can only partially abate the symptoms in these patients, and their cost has also been a concern. Rats respond to nausea-producing emetic stimuli by increasing consumption of non-nutritive substances like kaolin or clay, a phenomenon known as pica. In this study, we used this rat pica model to evaluate the effects of Scutellaria baicalensis, a commonly used oriental herbal medicine, on ritonavir-induced nausea.

**Results:** Rats treated with 20 mg/kg ritonavir significantly increased increases of kaolin consumption at 24 to 48 hr (p<0.01). Pretreatment with 0.3 and 3 mg/kg Scutellaria baicalensis extract significantly decreased ritonavir-induced kaolin intake in a dose-related manner (p<0.01). Compared to vehicle treatment, the extract completely prevented ritonavir-induced kaolin consumption at dose 3 mg/kg. The area under the curves (AUC) for kaolin intake from time 0 to 120 hr for vehicle only, ritonavir only, SBE 0.3 mg/kg plus ritonavir, and SBE 3 mg/kg plus ritonavir were 27.3 g*hr, 146.7 g*hr, 123.2 g*hr, and 32.7 g*hr, respectively. The reduction in area under the curves of kaolin intake from time 0 to 120 hr between ritonavir only and SBE 0.3 mg/kg plus ritonavir, ritonavir only and SBE 3 mg/kg plus ritonavir were 16.0% and 77.7%, respectively.

**Conclusion:** Scutellaria baicalensis significantly attenuated ritonavir-induced pica, and demonstrated a potential in treating ritonavir-induced nausea.

**Effects of Fructus Ligustri Lucidi extract on bone turnover and calcium balance in ovariectomized rats**


The aim of this study was to evaluate the effect of Fructus Ligustri Lucidi (FLL), a kidney-tonifying Chinese herbal medicine, on the biochemical markers of bone turnover, calcium metabolism and balance in osteoporotic rat model developed by ovariectomy. Four weeks after surgical operation, animals were randomly assigned to one of the four treatments for 14 weeks: sham-operated control treated with vehicle (sham, n=8), ovariectomized group treated with vehicle (OVX, n=8), OVX group treated with 17beta-estradiol (E2, n=10, 2 microg/kg/d) and OVX group treated with FLL extracts (FLL, n=10, 550 mg/kg/d). Serum osteocalcin and urinary deoxypyridinoline levels were upregulated in rats in response to OVX, suggesting that the bone turnover rate was accelerated in these animals. Treatment of OVX rats with FLL extract could prevent OVX-induced increase in bone turnover by suppression of both serum osteocalcin (p<0.05, vs. OVX) and urinary deoxypyridinoline (p<0.05, vs. OVX) levels. In addition, FLL extract could prevent OVX-induced loss of calcium in rats by increasing the intestinal calcium absorption rate (p<0.01, vs. OVX), suppressing urinary Ca excretion (p<0.05, vs. OVX) as well as increasing bone calcium content (p<0.05, vs. OVX). Our study is the first to report that FLL can modulate bone turnover and calcium balance in OVX rats and it might be a potential candidate for prevention and treatment of postmenopausal osteoporosis.

**Amelioration effects of traditional Chinese medicine on alcohol-induced fatty liver**


**Aim:** To examine the effects of traditional Chinese medicine (TCM) on alcohol-induced fatty liver in rats. TCM consists of Astragalus membranaceus, Morus alba, Crataegus pinnatifida, Alisma orientale, Salvia miltiorrhiza, and Pueraria lobata.

**Methods:** The rats were separated randomly into five groups. One (the CD group) was fed a control diet for 10 wk, another (the ED group) fed an ethanol-containing isocaloric liquid diet for 10 wk, and the last three (the TCM group) were
Research Abstracts

Fed an ethanol-containing isocaloric liquid diet for 10 wk and dosed orally with TCM (222 mg/kg.d, TCM222; 667 mg/kg.d, TCM667; and 2 000 mg/kg.d, TCM2000, respectively) weekly during the last 4 wk.

Results: ED group developed fatty liver according to lipid profile and liver histological findings. Compared with the control group, liver/body weight, serum triglyceride (TG) and total cholesterol (TC), liver TG and TC, serum alanine aminotransferase (ALT) and aspartic aminotransferase (AST) significantly increased in the ED group. Whereas, in the rats administered with TCM, liver/body weight, serum TG and TC, liver TG and TC, serum ALT and AST were significantly decreased, and the degree of hepatic lipid droplets was markedly improved compared with those in the ED group.

Conclusion: TCM treatment causes significant reduction in alcohol-induced lipid hepatic accumulation, reversing fatty liver and liver damage, and can be used as a remedy for alcoholic fatty liver.

Astragaloside IV from Astragalus membranaceus Shows Cardioprotection during Myocardial Ischemia in vivo and in vitro

Astragaloside IV is the major active constituent of Astragalus membranaceus, which has been widely used for the treatment of cardiovascular diseases in China. However, the effects of astragaloside IV on myocardial ischemia and its mechanisms of action remain largely unknown. In this study, we have examined the effects of astragaloside IV on myocardial infarction and coronary flow in vivo and in vitro. The possible roles of its antioxidative and nitric oxide-inducing properties were also explored. Astragaloside IV significantly reduced infarct size in dogs subjected to coronary ligation in vivo. Astragaloside IV also improved post-ischemic heart function and ameliorated reperfusion arrhythmias in rat hearts in vitro. The cardioprotection of astragaloside IV was accompanied by a significant increase in coronary flow both in vivo and in vitro. The nitric oxide synthase inhibitor, Nomega-nitro-L-arginine methyl ester partially abrogated astragaloside IV’s protective effect on heart function. Myocardial antioxidative enzyme superoxide dismutase activity increased with astragaloside IV administration. These data suggest the potential roles of antioxidative and nitric oxide-inducing properties of astragaloside IV in its protection from myocardial ischemia.

Polysaccharides from the root of Angelica sinensis protect bone marrow and gastrointestinal tissues against the cytotoxicity of cyclophosphamide in mice


Cyclophosphamide (CY) is a cytostatic agent that produces systemic toxicity especially on cells with high proliferative capacity, while polysaccharides from Angelica sinensis (AP) have been shown to increase the turnover of gastrointestinal mucosal and hemopoietic stem cells. It is not known whether AP has an effect on CY-induced cytotoxicity on bone marrow and gastrointestinal tract. In this study, we assessed the protective actions of AP on CY-induced leukopenia and proliferative arrest in the gastroduodenal mucosa in mice. Subcutaneous injection of CY (200 mg/kg) provoked dramatic decrease in white blood cell (WBC) count and number of blood vessels and proliferating cells in both the gastric and duodenal mucosae. Subcutaneous injection of AP significantly promoted the recovery from leukopenia and increased number of blood vessels and proliferating cells in both the gastric and duodenal mucosas. Subcutaneous injection of AP significantly promoted the recovery from leukopenia and increased number of blood vessels and proliferating cells in both the gastric and duodenal tissues. Western blotting revealed that CY significantly down-regulated the protein expression of vascular endothelial growth factor (VEGF), c-Myc and ornithine decarboxylase (ODC) in gastric mucosae but had no effect on epidermal growth factor (EGF) expression. AP also reversed the dampening effect of CY on VEGF expression in the gastric mucosa. These data suggest that AP is a cytoprotective agent which can protect against the cytotoxicity of CY on hematopoietic and gastrointestinal tissues when the polysaccharide is co-administered with CY in cancer patients during treatment regimen.

Radioprotective potential of ginseng

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Radioprotective potential of ginseng


A majority of potential radioprotective synthetic compounds have demonstrated limited clinical application owing to their inherent toxicity, and thus, the seeking of naturally occurring herbal products, such as ginseng, for their radioprotective capability has become an attractive alternative. In general, ginseng refers to the roots of the species of the genus Panax. As a medicinal herb, ginseng has been widely
used in traditional Chinese medicine for its wide spectrum of medicinal effects, such as tonic, immunomodulatory, anti-mutagenic, adaptogenic and antiaging activities. Many of its medicinal effects are attributed to the triterpene glycosides known as ginsenosides (saponins). This review addresses the issue of the radioprotective effects of ginseng on mammalian cells both in vitro and in vivo. Results indicate that the water-soluble extract of whole ginseng appears to give a better protection against radiation-induced DNA damage than does the isolated ginsenoside fractions. Since free radicals play an important role in radiation-induced damage, the underlying radioprotective mechanism of ginseng could be linked, either directly or indirectly, to its antioxidative capability by the scavenging free radicals responsible for DNA damage. In addition, ginseng’s radioprotective potential may also be related to its immunomodulating capabilities. Ginseng is a natural product with worldwide distribution, and in addition to its antitumor properties, ginseng appears to be a promising radioprotector for therapeutic or preventive protocols capable of attenuating the deleterious effects of radiation on human normal tissue, especially for cancer patients undergoing radiotherapy.

### Astragalus-based Chinese herbs and platinum-based chemotherapy for advanced non-small-cell lung cancer: meta-analysis of randomized trials

**Purpose:** Systemic treatments for advanced non-small-cell lung cancer have low efficacy and high toxicity. Some Chinese herbal medicines have been reported to increase chemotherapy efficacy and reduce toxicity. In particular, Astragalus has been shown to have immunologic benefits by stimulating macrophage and natural killer cell activity and inhibiting T-helper cell type 2 cytokines. Many published studies have assessed the use of Astragalus and other Chinese herbal medicines in combination with chemotherapy. We sought to evaluate evidence from randomized trials that Astragalus-based Chinese herbal medicine combined with platinum-based chemotherapy (versus platinum-based chemotherapy alone) improves survival, increases tumor response, improves performance status, or reduces chemotherapy toxicity.

**Methods:** We searched CBM, MEDLINE, TCMLARS, EMBASE, Cochrane Library, and CCRCRT databases for studies in any language. We grouped studies using the same herbal combinations for random-effects meta-analysis.

**Results:** Of 1,305 potentially relevant publications, 34 randomized studies representing 2,815 patients met inclusion criteria. Twelve studies (n=940 patients) reported reduced risk of death at 12 months (risk ratio [RR] = 0.67; 95% CI, 0.52 to 0.87). Thirty studies (n=2,472) reported improved tumor response data (RR=1.34; 95% CI, 1.24 to 1.46). In subgroup analyses, Jin Fu Kang in two studies (n=221 patients) reduced risk of death at 24 months (RR=0.58; 95% CI, 0.49 to 0.68) and in three studies (n=411) increased tumor response (RR= 1.76; 95% CI, 1.23 to 2.53). Ai Di injection (four studies; n= 257) stabilized or improved Karnofsky performance status (RR=1.28; 95% CI, 1.12 to 1.46).

**Conclusion:** Astragalus-based Chinese herbal medicine may increase effectiveness of platinum-based chemotherapy when combined with chemotherapy. These results require confirmation with rigorously controlled trials.
Effect of Lycium barbarum polysaccharide on the improvement of insulin resistance in NIDDM rats
枸杞子多糖提高非胰岛素依赖大鼠对胰岛素的敏感性

Lycium barbarum is one of the traditional oriental medicines. It has been reported to reduce blood glucose levels. In this study, the effect of Lycium barbarum polysaccharide (LBP) on the improvement of insulin resistance and lipid profile was studied in rats, a model for non-insulin dependent diabetes mellitus (NIDDM). The rats were divided into three groups: control, NIDDM control, and NIDDM+LBP. Diabetes model groups were made by feeding high-fat diet and subjecting to i.p. streptozotocin (50 mg/kg). LBP treatment for 3 weeks resulted in a significant decrease in the concentration of plasma triglyceride and weight in NIDDM rats. Furthermore, LBP markedly decreased the plasma cholesterol levels and fasting plasma insulin levels, and the postprandial glucose level at 30 min during oral glucose tolerance test and significantly increased the Insulin Sensitive Index in NIDDM rats. In the present study, we have tested that LBP can alleviate insulin resistance and the effect of LBP is associated with increasing cell-surface level of glucose transporter 4 (GLUT4) in skeletal muscle of NIDDM rats. Under insulin stimulus, GLUT4 content in plasma membrane in NIDDM control rats was significantly lower than that of control (p<0.01), and GLUT4 content in the plasma membrane in NIDDM+LBP rats was higher than that of NIDDM control rats (p<0.01). In conclusion, LBP can ameliorate insulin resistance, and the mechanism may be involved in increasing cell-surface level of GLUT4, improving GLUT4 trafficking and intracellular insulin signaling.
Acupuncture for upper-extremity rehabilitation in chronic stroke: a randomized sham-controlled study
针灸作为中风后上肢康复治疗的随机对照试验

Objective: To compare the effects of traditional Chinese acupuncture with sham acupuncture on upper-extremity (UE) function and quality of life (QOL) in patients with chronic hemiparesis from stroke.

Design: A prospective, sham-controlled, randomized controlled trial (RCT).

Setting: Patients recruited through a hospital stroke rehabilitation program.

Participants: Thirty-three subjects who incurred a stroke 0.8 to 24 years previously and had moderate to severe UE functional impairment.

Interventions: Active acupuncture tailored to traditional Chinese medicine diagnoses, including electroacupuncture, or sham acupuncture. Up to 20 treatment sessions (mean, 16.9) over a mean of 10.5 weeks.

Main outcome measures: UE motor function, spasticity, grip strength, range of motion (ROM), activities of daily living, QOL, and mood. All outcomes were measured at baseline and after treatment.

Results: Intention-to-treat (ITT) analyses found no statistically significant differences in outcomes between active and sham acupuncture groups. Analyses of protocol-compliant subjects revealed significant improvement in wrist spasticity (p<.01) and both wrist (p<.01) and shoulder (p<.01) ROM in the active acupuncture group, and improvement trends in UE motor function (p=.09) and digit ROM (p=.06).

Conclusions: Based on ITT analyses, we conclude that acupuncture does not improve UE function or QOL in patients with chronic stroke symptoms. However, gains in UE function observed in protocol-compliant subjects suggest traditional Chinese acupuncture may help patients with chronic stroke symptoms. These results must be interpreted cautiously because of small sample sizes and multiple, unadjusted, post hoc comparisons. A larger, more definitive RCT using a similar design is feasible and warranted.

Acupuncture for tinnitus: A series of six n=1 controlled trials
针刺治疗耳鸣有效

Objective: To explore patient perceived benefits of acupuncture for tinnitus.

Design: Controlled n=1 trials, with two phases A and B.

Subjects: Six patients with tinnitus.

Outcome measures: Primary outcome was Daily Diary records related to four tinnitus symptoms: loudness of tinnitus; pitch of tinnitus; waking hours affected with tinnitus; quality of sleep. Secondary outcomes were the Tinnitus Handicap Inventory (THI) and Measure Your Medical Outcome Profile (MYMOP).

Methods: Patients received a course of 10 acupuncture treatments over a 2-week period. Daily Diary entries related to the four tinnitus symptoms were recorded by patients for 14 days pre-treatment (phase A) and 14 days post-treatment (phase B). A hierarchical Bayesian model was used to combine the results from the individual patients to obtain estimates of the population and individual patient treatment effects, incorporating random variations at both levels (between patients and within patient). Tinnitus Handicap Inventory (THI) and Measure Your Medical Outcome Profile (MYMOP) were recorded at assessment points pre-treatment and post-treatment. RESULTS: Six patients participated in the trials, each receiving 10 treatments and completing all Daily Diary entries and outcome measures. For the symptoms of loudness and pitch, there were variable treatment effects between patients, with a trend for the median overall reduction for loudness of -2.49 (-5.04, 0.02) and for pitch -1.39 (-3.74, 0.89), 95% credibility intervals being shown in brackets. For the other two symptoms, the waking hours affected and quality of sleep, patients’ responses were more consistent, with a more credible overall median reduction for affected waking hours of -2.76 (-3.94, -1.63) and for quality of sleep -2.72 (-3.45, -2.03). The THI and MYMOP measures showed a trend of improvement after treatment.

Conclusion: The n=1 trial methodology, with an AB design and Bayesian analysis, can be considered of value in exploring treatment effects for small numbers of patients receiving individualised treatments, as is common within complementary medicine. When the treatment effects from six patients were synthesized, the results of this study suggest that acupuncture may have a beneficial role in the treatment of tinnitus.
**Effect of intensive acupuncture on pain-related social and psychological variables for women with chronic neck and shoulder pain - an RCT with six month and three year follow up**

针灸改善颈肩痛妇女的社交活动和身心健康


**Objectives:** This study examines whether intensive acupuncture treatment can improve several social and psychological variables for women with chronic pain in the neck and shoulders, and whether possible effects are long-lasting. The effects on pain have been reported elsewhere.

**Methods:** Twenty-four female office workers (47±9 years old) who had had neck and shoulder pain for 12±9 years, were randomly assigned to a test group or a control group. Acupuncture was applied 10 times during three to four weeks either at presumed acupuncture points for pain (test group) or at sham points (control group). In addition, acupressure was given to patients between treatments, at either real or sham points. Questionnaires for social and psychological variables were completed before each treatment, just after the course, and six months and three years later.

**Results:** The pain-related activity impairment at work was significantly less in the test group than the controls by the end of treatment (p<0.04). Also there were significant differences between the groups for quality of sleep, anxiety, depression and satisfaction with life (p<0.05). At six months and three years follow ups the acupuncture group showed further improvements in most variables and was again significantly different from the control group.

**Conclusion:** Intensive acupuncture treatment may improve activity at work and several relevant social and psychological variables for women with chronic pain in the neck and shoulders. The effect may last for at least three years.

**Electroacupuncture therapy for weight loss reduces serum total cholesterol, triglycerides, and LDL cholesterol levels in obese women**

电针治疗降低肥胖妇女的血脂水平


Our purpose in this study was to investigate the effect of acupuncture therapy on body weight and on levels of the serum total cholesterol, triglyceride, high-density lipoprotein (HDL) cholesterol and low-density lipoprotein (LDL) cholesterol in obese women. Fifty-five women were studied in three groups as follows: (1) control group (n=12; mean age=43.3±4.3, and mean body mass index (BMI)=32.2±3.4); (2) electroacupuncture (EA) (n=22; mean age=39.8±5.3, and BMI=34.8±3.3); and (3) diet restriction (n=21; mean age=42.7±3.9, and BMI=34.9±3.3). EA was performed using the ear points, Sanjiao (Hungry) and Shen Men (Stomach), and the body points, LI 4, LI 11, St 25, St 36, St 44 and Liv 3, once daily, for 30 minutes, for 20 days, whereas patients on diet restriction had a 1425 Kcal diet program, that consisted of 1425 Kcal daily for 20 days. There was a 4.8% weight reduction in patients with EA application, whereas patients on diet restriction had a 2.5% weight reduction. There were significant decreases in total cholesterol and triglyceride levels in EA and diet groups compared with the control group (p<0.05 in both cases). Furthermore, there was a decrease in LDL levels in the EA group compared with the control group (p<0.05). No significant changes could be found in HDL levels.
among the three groups. Our results suggest that EA application in obese women may decrease the serum total cholesterol, triglyceride, and LDL cholesterol levels by increasing the serum beta endorphin level. This lipolytic effect of EA may also reduce the morbidity of obesity by mobilizing the energy stores that result in weight reduction.

Acupuncture versus pharmacological approach to reduce Hyperemesis gravidarum discomfort
针刺治疗和药物治疗妊娠剧吐同样有效


**Aim:** Several reports have suggested the use of acupuncture as a useful treatment for hyperemesis gravidarum (HG), in particular the effects on nausea intensity was underlined. The aim of this study was to compare the efficacy of acupuncture sessions plus acupressure with a metoclopramide/vitamin B12 treatment.

**Methods:** In this study we randomized 88 pregnant patients suffering from HG to receive either acupuncture sessions plus acupressure (acupuncture group) or metoclopramide infusion (metoclopramide group) supplemented by vitamin B12 complex. Somatic symptoms and the ability to achieve the daily routine activity (functioning) were evaluated. Acupuncture sessions were performed at the hospital twice a week according to the traditional Chinese medicine criteria. Acupression was applied for 6-8 h/day. In the metoclopramide group, patients received at hospital metoclopramide infusion (20 mg/500 mL saline for 60 min) twice a week for 2 weeks. An oral supplementation with vitamin B12 complex (30 mg/day) was also prescribed.

**Results:** Both treatments reduced vomiting episodes and then nausea intensity with a consequent improvement in the rate of food intake. The effect of acupuncture seems to be progressive, increasing at the end of treatment whereas pharmacological approach has a prompt effect in responders remaining stable thereafter. Moreover, acupuncture was significantly more effective than drugs in improving functioning.

**Conclusions:** In our study for the first time acupuncture, applied accordingly to Chinese formula, was compared to drugs demonstrating the same effect of both treatments on HG symptoms. Interestingly, functioning was significantly improved just by acupuncture. Even if the effect of acupuncture on HG discomfort remains to be confirmed, the reports on the effect of acupuncture on psychosocial variables could represent a further advantage of acupuncture application and provide an incentive to widen the base of the research.

Preventive effect of acupuncture on histamine-induced itch: a blinded, randomized, placebo-controlled, crossover trial
针灸预防组胺引起的皮肤瘙痒


Acupuncture shows promise in the treatment of histamine-induced itching, according to clinical evidence presented at the World Allergy Congress. In a small randomised, double-blind, crossover trial, Dr. Pfab and colleagues evaluated the effect of acupuncture at an active point on the arm compared to acupuncture at a placebo site or no acupuncture at all. Subjects were 10 healthy volunteers with no history of skin disorders and no previous experience with acupuncture.

The active, or verum acupuncture point, called the Quchi point, was located on the extensor carpi radialis longus muscle on the dominant arm. Subjects in this branch of the study underwent single-point acupuncture for 15 seconds at this spot, followed 10 minutes later by a skin prick with a 1% histamine solution on the volar aspect of the dominant forearm.

In the placebo branch of the study, subjects underwent the 15-second acupuncture treatment in the dominant deltoid muscle, with the histamine injection 10 minutes later. Control subjects received only the histamine injection with no acupuncture.

All volunteers were observed for 20 minutes after the histamine injections. Skin reactions in the form of wheal and flare were measured, and itch intensity was measured on a visual analogue scale. The subjects also completed the Eppendorf Itch Questionnaire, an 80-item instrument designed to measure their descriptive and emotional responses to the itching. Each volunteer participated in all three arms of the study.

To evaluate differences in itch intensity, Dr. Pfab and his colleagues calculated the area under the curve, which they defined as percentage of the visual analogue scale multiplied by the time it took, in seconds, for patients to notice when their itching subsided. The researchers found that acupuncture at the active point was associated with significantly less itch intensity and less wheal and flare than acupuncture at a placebo site or no acupuncture at all.
Itch intensity was significantly lower, and subsided more quickly, following acupuncture at the verum point than in the placebo or control portions of the study. Corresponding wheal and flare sizes were significantly lower following acupuncture than in the control group, although there were no significant differences between the true and sham acupuncture groups in wheal and flare size. The mean for patients receiving active acupuncture was 18600%, compared to 22100% in patients undergoing sham acupuncture (p=0.05). Without acupuncture, the figure was 23500% (p=0.02 compared to active acupuncture). In the active acupuncture group, patients reported itching above the scratch threshold at 9 of 30 time points, compared to 23 with no acupuncture and 27 with sham acupuncture (p<0.001 for both, compared to active acupuncture). The groups did not differ in their answers to the descriptive portions of the Eppendorf questionnaire, but the emotional responses were significantly lower when subjects received true acupuncture than in the other phases of the study.

**Longer term clinical and economic benefits of offering acupuncture care to patients with chronic low back pain**

针灸治疗慢性腰痛临床疗效和经济效益分析


**Objectives:** To test whether patients with persistent non-specific low back pain, when offered access to traditional acupuncture care alongside conventional primary care, gained more long-term relief from pain than those offered conventional care only, for equal or less cost. Safety and acceptability of acupuncture care to patients, and the heterogeneity of outcomes were also tested.

**Design:** A pragmatic, two parallel group, randomised controlled trial. Patients in the experimental arm were offered the option of referral to the acupuncture service comprising six acupuncturists. The control group received usual care from their general practitioner (GP). Eligible patients were randomised in a ratio of 2:1 to the offer of acupuncture to receive between-acupuncturist effects to be tested.

**Setting:** Three non-NHS acupuncture clinics, with referrals from 39 GPs working in 16 practices in York, UK.

**Participants:** Patients aged 18-65 years with non-specific low back pain of 4-52 weeks’ duration, assessed as suitable for primary care management by their general practitioner.

**Interventions:** The trial protocol allowed up to ten individualised acupuncture treatments per patient. The acupuncturist determined the content and the number of treatments according to patient need.

**Main outcome measures:** The Short Form 36 (SF-36) Bodily Pain dimension (range 0-100 points), assessed at baseline, and 3, 12 and 24 months. The study was powered to detect a 10-point difference between groups at 12 months post-randomisation. Cost--utility analysis was conducted at 24 months using the EuroQol 5 Dimensions (EQ-5D) and a preference-based single index measure derived from the SF-36 (SF-6D). Secondary outcomes included the McGill Present Pain Index (PPI), Oswestry Pain Disability Index (ODI), all other SF-36 dimensions, medication use, pain-free months in the past year, worry about back pain, satisfaction with care received, and safety and acceptability of acupuncture care.

**Results:** A total of 159 patients were in the ‘acupuncture offer’ arm and 80 in the ‘usual care’ arm. All 159 patients randomised to the offer of acupuncture care chose to receive acupuncture treatment, and received an average of eight acupuncture treatments within the trial. Analysis of covariance, adjusting for baseline score, found an intervention effect of 5.6 points on the SF-36 Pain dimension (95% confidence interval (CI) -1.3 to 12.5) in favour of the acupuncture group at 12 months, and 8 points (95% CI 0.7 to 15.3) at 24 months. No evidence of heterogeneity of effect was found for the different acupuncturists. Patients receiving acupuncture care did not report any serious or life-threatening events. No significant treatment effect was found for any of the SF-36 dimensions other than Pain, or for the PPI or the ODI. Patients receiving acupuncture care reported a significantly greater reduction in worry about their back pain at 12 and 24 months compared with the usual care group. At 24 months, the acupuncture care group was significantly more likely to report 12 months pain free and less likely to report the use of medication for pain relief. The acupuncture service was found to be cost-effective at 24 months; the estimated cost per quality-adjusted (QALY) was 4241 pounds sterling (95% CI 191 pounds sterling to 28,026 pounds sterling) using the SF-6D scoring algorithm based on responses to the SF-36, and 3598 pounds sterling (95% CI 189 pounds sterling to 22,035 pounds sterling) using the EQ-5D health status instrument. The NHS costs were greater in the acupuncture care group than in the usual care group. However, the additional resource use was less than the costs of the acupuncture treatment itself, suggesting that some usual care resource use was offset.

**Conclusions:** Traditional acupuncture care delivered in a primary care setting was safe and acceptable to patients with non-specific low back pain. Acupuncture care and usual
Acupuncture care were both associated with clinically significant improvement at 12- and 24-month follow-up. Acupuncture care was significantly more effective in reducing bodily pain than usual care at 24-month follow-up. No benefits relating to function or disability were identified. GP referral to a service providing traditional acupuncture care offers a cost-effective intervention for reducing low back pain over a 2-year period. Further research is needed to examine many aspects of this treatment including its impact compared with other possible short-term packages of care (such as massage, chiropractic or physiotherapy), various aspects of cost-effectiveness, value to patients and implementation protocols.

Laser acupuncture for mild to moderate depression in a primary care setting - a randomised controlled trial


**Objective:** Depression is a major public health problem. There is some evidence supporting the effectiveness of needle acupuncture in its treatment. Laser stimulation, regarded here as a modality of acupuncture, is non-invasive and therefore free of infection risk; and it is acceptable to patients with needle phobia. The technique is relatively easily learned by community-based general practitioners. It is also amenable to sham control and therefore double-blinding in clinical trials. A double-blind randomised controlled trial was conducted to test the efficacy of low level laser acupuncture in mild to moderate depression.

**Methods:** Thirty patients with depression were randomised to receive either active or inactive laser treatment. The laser unit could be switched to one of two settings. One switch position delivered active laser acupuncture and the other was inactive (sham). In the active mode, 0.5J was delivered to each of six to eight individually tailored acupuncture sites per visit. All patients were treated twice weekly for four weeks then weekly for a further four weeks. The patients and the acupuncturist were both blinded to conditions. Outcome was assessed using the Beck Depression Inventory at baseline, weeks four and eight during treatment, and at 4 and 12 weeks following the treatment.
**Results:** At the end of the treatment period, Beck Depression Inventory scores fell from baseline by 16.1 points in the intervention group and by 6.8 points in the sham control group (p<0.001). The difference showed only a trend four weeks later, but was again significant after 12 weeks (p=0.007). Laser acupuncture was well tolerated with transient fatigue as the most common adverse effect.

**Conclusion:** Laser acupuncture may be worth further investigation as a treatment for mild to moderate depression in primary care.

### Acupuncture in patients with tension-type headache: randomised controlled trial

针刺治疗紧张性头痛有效


**Objective:** To investigate the effectiveness of acupuncture compared with minimal acupuncture and with no acupuncture in patients with tension-type headache.

**Design:** Three armed randomised controlled multicentre trial. Setting: 28 outpatient centres in Germany.

**Participants:** 270 patients (74% women, mean age 43 (SD 13) years) with episodic or chronic tension-type headache.

**Interventions:** Acupuncture, minimal acupuncture (superficial needling at non-acupuncture points), or waiting list control. Acupuncture and minimal acupuncture were administered by specialised physicians and consisted of 12 sessions per patient over eight weeks.

**Main outcome measure:** Difference in numbers of days with headache between the four weeks before randomisation and weeks 9-12 after randomisation, as recorded by participants in headache diaries.

**Results:** The number of days with headache decreased by 7.2 days in the acupuncture group compared with 6.6 days in the minimal acupuncture group and 1.5 days in the waiting list group (difference: acupuncture v minimal acupuncture, 0.6 days, 95% confidence interval -1.5 to 2.6 days, p=0.58; acupuncture v waiting list, 3.9 to 7.5 days, p<0.001). The proportion of responders (at least 50% reduction in days with headache) was 46% in the acupuncture group, 35% in the minimal acupuncture group, and 4% in the waiting list group.

**Conclusions:** The acupuncture intervention investigated in this trial was more effective than no treatment but not significantly more effective than minimal acupuncture for the treatment of tension-type headache.
Clinical evaluation of the traditional Chinese prescription Chi-Ju-Di-Huang-Wan for dry eye
杞菊地黄丸治疗干眼症


Background: Dry eye is a very common ocular disease characterized by eye dryness and photophobia. It often influences the patient’s normal life. This study evaluated the therapeutic effects of the Chinese herb, Chi-Ju-Di-Huang-Wan, for treatment of dry eye patients. It is one of the most commonly prescribed Chinese herbs used for eyes. However, there are no scientific reports about its effect.

Methods: This study included 80 dry eye patients. The patients were randomly divided into two groups. The experimental group was treated with topical eye drops and Chi-Ju-Di-Huang-Wan. The control group was given topical eye drops and placebo. All patients received tear film examinations including Schirmer’s test, Rose Bengal test, fluorescein stain test, break up time test and questionnaires.

Results: The results of the tear film tests were analysed by two independent t-tests between the two groups. No significant differences between the two groups according to the Schirmer’s test were found. There was a significant difference in the Rose Bengal test at week 2 and tear break up time at week 4 (p=0.04, 0.04, individually).

Conclusion: Chi-Ju-Di-Huang-Wan is an effective stabilizer of tear film and decreases the abnormality of corneal epithelium. It provides an alternative choice for dry eye treatment.

Improvement of accessory symptoms of hypertension by TSUMURA Orengedokuto Extract, a four herbal drugs containing Kampo-Medicine Granules for ethical use: a double-blind, placebo-controlled study
黄连解毒汤治疗高血压伴随症状有效


A double-blind, placebo-controlled study was conducted to evaluate the efficacy, safety, and utility of TSUMURA Orengedokuto Extract Granules for Ethical Use (TJ-15) as a treatment for the accessory symptoms of hypertension. Two capsules of the study drug were administered orally 3 times daily (i.e., before meals) for 8 weeks. Among 265 patients enrolled in the study, 134 were assigned to the TJ-15 group and 131 were assigned to the placebo group, of whom 204 patients (103 in the TJ-15 group and 101 in the placebo group) were included in the efficacy and utility analyze and 251 patients (128 in the TJ-15 group and 123 in the placebo group) were included in the safety analysis. Efficacy was significantly higher in the TJ-15 group based on the total score for the accessory symptoms of hypertensions which was the primary efficacy endpoint (Wilcoxon’s rank sum test, p=0.013). When each accessory symptom of hypertension was assessed separately, efficacy was higher for hot flushes and facial suffusion in the TJ-15 group (Wilcoxon’s rank sum test, p=0.034, and 0.022, respectively). There were no significant differences between the TJ-15 and the placebo groups with respect to the decrease of blood pressure or the antihypertensive effect. There was also no significant difference between the two groups with regard to the overall safety rating. The utility rating was significantly higher in the TJ-15 group than in the placebo group (Wilcoxon’s rank sum test, p=0.016). In conclusion, TJ-15 was superior to placebo with respect to efficacy, safety, and utility for the treatment of accessory symptoms of hypertension.
Studies of the pharmacokinetics of paeoniflorin in two Jing-Zhi-Guan-Xin formulations after oral administration to beagle dogs


Paeoniflorin is the principal bioactive component of Paeoniae Radix. The traditional Chinese medicine compound recipe (TCMCR) tablets of Jing-Zhi-Guan-Xin (JZGX), which is composed of Radix Salviae Miltiorrhizae, Radix Paeoniae Rubrae, Rhiza Chuan-xiong, Flos Carthami and Lignum Dalbergiae Odorafera, have been widely used in China and Japan. The plasma concentrations of paeoniflorin in beagle dogs after oral administration of two Jing-Zhi-Guan-Xin formulations (the dose used in the two formulations were both 200mg paeoniflorin) were measured using a simple and rapid HPLC method. The mean terminal half-lives (t(1/2)) of JZGX tablet and JZGX elementary osmotic pump tablet (EOPT) formulations of paeoniflorin were 147.52+/-28.98 and 276.60+/-24.24min, the maximum plasma concentrations (C(max)) of paeoniflorin were 210.49+/-23.89 and 94.36+/-14.01ng/ml, times to reach maximum concentrations (t(max)) were 130.00+/-30.98 and 280.00+/-48.99min, the area under the plasma concentration-time curves (AUC(0-infinity)) were 43066.50+/-10119.51 and 42266.87+/-2654.90ngmin/ml, the mean residence times (MRT) were 212.87+/-41.82 and 399.14+/-34.98min, respectively, and the relative bioavailability (Fr) of JZGX EOPT compared with JZGX tablet was 101.8+/-18.8%. These results, compared with the pharmacokinetic parameters of paeoniflorin after oral administration of Paeoniae Radix extract alone, indicated that the absorption of paeoniflorin after oral administration of the two JZGX formulations was significantly greater than that after oral administration of Paeoniae Radix extract alone.
**Prokinetic effect of a Kampo medicine, Hange-koboku-to (Banxia-houpo-tang), on patients with functional dyspepsia**

半夏厚朴汤治疗功能性消化不良


Limited evidence is available as to whether Kampo medicine modifies gastrointestinal function in humans. We investigated the effect of a Kampo medicine, Hange-koboku-to (Banxia-houpo-tang, HKT), on patients with functional dyspepsia (FD) and on healthy volunteers with regard to gastric motility. The gastric emptying rate (GER) in FD patients was significantly lower than in the healthy subjects. GER in FD patients and in healthy volunteers showed a significant increase after 2 weeks of medication with HKT. Furthermore, gastrointestinal symptoms improved significantly in the FD patients after the administration of HKT. These results suggest that HKT improves delayed gastric emptying and acts as a prokinetic agent.

**Chai-hu-gui-zhi-gan-jiang-tang regulates plasma interleukin-6 and soluble interleukin-6 receptor concentrations and improves depressed mood in climacteric women with insomnia**

柴胡桂枝干姜汤改善伴有失眠的更年期妇女抑郁症状


This study was performed to compare the effects of Chai-hu-gui-zhi-gan-jiang-tang (Saiko-keishi-kankyo-to), an herbal medicine, in improving depressed mood and on plasma interleukin-6 (IL-6) and soluble interleukin-6 receptor (sIL-6R) concentrations with those of anti-depressants in peri- and post-menopausal women. Ninety patients complaining of menopausal symptoms including insomnia who were diagnosed with mood disorder based on DSM-IV were recruited and separated into two groups (Chai-hu-gui-zhi-gan-jiang-tang group was selected on the basis of SHO for 42 cases, while anti-depressants were used for 48 cases), and plasma IL-6 and sIL-6R concentrations were determined before and after three months of the treatment. There were no significant differences in the decrease in both climacteric and Hamilton depression score after treatment between the two groups. Plasma IL-6 and sIL-6R concentrations were significantly lower in the Chai-hu-gui-zhi-gan-jiang-tang group (-34.8 +/- 15.5% and -22.4 +/- 14.6%, respectively) than in the anti-depressant group (7.5 +/- 4.8% and 2.4 +/- 3.8%, respectively) after 3 months of treatment. Correlations between rate of decrease in climacteric score and plasma IL-6 (R = 0.498, P = 0.0056) and sIL-6R (r=0.512, p=0.0045) concentrations were observed. Chai-hu-gui-zhi-gan-jiang-tang reduced plasma IL-6 and sIL-6R concentrations in relation to improvement of depressed mood during treatment. The findings of this study suggest that Chai-hu-gui-zhi-gan-jiang-tang has the potential to decrease morbidity by alleviation of stress reactions in peri- and post-menopausal women.

**Effectiveness of herbal medicine (Rokumigan and Hachimijiogan) for fatigue or loss of energy in patients with partial remitted major depressive disorder**

六味地黄丸和金匮肾气丸治疗严重抑郁症病人疲劳和乏力


Some patients with major depressive disorder (MDD) do not show remission of their depressive symptomatology. We investigated the efficacy of Rokumigan (TJ-87) and Hachimijiogan (TJ-7) in 20 patients with prolonged partial remitted MDD associated with fatigue or loss of energy. In these 20 patients, TJ-7 or TJ-87 was added to the previous regimen for 4 weeks. Six patients were ‘much improved’, six were ‘minimally improved’ (responders), and eight showed ‘no change’ (non-responders), on the Clinical Global Improvement Global Improvement scale. All responders had Shofuku-fujin (tenderness or weakness of the lower abdomen). In conclusion, we experienced 12 outpatients with prolonged partial remitted MDD with fatigue or loss of energy, which was successfully treated with TJ-87 or TJ-7.

**Anxiolytic effect of Gardeniae Fructus-extract containing active ingredient from Kamishoyosan (KSS), a Japanese traditional Kampo medicine**

加味逍遥散和栀子的抗焦虑作用


Kamishoyosan (KSS), a Kampo formula used to treat menopausal psychotic syndromes in women, consists of ten crude herbal drugs. The anxiolytic effect of KSS was investigated
Comparing the effects of estrogen and an herbal medicine on peripheral blood flow in post-menopausal women with hot flashes: hormone replacement therapy and Gui-Zhi-Fu-Ling-Wan, a Kampo medicine


We investigated the association between blood flow in the extremities and hot flashes, and compared change in blood flow following hormone replacement therapy (HRT) and Gui-zhi-fu-ling-wan (Keishi-bukuryo-gan), a herbal therapy in post-menopausal women with hot flashes. Three hundred and fifty-two post-menopausal women aged 46-58 years (mean: 53.4 +/- 3.6 years) with climacteric complaints participated in the study. One hundred and thirty-one patients with hot flashes were treated with HRT (64 cases) or herbal therapy (67 cases). Blood flow was measured with laser doppler fluxmetry under the jaw, in the middle finger and in the third toe. Post-menopausal women with hot flashes (129 cases) showed significantly higher blood flow under the jaw (13.6 +/- 4.13) than women without hot flashes (166 cases) (5.48 +/- 0.84) (p < 0.0001). Blood flow at this site decreased significantly with either therapy (p < 0.0001). On the other hand, the administration of Gui-zhi-fu-ling-wan significantly increased (p = 0.002) the blood flow in the lower extremities, whereas HRT decreased the blood flow. Thus, we have demonstrated that Gui-zhi-fu-ling-wan did not affect the activity of vasodilator neuropeptides on sensory neurons of systemic peripheral vessels uniformly. Therefore, Gui-zhi-fu-ling-wan, rather than HRT, is suggested as an appropriate therapy for treatment of hot flashes in the face and upper body with concomitant coldness in the lower body, which is one of the symptoms of menopause.
A randomized double blind placebo-controlled clinical trial of Hochuekkito, a traditional herbal medicine, in the treatment of elderly patients with weakness

Objectionive: To evaluate the effects of Hochuekkito, a traditional Japanese and Chinese medicine, in the treatment of elderly patients with general weakness. To devise a suitable study design for assessing the clinical effectiveness of traditional herbal medicines.

Methods: Fifteen elderly patients (mean +/- SD: age 78.4 +/- 7.8; m/f 3/12) participated in this study. A multicenter, prospective, randomized, double-blind, placebo-controlled study with N of one and responder restricted design was performed. After the run-in period, the patients were divided into responders and non-responders. Only responders were entered in the study, and were randomized into three groups: an active-placebo group, a placebo-active group and an active-active group. The study consisted of two 6-week terms with a 2-week washout period in between. We assessed the Short Form 36 Health Survey (SF-36) and Profile of Mood States (POMS) as an endpoint of quality of life (QOL). In addition, we assessed the biodefense status by measuring the natural killer cytolytic activity (NK activity), IL-2 producing activity of peripheral lymphocytes, lymphocyte proliferating activity and lymphocyte cell-surface antigens.

Results: The physical component summary of the SF-36 analysis significantly improved in the Hochuekkito-treated group. Four components (A-H: anger-hostility, F: fatigue, T-A: tension-anxiety, C: confusion) out of six improved in the Hochuekkito-treated group in the POMS analysis. Lymphocyte proliferating activity improved in the Hochuekkito-treated group but not significantly. Concerning the surface antigens of peripheral lymphocytes, the population of CD3 positive cells and CD3CD4 double positive cells increased in the Hochuekkito-treated group.

Conclusion: We revealed that Hochuekkito improved the QOL and immunological status of elderly patients with weakness by randomized controlled trial. Our study design might be useful for assessing the efficacy of traditional herbal medicine in the future.
A Chinese herbal medicine, Choto-San, improves cognitive function and activities of daily living of patients with dementia: A double-blind, randomized, placebo-controlled study

A double-blind, randomized, placebo-controlled study was conducted to examine the effects of two Chinese herbal medicines used in Japanese traditional medicine Choto-san) and Gosya-jinki-gan on cognitive function of Japanese inpatients diagnosed with dementia according to the Diagnostic and Statistical Manual of Mental Disorders. At the onset of this study, a history was taken, and physical and neurological examinations and computed tomography of the head were conducted. Mini-Mental State Examination (MMSE), Barthel Index (BI), and Zarit Caregiver Burden Scale assessed cognitive function, activities of daily living (ADLs), and caregiver burden (Z score), respectively. Patients taking cholinesterase inhibitors were excluded. This study enrolled 30 Japanese inpatients (mean age±SD 84.4±6.3), 13 of whom had mild to moderate dementia of the Alzheimer type (MMSE score: 14–25) and 17 of whom had Alzheimer’s disease (AD) (MMSE score: 10–21) and cerebrovascular disease (CVD); they were randomly assigned to the CS, GJG, or placebo (lactose) group. The study drugs were administered orally for 8 weeks, and MMSE, BI, and Z scores of the three groups were compared before and after administration.

The numbers of patients were as follows: 10 in the CS group (M:F=3:7, mean age: 85.1±5.7), 10 in the GJG group (M:F=2:8, mean age: 85.2±6.6), and 10 in the placebo group (M:F=2:8, mean age: 83.0±6.9). Each patient ingested 2.5 g of CS, GJG, or placebo (which had been chosen by the controller and wrapped in white paper) 30 min before every meal. The physician and others were blinded to the study drug being ingested by the patient.

After 8 weeks of administration, MMSE scores increased significantly compared with baseline values (repeated measures analysis of variance (ANOVA); p<.01) (from 15.5±4.0 to 17.5±4.9 points, 95% CI=−2.8 to −0.57) in the CS group but not in the GJG and placebo groups. BI scores increased significantly compared with baseline values (repeated measures ANOVA; p<.05) (from 67.5±34.6 to 73.5±35.8 points, 95% CI=−5.4 to −0.1; p=.046) in the CS group but not in the GJG

and placebo groups. No significant difference was found in Z score among the three groups. An earlier randomized study described positive effects of CS in patients with cerebrovascular dementia, and another showed that CS improves electrophysiological function of patients with poststroke mild cognitive impairment. The current study suggests that CS improves cognitive function and ADL in patients with dementia of the Alzheimer type and with AD and CVD. This may reflect effects on frontal lobe regional blood flow because CVD and AD present with decreased regional blood flow in the frontal lobe. Donepezil hydrochloride has been reported to increase cerebral blood flow mainly in the temporal to occipital lobes. Therefore, CS is conjectured to exert its synergic effects with donepezil hydrochloride in the relevant patients. Another study enrolling a greater number of patients will be required to further investigate the mechanism of CS’s action.