Research Snapshots

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RCT OF ACUTE PSORIASIS ACCORDING TO BLOOD-TYPE (XUE FEN) SYNDROME DIFFERENTIATION

BACKGROUND: The cause of psoriasis remains unclear. Recently, its incidence has shown an increase. Psoriasis often relapses after treatment which can result in great physical and mental impact on the patients.

OBJECTIVE: This randomised controlled trial (RCT) is aimed to evaluate the efficacy and safety of integrated Chinese-Western Medicine on acute psoriasis.

METHOD: One hundred outpatients met the eligibility criteria of typical clinical manifestations of acute psoriasis: erythema, papules, or erythema covered with silvery white scales accompanied by itching. Forty four patients were at the initial acute phase and the remaining patients had a sudden relapse from remission in chronic psoriasis. Participants were randomised to the treatment group (50 patients) or control group (50 patients).

Both groups were administered daily an intravenous infusion containing 40 mL Glycyrrhizin in 250 mL of 5% glucose solution. They also received topical application of Tacalcitol Ointment twice a day

The following oral Chinese herbal decoctions were given to the treatment group only, based on Xue Fen syndrome differentiation:

1. Blood heat syndrome (n = 16): Modified *Tuhuai* Decoction (*Tufuling* 30 g, *Shenghuaihua* 30 g, *Gancao* 9 g).

2. Blood dryness syndrome (n = 21): *Jiawei Siwu* Decoction (*Chuanxiong* 15 g, *Danggui* 15 g, *Baishao* 12 g, *Shudi* 12 g, *Huangqin* 15 g, *Fuping* 12 g, *Huaishanyao* 15 g, *Baizhu* 15 g, *Zhiheshouwu* 15 g, *Hongzao* 6 g).

3. Blood stasis syndrome (n = 13): *Chishao Ezhu* Decoction (*Sanleng* 15 g, *Ezhu* 15 g, *Chuanxiong* 15 g, *Xiangfu* 15 g, *Baishao* 15 g, *Chuanshanjia* 10 g, *Taoren* 10 g, *Guizhi* 10 g, *Fuling* 10 g, *Chishao* 12 g, *Niuxi* 20 g, *Shenghuangqi* 20 g, *Shuizhi* 6 g, *Tusizi* 30 g.

All patients in the treatment group received the following Chinese medicated bath every two days for three weeks: *Shengceboye* 100 g, *Tougucao* 100 g, *Baixianpi* 50 g, *Dazhaojiao* 50 g which was adjusted according to individual syndromes. Blood heat syndrome had additional *Machixian* 50 g, *Baijiangcao* 50 g, *Pugongying* 50 g; Blood dryness syndrome *Kushen* 50 g, *Difuzi* 50 g; and Blood stasis syndrome *Mudanpi* 50 g, *Shengaiye* 50 g. Herbs were seeped in 5000 mL water for 30 minutes.

OUTCOME MEASURE: Change in lesion area was measured according to the criteria specified in Standards of TCM Syndrome Diagnosis and Assessment of Efficacy.

1. Cure: lesions completely cleared or reduction of area ≥ 95%
2. Marked effect: reduction of lesion area ≥ 80% but < 95%
3. Effective: reduction of lesion area ≥ 50% but < 80% and
4. No Effect: reduction of lesion area <50%.

RESULTS: Lesion reduction was statistically significantly greater in the treatment group than in control group on overall efficacy: 94% vs 74% ($p < 0.01$). Of 50 patients in the treatment group, 47 responded while 37 patients responded to the control intervention in the same sample size as the treatment group. No serious adverse events were found in either group. Minor adverse events included dryness of mouth and skin, mild scaling and some itching.

CONCLUSION: Chinese herbs that clear heat, cool blood, resolve toxins, and move blood may transform macules and benefit patients with psoriasis. Tacalcitol inhibits abnormal proliferation and differentiation of epithelial cells, promotes normal differentiation of epithelial cells as well as having immune regulatory and anti-inflammatory actions. The combination of Chinese herbs with Western medication may improve curative effect on psoriasis in the acute phase without serious adverse events.

COMMENT: Psoriasis is a resistant skin disorder that often relapses, so new treatments are needed. This study demonstrates that integrated Chinese-Western therapy is effective and safe but there are some issues in the experimental

design. Since there is no placebo for the Chinese herbal medicine treatment, the improvement in this group could be due to the addition of an extra intervention. Also, no separate results are given for the three syndrome groups so we do not know whether this approach is effective in some syndromes but not for others. All details of intervention and measure, such as therapy course of each intervention and measure time of each measure, should be completed and stated in the method item. However, some relevant information was not clarified in the article, which impacts the accuracy of the study. According to Zhu Renkang, a famous traditional Chinese medicine expert in psoriasis, the aetiology and pathogenesis relates to blood heat at the onset and in acute relapses. Glycyrrhizin is commonly used for psoriasis outpatients in China and has been the subject of a number of clinical studies.

Li QS. A clinical study of Chinese Medicine Integrated Western Medicine for acute psoriasis. Journal of Emergency in Traditional Chinese Medicine. 2011; 20(2):214–5.

Shiqiang Deng and Brian May

TAI CHI EXERCISE FOR TREATMENT OF PAIN AND DISABILITY IN PEOPLE WITH PERSISTENT LOW BACK PAIN: A RANDOMISED CONTROLLED TRIAL

The study is a two-armed parallel randomised clinical trial to investigate the efficacy of a 10 week Tai Chi (TC) program on sufferers of persistent non-specific low back pain. The 160 participants were screened and then randomly allocated to either a TC intervention (n = 80) or a waiting list control group (n = 80). The results from this study showed that those who received the TC intervention had a significantly lower score of perceived pain through the primary measure of the bothersomeness of pain and secondary outcome measures using Roland-Morris Disability Questionnaire, Pain Disability Index and the Quebec Back Pain Disability Scale.

The study was conducted in Sydney, New South Wales, Australia and over a period of two years, with initial recruitment starting in July 2008 and the final outcomes collected in September 2010. All participants for this study were recruited from the Sydney metropolitan area and interventions held within community venues, not clinical facilities, in Sydney. Ethics for the trial was approved by the University of Sydney Human Research Ethics Committee.

This study is the first RCT of TC for sufferers of persistent low back pain symptoms and the significance of results found this study showed that TC is a valid and successful treatment for low back pain. The study stated that 75% of interviewed participants reported that the treatment effect met their requirements. However the results were also similar to previous meta-analysis of 14 RCTs comparing exercise to non-exercise groups for the treatment of low back pain[1], indicating that the results from this study can only show an equivalency to standard exercise for low back pain. The differentiation between exercise and TC lies in that the term TC is an umbrella term referring to a variety of ancient Chinese mind-body practices, such as mediations, qigong and martial arts choreography, with the emphasis to promote longevity and health.[3–4]

The methodology for this study has several strengths as well as several limitations, whilst the strengths further validate the reliability of the results collected, many of the limitations do reflect negatively on the affirmative outcomes from the study.

The strength of this RCT lies in the large sample size to give credible data regarding the effects of the tai chi on back pain. This number allows the statistical data to be analysed at a greater statistical power further validating the results obtained. The use of a checklist for the TC trainers and assessment of trainers ensured the study protocol was adhered to and provided a good method to ensure reliability and consistency of the intervention administered.

One of the limitations with the experimental design was the exclusion criteria for the volunteers that only relate to spinal pathology, surgery or contraindications to exercise. There was no attempt to differentiate the aetiology of the back pain or consideration to other ailments or medical conditions, either physiological or somatoform which might affect an individual's perception of back pain.

Whilst the two armed parallel RCT is a valid design, it does bring up the issue of specifying if the outcomes achieved were from a TC specific intervention or exercise in general, hence the need of a third arm of active control of exercise for participants to differentiate if there is any efficacy with the non-exercise aspects of TC practice.

The experimental design expected both groups to continue their usual health care for the duration of the trial; as such the modality and frequency of the health care received should have been listed to ensure there were no statistically significance between groups. Furthermore there was no process in place to evaluate if participants in the TC group exclusively practised TC or if they undertook other forms of exercise.

In terms of the dosage of TC intervention, there was a total of 18

sessions with each session lasting 40 minutes, a total of 720 minutes. When this dosage is compared to the findings from the 2008 report,[2] the dosage given is much lower than the average (2877 minutes) dosage of TC trials from 1996 to 2007. Whilst this figure gives no indication of the dosage required for a clinical outcome to occur in TC it does indicate that a lower dosage can be enough to initiate a change in outcome and raises the question whether or not results would be more significant if a longer dosage was given.

Unfortunately the study did not incorporate any measures for any follow up and outcome measures were only taken at baseline and at the conclusion of the trial. As the authors stated in their discussion the results obtained can only be deemed as short term without validation of follow up data.

Hall AM, Maher CG, Lam P, Ferreira M, Latimer J. Tai chi exercise for treatment of pain and disability in people with persistent low back pain: A randomised controlled trial. Arthritis Care Res (Hoboken) 2011;63(11): 1576–83.

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Shuai Zheng

A MODEL OF INTEGRATIVE CARE FOR LOW BACK PAIN

AIM: A new and interesting take on exploring low back pain this pilot research project aims to test the view that coordinated access to multi-disciplinary teams of health professionals including licensed acupuncturists working in a hospital setting would enhance clinical outcomes for adults with low back pain when compared to offering patients usual care. Usual care was defined as subjects treated in their usual primary care facility, which typically included pharmaceuticals such as NSAID's and muscle relaxants, and bed rest, education, physical therapy and activity alteration. In addition to acupuncture, integrative care included a broad range of complementary alternative medicine (CAM) practitioners.

DESIGN: The pilot project was a randomised trial comparing an individual program of integrative care plus usual care to usual care alone for adults with low back pain.

RESULTS AND CONCLUSIONS: Early findings suggest that it is relatively easy to assemble a team of integrative care practitioners; that CAM treatment is safe and that such an approach showed a promising trend for the benefit of treating patients with persistent low back pain . The findings also hint at the likelihood that such an integrative care approach is very likely to contribute to significant savings to a national health care budget.

Eisenberg, D. M. et al (2011) 'A model of integrative care for low back pain'. Journal of Alternative and Complementary Medicine. 18(4):354-362.

Peter Ferrigno
