REPORT



SEMINAR IN METHODOLOGY OF CLINICAL RESEARCH IN TRADITIONAL CHINESE MEDICINE

BEIJING 10-12 OCTOBER 2005, SHANGHAI 13-15 OCTOBER 2005

北京中醫藥大學

NAFKAM

上海中医药大学 Shanghai University of T.C.M

TABLE OF CONTENTS

BACKGROUND INFORMATION 2

PURPOSE OF THE SEMINARS 2

ORGANIZERS 3

FINANCING 3

PARTICIPANTS 3

NAFKAM'S DELEGATION 3

THE COURSE OF THE SEMINARS 3

EVALUATION 3

FURTHER DEVELOPMENTS 3

ATTACHMENT 1 4
THE COURSE OF THE SEMINARS

ATTACHMENT 2 7
SEMINAR PARTICIPANTS' EVALUATION

ATTACHMENT 3 8
NAFKAM'S EVALUATION

ATTACHMENT 4 10
NAFKAMs delegation

REPORT

SEMINAR IN METHODOLOGY OF CLINICAL RESEARCH IN TRADITIONAL CHINESE MEDICINE

BEIJING 10-12 OCTOBER 2005, SHANGHAI 13-15 OCTOBER 2005

BACKGROUND INFORMATION

In 1999 China and Norway agreed to a Letter of Intent regarding collaboration within the field of health and medicine, and a three-year plan of action was signed when the Norwegian Minister of Health, Dagfinn Høybråten, visited China in October 2002.

The Norwegian Directorate for Health and Social Affairs has assigned The National Research Center in Complementary and Alternative Medicine (NAFKAM) the duty of administering the scientific and professional aspects of the section of the collaboration regarding Traditional Chinese Medicine (TCM).

The collaboration includes

1. Dissemination of knowledge about TCM to Norwegian researchers, health service providers, and practitioners of alternative medicine through collaboration with for example The Cochrane Collaboration.
2. Cooperation in research and education related to TCM. Facilitate research on current clinical problems, with the intention of possibly integrating TCM practice with Norwegian health service.
3. Exploring the possibilities of utilizing TCM in the treatment of mental illnesses, including depression.
4. Exchanges of health workers, practitioners and students with a focus on the integration of TCM and Western medicine.

NAFKAM has three employees involved in the China-Norway Collaboration:
Researcher and acupuncturist Terje Alraek, PhD (Director), Researcher Jianping Liu PhD, MD (Professor II), and Brit J. Drageset (Administrative Coordinator). In March 2005 Professor Liu moved from England to Beijing where he is director of the newly established Evidence Based Chinese Medicine Center for Clinical Research and Evaluation at the Beijing University of Chinese Medicine.

PURPOSE OF THE SEMINARS

Within the subject Traditional Chinese Medicine, there are naturally many ways that China can contribute to the collaboration. There is, however, a general need to strengthen the knowledge of research methodology within the community of Chinese TCM researchers and practitioners, and we see these seminars as a first step of Norway's contribution to assist the strengthening of research competence in China.

Objectives of the seminar

- Understand and be able to plan study designs in clinical research
- Understand the basic features of randomized controlled trials
- Recognize components of qualitative studies
- Be able to appraise critically the clinical research in TCM
- Use CONSORT statement checklist to design and report a randomized clinical trial
- Report acupuncture clinical trials according to STRICTA

ORGANIZERS

The seminars were cosponsored by NAFKAM and the Beijing University of Chinese Medicine and the Shanghai University of Traditional Chinese Medicine, respectively. NAFKAM was responsible for the content of the seminars, while the two universities were responsible for all the practical arrangements, with Jianping Liu as the coordinator in China.

FINANCING

The University of Tromso received funding for bilateral collaboration from the Norwegian Research Council in 2005. From these funds NAFKAM (the China-Norway Collaboration) received 60 000 NOK as funding for the research seminars in Beijing and Shanghai.
Meals during the seminars and local transportation for NAFKAM's delegation were covered by the Chinese hosts, while NAFKAM covered travel expenses for the delegation (including room and board). Expenses for translation of the power point presentations were also covered by NAFKAM. Participants paid a seminar fee (200 Yuan) to cover meals and training materials.

PARTICIPANTS

The participants were mainly TCM practitioners and researchers from different hospitals, and/or post graduate students who have majored in TCM. The number of participants was 23 in Beijing and 63 in Shanghai. Besides the registered participants, university students were also present during the seminars.

NAFKAM'S DELEGATION

The seminar presentations were made by Jianping Liu, Vinjar Fonnebo (Director of NAFKAM), and Terje Alraek. They also facilitated the group work. Brit J. Drageset participated as administrative assistant. (For information about the members of the delegation, see Attachment 4)

THE COURSE OF THE SEMINARS

See Attachment 1.

EVALUATION

The participants turned in evaluation forms in Chinese. A summary of the results has been translated into English by Jianping Liu. (Attachment 2)
NAFKAM's own evaluation of the seminars is also attached. (Attachment 3)

FURTHER DEVELOPMENTS

According to Jianping Liu, there is a need for this type of seminars in China – broad elementary seminars in TCM introducing the different methods, mostly for clinicians entering into research.

There is also a need for topic specific seminars, with the qualitative method being the most important. Another advanced seminar would cover best/worst-cases, surveys and cohort studies. If there is a demand for an RCT-seminar, this would also be developed.

With the necessary funding, it will be possible to expand the activity and offer basic seminars in rural areas, and advanced seminars in the larger cities. This could also be expanded to other countries.
A basic seminar is being planned for Lhasa, Tibet in 2006.

Finally, Norway would benefit from topic specific seminars held in Norway where Chinese practitioners teach Norwegian practitioners who want to do research.

This report can be downloaded from
http://uit.no/nafkam/1681/6

ATTACHMENT 1

THE COURSE OF THE SEMINARS

The seminar schedule was quite tight, and in Beijing we started promptly at 8:00 am. During the opening session representatives from the university were present (Vice President Qinguo Wang, Dean of the School of Pre Clinical Medicine Yuhang Li, and Vice Party Secretary Xiaohong Gu). After the opening speech by Vice President Wang, Vinjar Fonnebo and Terje Alraek spoke, gifts were exchanged, and a group photo was taken before the lectures started.



From the opening session of the Beijing seminar.



Seminar participants in Beijing.

The text of each slide of the power point presentations had been translated into Chinese, and all the presentations were gathered in a compendium along with relevant articles. The participants were expected to know some English, and we had not planned on having full verbal translation during the presentations. (Translators within the subject are hard to find, and expensive to hire.) As the first day proceeded, it became clear that the knowledge of the English language was limited for some of the participants, and gradually more of the presentations were translated by Jianping Liu. The participants were active, though, and valuable discussions took place both during the sessions and the breaks.



Participants at the Beijing seminar.

We had a welcomed lunch break for 2 hours, and lunch was served for everyone at a restaurant next door to the campus. At the end of the day (at 18:00 on the two first days) dinner was served at the same place – wonderful meals with the variety of dishes that makes eating in China such a pleasure!

On the second evening we were invited to the Xiyuan Hospital. Several doctors from that hospital participated in the seminar. NAFKAM is collaborating with Xiyuan in a pilot study on colon cancer, and we had some discussions about the study. We also had the opportunity to try out the chairs in their music therapy room – with built in massage in addition to the music.



Vinjar Fonnebo and Terje Alraek enjoying the music therapy chairs at Xiyuan Hospital.

The seminar ended at lunch-time on the third day with closing speeches and the handing out of certificates. Later on that afternoon we flew to Shanghai to be ready for the next seminar the following morning.

On arrival at the Shanghai University of TCM, we were surprised to find a large audience (we had not received the final number beforehand). In addition to the 63 registered participants, there were also some students sitting in on the presentations.

The seminar was opened by the official in charge of TCM at the Shanghai Administration of Health Care, Hua Liu. Vice President Ping Liu then spoke, followed by Vinjar Fonnebo, and gifts were exchanged.



Vice President Liu during the opening session.

The seminar schedule had been adapted by the organizers at the Shanghai University, and the program started at 08:30 in the mornings and finished by 16:30. Lunch break lasted for an hour, and lunch was served at the campus cafeteria. Because of the large number of participants and only three group leaders, the group work was replaced by plenary sessions of questions and answers. During the plenary sessions the participants were active, and many important questions were raised.



Attentive participants in Shanghai.



Jianping Liu and Hua Liu enjoying their lunch.

Translations were made by Jianping Liu during the whole seminar – whenever he did not lecture in Chinese, and his contribution was invaluable.



Dinner in Shanghai. Representatives from the Shanghai University of TCM, the Shanghai Municipal Health Bureau, and NAFKAM.

On the evening of the second day a dinner was hosted by the University. Vice President Liu was present, as well as Vice Director of the University's Centre for Evidence Based Chinese Medicine Research, Mr. Jie Li, Executive Vice Director of Shanghai EBM Center for TCM, Ms. Chu Li Ming, and Director of Science and Technology Department of the Shanghai Administration of Health Care, Mr. Kan Zhang.



Seminar certificates are being handed out.

During the closing session of the seminar (before lunch on the third day) a speech was given by Director Kan Zhang. Terje Alraek gave some closing remarks on behalf of NAFKAM, and the certificates were then handed out to the participants.

ATTACHMENT 2

SEMINAR PARTICIPANTS' EVALUATION

FEEDBACK SUMMARY FROM BEIJING SEMINAR (10-12 OCT. 2005)

Jianping Liu

A questionnaire in Chinese was issues to 23 registered participants, and the response rate was 100%.

Question 1. Way of presentation in terms of language (English or English plus Chinese)?

82% (19/23) would like English presentation translated into Chinese, others prefer English presentation.

Question 2. Speed of presenting (adequate, too fast, too slow)

80% (18/23) thought the speed was adequate, the rest thought it was too fast.

Question 3. About the language of the presentation slides

91% thought the slides in both English and Chinese were adequate, and 2 persons would like the slides in English only.

Question 4. Seminar training materials (A: very satisfactory, B: satisfactory, C: average, D: unsatisfactory)

13% chose A, 78% chose B, 9% chose C.

Question 5. Adequacy of the length of the seminar (adequate, inadequate)

12 persons thought the seminar length was adequate. Nearly 50% (11 persons) thought the length of the seminar was not adequate, among them, 6 persons suggested 1 week, 3 persons suggested 2 weeks, and 2 persons suggested 1 month.

Question 6. Evaluation of 'group work' (A: very satisfactory, B: satisfactory, C: average, D: unsatisfactory)

22% (5/23) chose A, 61% (14/23) chose B, 17% (4/23) chose C.

Question 7. Contents of the seminar (A: excellent, B: good, C: average, D: bad)

35% (8/23) chose A, 61% (14/23) chose B, 4% (1/23) chose C.

Question 8. General evaluation to this seminar (A: very satisfactory, B: satisfactory, C: average, D: unsatisfactory)

4% (1/23) chose A, 78% (18/23) chose B, 17% (4/23) chose C.

Suggestions from the participants:

1. The time was too short, and some of the presentations were not elucidated enough, especially the details in clinical research. Need more discussions with lecturers.
2. It would be better to present the design with practical examples, and address more details such as quality control, follow-up and how to operate (procedures).
3. Would like to know more about the future development of evidence-based Chinese medicine, and address some of the issues that need to be solved.
4. Longer time for discussion, for example, have one day to discuss specific topic brought by the participant.
5. Provide more typical case study analysis.
6. Better to issue the training materials beforehand so we can read in advance and to get better understanding.
7. To perform the data analyses through presentations in computer lab for some sessions.
8. The translation for the presentation took a lot of time, and took time away from digesting the contents; hope to focus on knowledge so TCM practitioners can learn more from Western medicine.
9. More time to be assigned to a couple of Dr Liu's presentations in order for the participants to follow the lecture more easily.

ATTACHMENT 3

NAFKAM'S EVALUATION

The seminars gave comprehensive knowledge on different approaches to doing TCM research

Randomized Controlled Studies (RCTs)
Qualitative research
Surveys
Cohort studies
Systematic reviews

Other seminars in TCM often focus on RCTs. The other four approaches in NAFKAM's seminar have, to our knowledge, not been focused upon before. The Chinese researchers within TCM have a fair knowledge about randomized controlled trials, and at the same time these trials are challenging to perform in China, (since a greater part of the population have received acupuncture, and it is considered un-ethical not to give real acupuncture treatment when this treatment is seen as an efficient treatment.) They are eager to receive confirmation from Western researchers that their research will be accepted in the West.

The seminar in Beijing had several sessions of group work. Part of this time was spent reading articles which were then discussed. The group work was a good way to activate all the participants. There was little time for plenary questions and answers.
The Shanghai seminar did not include group work. There were too many participants for the three possible group leaders. In stead, the plenary sessions of questions and answers were longer, and many important questions were raised.

Learning Points for Future Seminars

1. It is unnecessary to present the main treatment models of complementary and alternative medicine (CAM) used in the West – just mention that in the West TCM is considered to be part of CAM.
2. It is unnecessary to spend much time describing the theory of RCTs as long as the participants have a PhD.
3. There is a need for more practical steps on procedures for qualitative research, surveys and cohort studies.
4. The presentations on the different procedures could be more closely related to TCM
5. Accommodate the participants' wish for "cook book" approaches, and at the same time encourage them to broader thinking around the research questions and procedures.
6. Lengthen the time frame for the seminars to 3-4 days.
7. Give enough time both for plenary questions-and-answers sessions and group work
8. Give criteria for evaluating studies other than RCTs. Each session (of the basic seminar) to be followed by evaluation of papers.
9. Participants should receive the necessary materials in advance in order to be prepared for the group work.
10. Create two main types of seminars: Basic courses where students of TCM may attend, and advanced courses for PhD graduates only (one seminar for qualitative studies, and one for best-worst cases, surveys and cohort studies, and finally a course for Randomized Controlled Studies if there is a wish for this).

11. Inclusion criteria:
    Basic courses: clinicians entering into research and/or PhD graduates
    Advanced courses: researchers in TCM and/or those having attended a basic seminar
12. State clearer criteria for participation
13. Number of participants at each seminar: minimum 20, maximum 50.
14. All presentations (power point presentations) at both types of seminars should have Chinese and English text in the same slide, with the whole block of text coming into the picture simultaneously.
15. The basic courses need full translation of verbal presentations, and the time needs to be planned accordingly.
16. Advanced courses should have translator available for when the need arises during the seminar.
17. Encourage participants to create networks and cooperate with other researchers when planning and executing studies.
18. Offer professional assistance from outside of China to researchers who want to plan qualitative- and cohort studies.

ATTACHMENT 4

NAFKAM'S DELEGATION

Mr Vinjar Fonnebo

Born 080852

Professor and director
Phone +47 77 64 66 50
E-mail: Vinjar.Fonnebo@fagmed.uit.no

Vinjar Fonnebo is Professor of Preventative Medicine and leader of the National Research Center in Complementary and Alternative Medicine (NAFKAM). His medical education and training was done at the University of Tromso and MSc Epidemiology at London School of Hygiene and Tropical Medicine, UK. Fonnebo is currently holding the position as professor in Preventative Medicine at the University of Tromso. In addition he is involved in research collaborations with colleagues at the Universities of Oslo, Bergen and Trondheim in Norway; Maastricht, the Netherlands; and Arizona, USA. Over the last five years he has been teaching Epidemiology and Preventative Medicine as an international guest lecturer, as well as giving presentations at several international conferences. His current research projects include the use of complementary and alternative medicine in cancer care, the epidemiology of osteoporosis and fractures and fermented soy as a treatment of low bone density.

Fonnebo's research interests include:
1.The health effect of belonging to a religious group advocating a healthy life style.
2.The effects of health education via media or community-based interventions.
3.The epidemiology of osteoporosis and fractures.
4.Complementary and alternative medicine.

Mr Jianping Liu

Born 20.12.61

Professor II (based in Beijing, China)
MD, PhD
E-mail: Jianping.Liu@fagmed.uit.no; jianping_l@hotmail.com

Jianping Liu joined the NAFKAM in October 2002. His main job is based in the Evidence-Based Chinese Medicine Center for Clinical Research and Evaluation at Beijing University of Chinese Medicine in China. He completed his PhD in infectious disease in 1992, and had a background in clinical medicine including practice in infectious diseases as a physician, traditional Chinese medicine, epidemiology, clinical epidemiology, and Cochrane activities. His research interests are in the areas of research synthesis of clinical evidence in interventions of Traditional Chinese Medicine, infectious diseases, and clinical trials. His work includes producing and disseminating systematic reviews in infectious diseases, methodological research, working with and assisting Cochrane reviewers from developing countries to build capability and skills in systematic reviews, initiating clinical trial projects originated from evidence gap in systematic reviews. His current research projects include systematic reviews on herbal interventions for hepatitis, SARS, HIV/AIDS, viral myocarditis, type 2 diabetes mellitus, and irritable bowel syndrome.

Dr Liu is an adviser for WHO-WPRO in traditional medicine; a member of the Cochrane Complementary Medicine Field Advisory Board; member of the International Society for Complementary Medicine Research; member of International Society of Chinese Medicine; editor of the Cochrane Hepato-Biliary Group; editor of Chinese Medicine Journal; editor of the Chinese Journal of Epidemiology; and editor of the Chinese Journal of Evidence-Based Medicine.

Mr Terje Alraek

Born 04.05.55

Senior Researcher
Director China-Norway Collaboration in TCM
Acupuncturist, PhD
Phone +47 77 64 66 50
E-mail: Terje.Alraek@fagmed.uit.no

Mr. Alraek defended his thesis "Acupuncture in the prevention of recurrent uncomplicated lower urinary tract infection in adult women" on June the 8th 2004 at the University of Bergen, Norway. Thereafter he has been working at NAFKAM, University of Tromsø where he is a researcher and director of the China-Norway collaboration in traditional Chinese medicine.
Mr. Terje Alraek has 3 years of acupuncture study at International College of Oriental Medicine, UK, (Qualified 1982) and 20 years in clinical practice. He has also completed 11/2 year study in traditional Chinese herbal medicine (Oslo, 1998)
Since 1994 he has been involved in acupuncture research on recurrent cystitis and has published several papers on this topic:

1. Alræk T, Aune A, Bærheim A. Traditional Chinese Medicine syndromes in women with frequently recurring cystitis. Frequencies of syndromes and symptoms. Complement Ther Med 2000; 8:260-265.

2. Alraek T, Baerheim A. An empty and happy feeling in the bladder..: health changes experienced by women after acupuncture for recurrent cystitis. Complement Ther Med 2001; 9:219-223.

3. Alraek T, Soedal FIL, Fagerheim US, Digranes A, Baerheim A. Acupuncture treatment in the prevention of uncomplicated recurrent lower urinary tract infections in adult women. Am J Public Health 2002;10:1609-1611.

4. Alraek T & Baerheim A. The effect of prophylactic acupuncture treatment in women with recurrent cystitis; Kidney patients fare better. J Altern Complement Med 2003; 9:651-659

Ms Brit J. Drageset

Phone +47 77 64 66 50
E-mail: Brit.Drageset@fagmed.uit.no

Ms Brit J. Drageset was born in 1950 and has a Bachelor of Science from the University of Trondheim in 1973. She has worked as bilingual (English-Norwegian) secretary for many years. Ms Drageset is the administrative coordinator of the Norway-China collaboration within TCM.

This report can be downloaded from
http://uit.no/nafkam/1681/6

The National Research Center in Complementary and Alternative Medicine
University of Tromso, N-9037 Tromso, Norway
Tel. (+47) 77646650 Fax. (+ 47) 77646866
Email: nafkam@fagmed.uit.no
www.nafkam.no