



**Good Practice in Traditional Chinese Medicine Research in  
the Post-genomic Era**

**GP-TCM**

**223154**

**D6.10**

**Final Report published in scientific journals**



<b>Document description</b>	
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## 1 WP6 FINAL REPORT

All the WP6's work undertaken between March 2009 and April 2012 were prepared and summarised, which includes all the activities, contributions (articles published, in preparation and dissemination activities that have taken place relating to the project), as well as a summary of all work performed. The report at the Final Conference is fully described in D6.9 as the WP6 final report which was presented in the Final Conference in Kerkrade, Holland on 13<sup>th</sup> April 2012.

### PAPERS PUBLISHED IN THE SPECIAL ISSUE OF THE JOURNAL OF ETHNOPHARMACOLOGY

1.1 Following two articles were produced as a result of WP6's joint efforts and were published in the Special issue of the Journal of Ethnopharmacology

#### ARTICLE 1:

**Andrew Flower, Claudia Witt, Jian Ping Liu, Gudrun Ulrich-Merzenich, He Yue, George Lewith. Guidelines for randomised controlled trials investigating Chinese herbal medicine. Journal of Ethnopharmacology 140 (2012) 550– 554**

**Web link:** <http://www.sciencedirect.com/science/article/pii/S0378874111008956>

#### **Abstract**

**Ethnographic relevance:** Clinical trials investigating Chinese herbal medicine (CHM) have been frequently criticised for their lack of scientific rigour. As part of the GP-TCM project a team of experienced clinical researchers and CHM practitioners have developed clinical trial guidelines for CHM that combine an appreciation for traditional methods of practice with detailed and practical advice on research methodology.

**Materials and methods:** This paper presents an executive summary of this work. It introduces the practice of CHM and the key considerations that need to be addressed whilst researching this traditional medical system.

**Results:** These guidelines emphasise the importance of identifying best practice, and then developing and applying appropriate and rigorous research methodologies to investigate CHM as a whole system.

**Conclusions:** It is hoped that this will encourage a thoughtful and meticulous process of investigation that will clarify the contribution that CHM can make to our future healthcare. Innovative new approaches are considered including the application of the new "omic" technologies and systems biology as a way of enhancing our understanding of traditional practice.

#### ARTICLE 2:

**Web link:** <http://www.sciencedirect.com/science/article/pii/S037887411200044X>

**Hui Luo, Qing Li , Andrew Flower, George Lewith, Jianping Liu.**



**Comparison of effectiveness and safety between granules and decoction of Chinese herbal medicine: A systematic review of randomized clinical trials. Journal of Ethnopharmacology 140 (2012) 555– 567**

**Abstract :**

**Background:** The clinical use of Chinese herbal medicine granules is gradually increasing. However, there is still no systematic review comparing the effectiveness and safety of granules with the more traditional method of herbal decoctions.

**Method:** A literature search was conducted using China National Knowledge Infrastructure Databases (CNKI), Chinese Science and Technology Periodical Database (VIP), China Biomedical Database web (CBM), Wanfang Database, PubMed, and the Cochrane Library until March 10, 2011. Clinical controlled trials (CCTs) including randomized trials (RCTs) comparing the effectiveness and safety between Chinese herbal medicine granules and decoction were included. Two authors conducted the literature searches, and extracted data independently. The assessment of methodological quality of RCTs was based on the risk of bias from the Cochrane Handbook, and the main outcome data of trials were analyzed by using RevMan 5.0 software. Risk ratio (RR) or mean difference (MD) with a 95% confidence interval (CI) were used as effect measure.

**Results:** 56 clinical trials (n = 9748) including 42 RCTs and 14 CCTs were included, and all trials were conducted in China and published in Chinese literature. 40 types of diseases and 15 syndromes of traditional Chinese medicine (TCM) were reported. Granules were provided by pharmaceutical companies in 13 trials. The included RCTs were of generally low methodological quality: 7 trials reported adequate randomization methods, and 2 of these reported allocation concealment. 10 trials used blinding, of which 5 trials used placebo which were delivered double blind (blinded participants and practitioners). 98.2% (55/56) of studies showed that there was no significant statistical difference between granules and decoctions of Chinese herbal medicine for their effectiveness. No severe adverse effects in either group were reported.

**Conclusions:** Due to the poor methodological quality of most of the included trials, it is not possible to reach a definitive conclusion whether both Chinese herbal medicine granules and decoctions have the same degree of effectiveness and safety in clinical practice, but this preliminary evidence supports the continued use of granules in clinical practice and research. Standardization of granules and further more rigorous pharmacological, toxicological and clinical studies are needed to demonstrate the equivalence with decoctions.

**Article 1 in the special issue provides a summarized version of the clinical trial guidelines. The full set of guidelines are available as a separate document on the GP-TVM website. These are comprehensive and cover the methodology required for conducting clinical trials in herbal medicine. A summary is given below in 1.2.**

**1.2 The full guidelines for conducting clinical trials in Chinese herbal medicine have been located on the GP-TCM website.**

Flower A, Witt C, Liu JP, Ulrich-Merzenich, G, Muir K, Yu H, Prude M, Lewith G. GP-TCM Guidelines for randomized controlled trials investigating Chinese herbal medicine (CHM)

**Abstract:**

The aim of this document is to develop guidelines that can be applied to improve the design and rigour of Randomized Controlled Trials (RCT's) investigating the use of Chinese herbal medicine (CHM). It is not intended as a comprehensive research strategy for CHM although there are issues relating to the use of RCT's that will be relevant when using other research methods such as observational studies, case controlled studies, surveys and qualitative research.



The primary objectives of this paper are:

- to introduce CHM as a complex medical intervention
- to explore the range and possibilities of research options using the RCT model
- to propose ways in which this traditional medical system and these modern experimental tools can interact successfully to create sound evidence based practice.

The initial sections of these guidelines describe the real and already evident risk that subjecting CHM to the scrutiny of RCT's can distort the practice of CHM in such a way as to undermine the relevance of the data that is produced. However, it is our contention, that if the RCT design is thoughtfully used and sensitive to the nuances of CHM, especially individualized prescriptions, then it can be a rigorous and pragmatic way of investigating the contribution that CHM can make to contemporary health care.

**Given the close relationship of WP6 and WP8 in terms of capturing TCM practice and disseminating GP-TCM activities, such as the joint survey, some of the information provided below are also captured in WP8 documentation.**

### 1.3 Published abstracts

- Liao X, Lui J, Lorenc A, Robinson N. How do Chinese Medicine (CM) doctors communicate with their patients? A qualitative analysis. *European Journal of Integrative Medicine* 2010; 2: 199-200.
- Liao X, Liu J, Robinson N. Using qualitative research to investigate Chinese medicine doctors' practice. *Journal of Traditional Chinese Medicine* 2011; 31(Supplement): 33.

### 1.4 Other publications

- Robinson N. 'Globalising' – 'Integrating' Traditional Chinese Medicine. *The Acupuncturist*. British Acupuncture Council, 2010/ November p19-20.
- Huijuan C, Liu JP, George T, Lewith. Traditional Chinese Medicine for Treatment of Fibromyalgia: A Systematic Review of Randomized Controlled Trials. *The Journal of Alternative and Complementary Medicine*. April 2010, 16(4): 397-409. doi:10.1089/acm.2009.0599.
- Robinson N. Integrative medicine- Traditional Chinese Medicine, a model? *Chin J Integrative Medicine* 2011; 17: 1-5.
- Bovey M, Robinson N. Researching China. *The Acupuncturist*. British Acupuncture Council, 2011/ Autumn p20-21.
- Yu H, Wang S, Liu J, Lewith G. Why do cancer patients use Chinese Medicine? --- A qualitative interview study in China. *European J Integrative Medicine* 2012; doi:10.1016/j.eujim.2012.02.007

### 1.5 Editorials

- Robinson N. *European Journal of Integrative Medicine* 2012; (2) e. (in press)
- Robinson N. *European Journal of Integrative Medicine* 2011; (3) e47-48. doi:10.1016/j.eujim.2011.04.023
- Robinson N. *European Journal of Integrative Medicine* 3 2011; (4) e247 doi:10.1016/j.eujim.2011.04.023

### 1.6 Papers in preparation for publication from GP-TCM collaboration

- Robinson N, Lorenc A, Lophatananon A, Muir K. Traditional Chinese Herbal medicine practice- a comparison between EU and Chinese traditional practitioners (in preparation) a WP6 Output from the survey.
- Qu, F, Robinson N. Traditional Medicine- challenges for research (book chapter in *Complementary and Alternative Medicine: Evaluating Methods and Assessing Effectiveness* Eds. McCarthy, Peter W and Mark Langweiler. Jones and Bartlett learning (in preparation)



In addition a paper is being prepared by the group for the special invited issue of Science in December 2012 in which GP-TCM work will be showcased. This will be a unique opportunity for further demonstrate GP-TCM outputs. A paper is being drafted by WP6 members, Nicola Robinson, Claudia Witt and Jianping Liu and outline of the draft publication is given below and will be entitled:

#### Optimizing clinical evidence from TCM for effective health care

- Results from Meta-Analyses of TCM trials have demonstrated quality problems as well as an evidence gap between practice and research.
- Clinical practice is built on knowledge, clinical experience and patient preferences, which are influenced by values and belief systems.
- Omics in clinical research can direct the way to bridge the gap between personalized approach of Chinese medicine theory and Western science
- The strategic research framework of TCM has to follow a patient centered approach using mixed methods research methodology and involve stakeholders.
- A good example is the current movement in conventional medicine known as Comparative Effectiveness Research, which can combine the framework of evidence based medicine with producing results that have more relevance to stakeholders. Based on this, strategic recommendation for clinical TCM trials will be provided.

#### 1.7 Published Conference presentations

- Liao X, Liu J, Robinson N. A qualitative exploration of CM practitioners' treatment of chronic diseases in Beijing and London. International Congress on Complementary Medicine Research (ICCMR) Tromso, 19-21 May, 2010.
- Robinson N, Lorenc A, Ding W, Jia J, Bovey, M, Wang X. The evidence challenge for TCM. Good practice in Traditional Chinese Medicine. Leiden, Holland. 15-18<sup>th</sup> April, 2012.

#### 1.8 Oral presentations

- Robinson N. 10.5.2011 Developing the future for research activities through GP-TCM through collaboration and partnership working. Capital Medical university, Beijing
- Robinson N. 6.2011 Does TCM have a role in public health? All parliamentary group on China. Houses of Parliament.
- Liu. JP 20-25. 7. 2011 Invited oral presentation on "Cochrane systematic reviews on TCM" at GP-TCM Annual Conference. Braga, Portugal.
- Robinson N. 2.9 2011 "Can practitioner and patient centred research support the evidence base for TCM?" The 8<sup>th</sup> World Congress of Chinese medicine. Traditional Chinese Medicine benefits human health. Westminster Central Hall, London.
- Robinson N. 17.9.2011 Integrating traditional Chinese medicine – opportunities and challenges? British Acupuncture Council Conference.
- Robinson N. 22-24.9.2011 Acupuncture – Finding the evidence – the experience of GP-TCM. International Symposium on acupuncture. Beijing. China.
- Robinson N. 30-31.11.2011. TCM – An integrative approach to disease prevention and health promotion. Beijing Forum on Traditional Chinese Medicine- sub forum on TCM Cultural inheritance and scientific development. Beijing, China.
- Robinson N. 23.1.2012. What do we mean by integrated health in TCM? A comparison of UK and Chinese systems. Parliamentary Group on Integrative health, London, UK
- Robinson N. 13.4.2012 WP8 - Good Practice in Traditional Chinese Medicine Research in the Post-genomic Era, Rolduc, Kerkrade, Holland.
- Robinson N. 17. 4.2012 The evidence challenge for GP-TCM, The GP-TCM Congress Leiden, Holland.
- Liu ZL, Liu JP. 15-18 April, 2012 An epidemiological survey of cancer patients practicing Guolin Qigong in China. The GP-TCM Congress, Leiden, Holland.
- Robinson N 11.5.2012 Research Priorities for TCM, Bologna, Italy.