



**FOUNDATION FOR TRADITIONAL CHINESE MEDICINE**

**ANNUAL REPORT**

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**Foundation for Traditional Chinese Medicine**

**296 Tadcaster Road**

**York, YO24 1ET, UK**

**Tel: 44+(0)1904 709688**

**Fax: 44+(0)1904 630154**

**[email@ftcm.org.uk](mailto:email@ftcm.org.uk)**

**[www.ftcm.org.uk](http://www.ftcm.org.uk)**



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## Introduction

The Foundation is a small yet dynamic organisation committed to promoting high quality research into our understanding of acupuncture as well as evaluating acupuncture's benefits, cost effectiveness and safety. Established in 1991, the Foundation provides an organisational base for promoting research into acupuncture. In essence our primary goal then and now is: “... *through research and education, to bring the traditional Chinese system of acupuncture more centrally into the national health care system*”

The Foundation is involved in a number of research activities and projects. The largest project has been a pragmatic randomised controlled trial evaluating the cost effectiveness of acupuncture in the treatment of low back pain. The evidence on the safety of acupuncture has also been an important area of research for the Foundation, and surveys of practitioners' and patients' reports of adverse events have been published in leading medical journals. With the recent appointment of the current Research Director, Hugh MacPherson, to a post at the Department of Health Sciences, University of York, we now have a range of new projects exploring acupuncture's potential for several conditions, as well as a neuroscience project where we are exploring the brain images generated by acupuncture needling of a point on the hand. In this research we are supported by Pro Vice Chancellor Professor Trevor Sheldon. Also in several projects we continue to be working closely with Professor Kate Thomas of the University of Leeds.

The Foundation for Traditional Chinese Medicine is a research charity (no: 702083) with Lord Colwyn as Patron, and Boards of Trustees and Advisors (see Appendix 1 for details of who's who). Funding has come from a combination of core funding from grant-making trusts and project funding from statutory and other sources. Donations from individuals and grant-making trusts have been a valued source of funding for the work of the Foundation.



## Research Projects

### **York Acupuncture for Low Back Pain Trial (YacBac): a pragmatic randomised controlled trial**

Back pain is a major cause of ill health and time lost from work. The conventional medical treatments often have limited success and the NHS has identified back pain as a priority condition for research. In preparation for a randomised controlled trial, we carried out a feasibility study (Fitter & MacPherson, 1995) followed by a larger pilot study (MacPherson et al 1999), which together provided a platform for an application for funding a large-scale trial. With Kate Thomas, then of the Medical Care Research Unit at Sheffield University as principal investigator, and funded by the Department of Health R & D Health Technology Assessment Programme, we conducted a pragmatic randomised controlled trial to evaluate the clinical impact and cost effectiveness of acupuncture for chronic low back pain, publishing the protocol in 1999 (Thomas et al 1999).

In the trial, we recruited 43 general practitioners who referred 241 patients for up to 10 acupuncture treatments provided by six local acupuncturists. Both groups continued to receive conventional primary care from their general practitioner. The key outcome measure was bodily pain, as measured by the SF-36, at 12 and 24 months after randomisation. The results were in favour of the acupuncture group at 12 months and became significant at 24 months: analysis of covariance, adjusting for baseline score, found a positive effect for acupuncture of 5.6 points on the SF-36 Pain dimension (95% CI -1.3 to 12.5,  $p=0.11$ ) increasing at 12 months to 8 points (95% CI 0.7 to 15.3,  $p=0.03$ ) at 24 months. Acupuncture patients also reported a significantly greater reduction in worry about their back pain. In addition the acupuncture service was found to be cost-effective. It is hoped that these results will be published soon in a major medical journal. The full report is now published as a monograph by the Health Technology Assessment Programme. (Thomas et al 2005)

In a sub-study we also explored the traditional acupuncture diagnostic concordance between the six acupuncturists. The acupuncture diagnosis was based on up to three pre-defined low back pain syndromes, for which inter-rater reliability was assessed. The most commonly diagnosed syndrome was Qi and Blood Stagnation (88% of patients), followed by Kidney Deficiency (53%) and then Bi Syndrome (28%). Where patients were rated twice, 47% to 80% of classifications were congruent, and Cohen's Kappa was between 0 ("same as chance") and 0.67 ("good"). These results, along with a full description of treatment, have recently been published (MacPherson et al 2004).



## **Acupuncture Safety Project:** **two surveys of adverse events associated with acupuncture**

The safety of acupuncture has come under scrutiny in the UK over the past five years. As part of establishing the evidence on safety, the Foundation researched the medical literature and published a series of review articles each one written for a different audience (MacPherson & Gould 1998, MacPherson 1998, MacPherson 1999a, MacPherson 1999c, MacPherson & Lewith 2000). These papers sifted the evidence, examined the quality of reporting and made proposals for prospective studies to evaluate risks and safety for acupuncture patients.

In 1999 the British Acupuncture Council commissioned the Foundation to undertake a nation-wide prospective survey of practitioner reports on adverse events. The survey involved 574 practitioners who reported for four weeks during May 2000 on all the significant events as well as any minor transient reactions that took place as a result of the treatment they provided. Between them the practitioners reported events covering over 34,000 acupuncture treatments. There were no serious adverse events and 43 significant minor adverse events. A short report was published in the British Medical Journal (MacPherson et al 2001a), followed by a full report (MacPherson et al 2001b).

As an extension of this work, the British Acupuncture Council funded a follow-up survey of adverse events as experienced by patients. One third of all BAAC members helped us recruit 9,408 patients, of whom 6,348 (67%) completed three-month questionnaires. At three months, 682 patients reported adverse events caused directly by the needling process. The most common was severe tiredness and exhaustion. Three events were serious defined as requiring hospitalisation, causing permanent disability or being life threatening. There was no evidence that patients not funded by the National Health Service or not in contact with their general practitioner or hospital specialist were at greater risk. Six patients reported a worsening of symptoms after taking advice on medication and two patients reported delayed conventional treatment. Our recently published results show that acupuncture is a relatively safe intervention when practised by qualified and regulated practitioners (MacPherson et al 2004). In two sub-studies, one on the profiles of these patients (MacPherson et al 2005a) and one on the short-term reactions to treatment that they experienced (MacPherson et al 2005b) will be published soon.



## **Acupuncture for Menorrhagia Project (ACUMEN)**

With over 40,000 hysterectomies being performed every year in the UK, the need for women to have a less invasive and more supportive treatment for heavy menstrual periods continues to be an important issue. Because women can be on a waiting list for a hysterectomy for between one and two years, and many would rather not have one, there is an opportunity to evaluate acupuncture as an alternative treatment. Research in China suggests that around two-thirds of women with heavy menstrual periods can be significantly helped with acupuncture. Based on these findings, and the experiences of patients and practitioners in the West, the ACUMEN Project was designed by Alison Gamon, a PhD student at the Department of Health Sciences at the University of York, in collaboration with the Foundation and Professor Kate Thomas. Funding has come from an independent grant-making trust and the Department of Health Sciences, York University.

The initial phase of this project involves an exploratory trial designed to explore a possible role for acupuncture in the treatment of menorrhagia, as a preparation for a full scale randomised controlled trial. In the exploratory trial, 40 patients were randomised to the offer of acupuncture in conjunction with normal GP care while the other half received normal GP care only. The acupuncture group received up to 20 acupuncture sessions on a weekly basis. This trial is now being written up and will be published in 2006. This research has aimed to explore the feasibility of the design and acceptability of acupuncture to patients, as well as testing referral and other procedures, assessing outcome measures, and monitoring costs and safety.

## **Chinese Herbal Medicine Safety Project**

With the aim of providing information about adverse events associated with herbal medicine, we conducted a pilot for a national survey project to assess the level of safety for patients receiving treatment with Chinese herbs. Our wider goal is to help patients make informed choices about treatment and provide policy makers with robust evidence on safety as a contribution to decision-making on widening access within the NHS,

MSc student Bin Liu has worked with the Research Director in conducting this pilot. We invited practitioner members of the Register of Chinese Herbal Medicine to participate, and 72 practitioners helped us recruit 170 patients, of whom 126 (74%) have provided us with details of adverse events that they associated with taking Chinese herbal medicine over a four week period. These results will be published soon. (MacPherson & Bin Liu 2005).



## **STandards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA)**

The need for better standards of reporting of controlled trials of acupuncture is evident from the difficulties associated with their interpretation and analysis. Hugh MacPherson has worked with an international group of acupuncture researchers and the editors of several leading journals in the field to address this issue. As a result a set of recommendations for better reporting of trials was developed, called the STRICTA recommendations: STandards for Reporting Interventions in Controlled Trials of Acupuncture. The guiding principle was a commitment to achieving a broad enough set of recommendations that would cover the most common approaches to both acupuncture and research design.

These recommendations were published in parallel by the key journals in the field (MacPherson et al 2001 and 2002). Participating journals are Acupuncture in Medicine, Clinical Acupuncture and Oriental Medicine, Complementary Therapies in Medicine, Journal of Alternative and Complementary Medicine and Medical Acupuncture. These journals are committed to adding the STRICTA recommendations to their instructions for authors. Translations and re-publication in Japan, China and Korea has been of value in broadening their impact. Further investigations in this area have been initiated elsewhere, and we continue to be involved in extending the influence of these recommendations internationally.

## **Acupuncture for Depression Programme**

This programme of research is being conducted jointly between the Foundation for Traditional Chinese Medicine and the Department of Health Sciences at the University of York where the Research Director holds a Department of Health post-doctoral fellowship. The aim of the research is to determine acupuncture's potential role as a treatment modality in primary care.

Depression is the second most common cause of disability in the world and in the UK it is the third most common reason for consulting in primary care. The limited evidence from the medical literature suggests acupuncture may be effective in the treatment of depression, and some patients see it as an attractive non-drug option. A small study we conducted with an uncontrolled case series of 10 patients has recently been published (MacPherson et al 2004). However the controlled trial evidence on the clinical effects of acupuncture is weak, in contrast to its increasing popularity. As a next step, some feasibility and piloting work is now needed.

This programme is initially tackling a series of methodological challenges associated with design and implementation of a trial of acupuncture for depression (Phase 1), leading to the implementation of an exploratory randomised controlled



trial (Phase 2), followed by an optimally designed multi-centre trial (Phase 3) to evaluate the clinical and economic impact of offering acupuncture for primary care patients with depression. We are developing specific methodological tools for the evaluation of acupuncture in real life settings, in order to generate meaningful and credible evidence that can inform decision-making.

The five methodological challenges in Phase 1 are:

- ❖ Investigating acupuncture's potential therapeutic niche in primary care.
- ❖ Establishing by consensus a protocol for the treatment of depression
- ❖ Identifying and testing a measure of the therapeutic relationship
- ❖ Identifying outcome measures sensitive to acupuncture's broader effects
- ❖ Exploring how trial evidence may influence GP referral for acupuncture .

This programme of research is supported by two PhD students: Sylvia Schroer who is a Department of Health award-holder, and Beverley Lawton who has a Department of Health Sciences, University of York scholarship.

### **Acupuncture for Non-cardiac Chest Pain**

Patients with chest pain commonly present in primary care, followed by referral to cardiac clinics in secondary care. However as many as 50% of patients referred to such cardiac clinics are found to have no problem with their heart. The causes of non-cardiac chest pain are not always clear, however there is evidence that they could be musculo-skeletal, gastro-intestinal, respiratory or psychiatric, the commonest cause being musculo-skeletal. Non-cardiac patients are usually referred back to primary care, where they often continue to experience chest pain, with as many as three-quarters experiencing limitations in activities, concern about the cause of their symptoms and dissatisfaction with medical care. Acupuncture is increasingly being used to treat non-cardiac chest pain despite an absence of research into effectiveness.

We are undertaking this research in two phases. In the first phase we have surveyed patients who attended the Rapid Access Chest Pain Unit at York Hospital, but whose chest pain was non-cardiac in origin. The survey has captured vital information about this population, including their diagnosis and treatment, their chest pain levels, and if still in pain, their interest in receiving acupuncture. In this first phase, our collaborators include Dr Jo Dumville, a Research Fellow at the University of York, and Dr Kathryn Griffith, a GP and Clinical Assistant in Cardiology at the York District Hospital where she works at the Rapid Access Chest Pain Clinic two days a week. At the University of York, Bob Lewin, Professor of Cardiac Rehabilitation and Dr Jeremy Miles have provided important input. This phase will inform our design for the second phase which will be a pilot for a pragmatic randomised controlled trial.



## **Acupuncture for Chronic Neck Pain**

Chronic neck pain is a prevalent problem in general practice and conventional treatments have limited success. Patients are seeking acupuncture outside the NHS in increasing numbers, yet the current evidence on acupuncture for neck pain is inconclusive. As a result, there is a growing public and scientific imperative to know whether acupuncture is worth offering as a referral option in primary care. In this project, we plan to conduct an open pragmatic randomised controlled trial of acupuncture for patients with neck pain, evaluating the clinical and economic impact when it is provided as an adjunct to normal GP management. As well as informing decisions made by patients and general practitioners, the knowledge gained on cost-effectiveness will contribute to policy decisions on widening access to acupuncture within primary care. In this project we are working with Gemma Salter, an MRC funded MSc student, and Professor David Torgerson, Director of the York Trials Unit. A small pilot has been conducted in which we recruited 24 patients and provided those randomised to acupuncture with 10 sessions of acupuncture. We have recently completed the three month follow-up for this study, and we are writing up a paper outlining the findings in the context of designing and conducting a large scale trial.

## **Neuroimaging of acupuncture**

Even with a growing body of evidence for acupuncture, there are many sceptics who would like to see “objective” evidence of acupuncture’s impact on biological correlates. One new area of research where such “objective” evidence has now become possible is in the mapping of the effect of acupuncture techniques on regionally specific structures within the brain. Such specific and quantifiable data could extend the evidence base for the mechanisms underlying acupuncture, and potentially contributing to the explanations of its clinical impact. Some recent studies have suggested the remarkable possibility of correlations between classical acupuncture points and cerebral activity not linked by known neural pathways. This research points to exciting opportunities to map the impact of needling specific acupuncture points on brain structures.

We are now working closely with the York Neuroimaging Centre to investigate the impact on brain images of needling Hegu (LI-4). Our primary aim is to investigate the extent of activation and deactivation of the brain associated with both deep and superficial needling. Secondary objectives were to explore variations on the brain images associated with the participant’s sex, prior belief about acupuncture, and the sensation felt at the site of needling. We have conducted experimental trials with using both fMRI and MEG scanners. We hope that the first results will be available in 2006.



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#### Articles in press.

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Jackson A, MacPherson H, Hahn SY. "Acupuncture for tinnitus: a series of six n=1 controlled trials." (In press 2004 Complementary Therapies in Medicine)

MacPherson H, Thomas KJ. Short-term reactions to acupuncture: a cross-sectional survey of patient reports. (In press 2005 to Acupuncture in Medicine.)

MacPherson H. Strengthening the case that acupuncture is safe in competent hands. (In press 2005 European Journal of Oriental Medicine.)

#### Recent conference presentations

1<sup>st</sup>-2<sup>nd</sup> July 2004: ACHRN (Alternative & Complementary Health Research Network), Nottingham University, UK. Longer term outcomes in a trial of acupuncture for low back pain.

25<sup>th</sup> September 2004: British Acupuncture Council, London. Invited presentation Acupuncture for Low Back Pain.

1<sup>st</sup> October 2004: Society for Acupuncture Research, San Francisco. Invited presentation: Standards for reporting the intervention in clinical trials of acupuncture.

2<sup>nd</sup> October 2004: Society for Acupuncture Research, San Francisco. Acupuncture for tinnitus – a series of n-of-1 trials.

2<sup>nd</sup> December 2004: Asian Medicine, Tradition and Modernity Conference organised by the International Society for Traditional Asian Medicine, London. Evidence-based acupuncture: a challenge ahead.

4<sup>th</sup> March 2005: Wolds Primary Care Research Network, Hull. Acupuncture for low back pain in primary care.

14<sup>th</sup> May 2005: Annual Acupuncture Research Symposium. Chair and Closing keynote speaker. Strategies for Acupuncture Research.

30<sup>th</sup> June 2005: Alternative & Complementary Medicine Health Research Network. Can individualised treatments be standardised? A consensus method to develop a treatment protocol of acupuncture trial for depression.



## Appendix 1: Who's who at the Foundation for Traditional Chinese Medicine

### Patron

**Rt. Hon. Lord Colwyn** CBE, BDS, LDS, RCS is President of the Parliamentary Group for Alternative and Complementary Medicine and President of the Natural Medicines Society.

### Board Of Trustees

**Jennifer Dale** is an acupuncturist with the British Acupuncture Council and a member of the Management Committee of the Acupuncture Research Resources Centre.

**Dr. Mike Fitter** (Chair of the Trustees) worked for the Medical Research Council for 19 years and more recently has been Research Director first at the Foundation from 1993 to 1997 and then at the Northern College of Acupuncture from 1997 to 2003.

**Fenella Jeffers** represents the voice of the patient, and she has a Masters degree in Women's Studies from the University of York.

**Charles Ristic** is a General Practitioner with a long-term interest in complementary medicine.

**Mark Tempest** is a solicitor based in York with a speciality of medical litigation.

### Consultants

**Richard Blackwell**, currently Principal of the Northern College of Acupuncture, worked for the Foundation for Traditional Chinese Medicine as its first Research Director 1992 to 1993 and since then has been a consultant.

**Sato Liu** is Executive Director of the Natural Medicines Society, the largest consumer group representing users of complementary medicine.

**Kate Thomas** is Deputy Director of the Department of Health funded Medical Care Research Unit at the University of Sheffield. She collaborates with the Foundation on a number of projects.



## Board Of Advisers

**Dr Stephen Birch** is a practising acupuncturist based in Amsterdam where he heads the Stichting (Foundation) for Traditional East Asian Medicine, an independent institute with a particular interest in acupuncture research.

**Professor Roy Carr-Hill** works at the Centre for Health Economics at the University of York and is also expert advisor to the UK Clearing House on Health Outcomes at Leeds.

**Dr. Peter Davies** is Head of the School of Integrated Health, University of Westminster and a Trustee of the Research Council for Complementary Medicine.

**Dr Kim Jobst** is a Consultant Physician at the Nuffield Hospital Hereford, Visiting Professor of Complementary Medicine at Oxford Brookes University, and editor of the Journal of Alternative and Complementary Medicine.

**Dr Julian Kenyon** is Medical Director of the Dove Clinic for Integrated Medicine, near Winchester, Hampshire, as well as Founder/President of the British Society for Integrated Medicine.

**Dr George Lewith** is Honorary Senior Research Fellow and Honorary Consultant Physician at the University of Southampton, and Visiting Professor at the University of Westminster.

**Dr David Reilly** is a clinician and researcher who is Lead Consultant at the Glasgow Homeopathic Hospital and consultant to Harvard Medical School.

**Dr David St. George** is Director of Research & Clinical Effectiveness at the University Hospitals NHS Trust in Southampton.

## Foundation Staff

**Dr Hugh MacPherson** has been Research Director of the Foundation for Traditional Chinese Medicine since 1997. He founded and has been Principal and Honorary and President of the Northern College of Acupuncture. Since June 2003, he has a joint appointment as a Senior Research Fellow with the Department of Health Sciences, University of York.