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

GP-TCM

223154

D6.9

Presentation of findings at the Final Conference on clinical functional genomic approaches to CHM

Document description	
Name of document	Presentation of findings at the Final Conference on clinical functional genomic approaches to CHM
Abstract	Prepare and summary of WP6's work over the full course of the project including all the activities and contributions as well as summary of all work performed i.e. "the WP6 final report".
Document identifier	D 6.9
Document class	Deliverable
Version	1.0
Author(s)	Nicola Robinson, Ken Muir, Artitaya Lophatananon
Date of creation	25/04/2012
Date of last modification	29/04/2012
Status	Final
Destination	European Commission
WP number	WP6

TABLE OF CONTENTS

1 THE WP6 FINAL REPORT

- **A brief introduction to the WP objectives;**
  - To focus on clinical studies in Chinese Herbal Medicine (CHM).
  - To develop a competent network of clinical scientists working at the interface of CHM and Western Medicine with leadership and energy.
  - To develop an unbiased review of current research in the functional genomics of CHM.
  - To define areas of special interest for study in CHM clinical research with special emphasis on practical, safe and potentially effective areas with a real hope of improving patient care through informing future clinical practice.
  - To establish expert guidelines for clinical research in functional genomics and CHM. To provide these online in an interactive format.
  - To establish an EU-Chinese forum for ongoing discussion and improvements in CHM clinical research.

- **A brief history of WP membership and leadership development:**
  - The members of the work package originally consisted of 8 beneficiary members and 17 non-beneficiary members.
  - WP6 group was first established by Prof. George Lewith and now co-led by Prof. Kenneth Muir from the University of Warwick and Prof. Nicola Robinson from London South Bank University. Prof. Boli Zhang from Tianjin University is acting as advisory board member. Initially, Dr. Jin Xu, University of Warwick acted as WP6 administrative personnel however Dr Xu resigned and this position was replaced by Dr. Artitaya Lophatananon (Dr. Lophatananon is also from the University of Warwick and has received funding for the work she has carried out on behalf of WP6.
  - The WP6 increased its non beneficiary members making the total number of 17 non-beneficiary members.

- **Year 3 WP activities:**

  In year 3, WP6 had 3 deliverables.

  - D6.8 – Conducting a survey of Chinese herbal practitioners to provide information on the topic focus for future research. Provision of recommendations on the application of functional genomic studies for the study of CHMs in patients (month 24)

    Activities; Preparation of a report highlighting the role of “omics” or “high throughput” technologies in CHM research has been submitted to Co-ordinating Office. The report covers;

    - The authenticity and quality of the plant material:
    - Analysis of the mode of action of single plants and multi-component mixtures
    - Assessment of the toxicity of CHM
    - Drug metabolism (individual responses)
    - Conduct and analysis a survey on the practice and perceptions of TCM practitioners (in conjunction with WP8)

  - D6.9 - Presentation of findings at the Final Conference on clinical functional genomic approaches to CHM (month 36)

    Activities; Presentation of outputs took place at the Final Conference in Holland led by Prof. Nicola Robinson

  - D6.10 - Final report published in scientific journals

Activities: 2 articles from the WP6 collaboration have been accepted for publication in the Journal of Ethnopharmacology special issue. A third paper is being drafted for a similar scientific publication which focusses on Chinese Herbal practitioners survey on their education, training and their perceptions of and priorities for research, and their willingness to collaborate in future clinical trials. The survey

- Comparison of effectiveness and safety between granules and decoction of Chinese herbal medicine: A systematic review of randomized clinical trials. Luo H, Li Q, Flower A, Lewith G, Liu J. J Ethnopharmacol. 2012; 140: 555-567
  http://www.sciencedirect.com/science/article/pii/S037887411200044X
- Guidelines for randomised controlled trials investigating Chinese herbal medicine. Flower A, Witt C, Liu JP, Ulrich-Merzenich G, Yu H, Lewith G. J Ethnopharmacol. 2012; 140: 550-554.

  http://www.sciencedirect.com/science/article/pii/S0378874111008956

- **Year 3 deliverables:**
  - D6.8: Recommendations on the application of functional genomic studies to the study of CHMs in patients (month 24). A report was produced and submitted to the Co-ordinating office at month 24 and after QA, finalised in month 27.on time.
  - D6.9: Presentation of findings at the Final Conference on clinical functional genomic approaches to CHM (month 36). The presentation will take place in the GP-TCM conference in Holland in 2012.
  - D6.10 Final report published in scientific journals. The third article from WP6 (described in D6.10) is currently in preparation and will dovetail with the information identified and now published from within the other work packages. It is anticipated the article will be ready for the submission by October 2012 at the latest.

- **Year 3 experiences gained and lessons:**
  - **The deliverable 6.8 was to produce a report on -** Recommendations on the application of functional genomic studies to the study of CHMs in patients. Due to a relative lack of good quality studies in this area, it was not possible to identify appropriate material around the chosen disease areas prioritised for the GP-TCM special focus. Instead the studies reviewed highlight the general approach and scope that such new approaches offer.

- **WP summary to Year 1-3:**
  - The clinical CHM network was created and the network includes Pan European Federation of TCM- a European TCM professional organisation, association of Traditional Chinese Medicine (UK), CAMbrella and RCHM.
  - WP6 and WP8 (Acupuncture) launched a TCM practitioner survey across Europe and China. The survey (WP6 part) explored the expertise of TCM professionals, to identify the most common conditions treated by TCM practitioners and their views on effectiveness to ultimately help develop clinical guidelines of TCM usage internationally.
  - WP6 has produced the report focuses on systematic reviews published in the Cochrane library and other peer reviewed English language journals. These provide more robust evidence than can be obtained from most individual clinical trials.

- A report highlighting the role of “omics” or “high throughput” technologies in CHM research.

- **WP plans for future activities towards the extended lifespan of the FP7 GP-TCM project**

  - Submit article from the CHM survey findings in by October 2012.
  - Explore future opportunities to progress these activities in order to develop a clinical trial network

- **WP suggestions to the GP-TCM Research Association regarding the future of the area covered by this WP**

  - The development of appropriate clinical studies and clinical trials in TCM and acupuncture is the main focus of the future work on the WP6

- **WP Finances (details of your current WP budget):**

  A total of €35,809 was provided for the kick off meetings and for conducting and analysing the survey. Some of these funds were used for a WP6 and 8 combined face to face meeting in Sept 2012. This was facilitated by Capital Medical University in Beijing and was useful in order to obtain consensus for activities during the final year of the project and discuss potential publications and future collaborative opportunities.

- **Final Conclusions:**

  - WP6 has formed an expert panel by involving other WP members. The WP6 members took an inclusive approach to this task and invited clinical scientists to an initial exploratory conference.
  - WP6 has created a review of existing literature and synthesis of knowledge and definition of areas where new knowledge is needed.
  - Guidelines and recommendations on conducting clinical trials in CHM have been produced which will help research in this area in the future
  - The results from the online survey address the views of clinicians and patients (across the EU states) on CHMs on specific clinical conditions and the areas where future clinical trials should focus.
  - WP6 also defined the possible approaches by which functional genomics can be applied to the study of CHM efficacy and the elucidation of CHM mode of action.

- **Minutes of Final conference:**

13.4.2012 Kerkrade, Holland

The WP6 aims and objectives were outlined. Details on the deliverables were presented:

- The ‘omics’ report
- Clinical trial guidelines
- The survey on the practice and perceptions of TCM practitioners in EU and China from the WP6/8 practitioner survey
- Comparing of effectiveness CHM granules versus decoctions: the systematic review SR of 42 RCTs, 56 studies in total.

Summary: 2 articles had been accepted on the above deliverables for the Special Issue and the full clinical trial guidelines were now on the GPTCM website, further publications on survey were planned.

Professor Robinson prompted the following feedback and questions on the key issues requiring resolution:

- Which disease groups are amenable to this approach?
- What are the best methodologies?
- What are the ethical issues and how can they be addressed?
- What forms of clinical sampling can be performed and what analyses are needed on such samples
- How can this new knowledge be disseminated?
- How can the success of these approaches be used to reconcile CHM and Western approaches to treatment?

Discussions:

Vivian Wong, The survey data presented on practitioners did not include the Hong Kong data. In China practitioners are hospital based, HK practitioners are in the community as general practitioners and so are similar to European practitioners, UK in particular. The diseases and the conditions seen in regular practice therefore differs. The practitioners' response to being involved in future clinical trials was significantly different between EU and China with the Chinese respondents less likely to want to take part in these. It was suggested that this was likely because there are so many patients to treat, the practitioners on the Chinese mainland were too busy to do clinical studies.

The perception of what was likely to be an adverse event would also vary between Chinese and EU practitioners and could account for the differences observed in the survey.

The quality of clinical trial research, was discussed and requirements for conducting research in China and now become much stricter, researchers doing a clinical study should be qualified for GCP, Andrew Flower mentioned that still reporting was still poor.

Another challenge identified was assessing syndrome differentiation and incorporating this into clinical trial design as this could improve clinical outcomes as ir reflected practice.

Doing research on a practice basis, using individualized decoction was discussed. Challenges were acknowledged: comparing individualized decoction, standardized formula and semi-standardised formula.

Generalising trials in China to the UK context was discussed and there was concern that the positive effects of granules due to publication bias and commercial interest could operate.

Jianping Liu stated that new drug studies are quite different to clinical studies. Most of the published TCM clinical studies were not new drug studies and most of the new drug studies were not published. New drug studies were therefore not accessed. One way to improve the quality of clinical studies was to publish the protocols and compare them. The Chinese government has now established 10 clinical bases focusing on TCM studies in more than 10 hospitals. More than 300 million has been budgeted to educate the TCM clinical study researchers.

Jiang Dan commented on how using the practitioner survey as a clinical platform was helpful to obtain clinical data. The need to collaborate with China, HK, and UK to identify research funding was a necessity.

The importance of qualitative research was mentioned as being an important component of clinical trials.

There was a need to incorporate a new model for incorporating GP into clinical trials on CHM.

Guo De-An, stated that although clinical trials could demonstrate clear, solid evidence of efficacy, were randomised clinical studies suitable for TCM? In addition to funding from government, industry can be used to fund research.

This presentation had a lively and interested debate and was well received by participants.