



FOUNDATION FOR TRADITIONAL CHINESE MEDICINE

ANNUAL REPORT

JULY 2005 TO JUNE 2006

Established in 1991, the Foundation provides an organisational base for promoting research into traditional acupuncture. Since June 2003 the Foundation has worked in partnership with the Department of Health Sciences, University of York. The Foundation's Research Director Hugh MacPherson has a joint appointment as a Senior Research Fellow with the Department of Health Sciences at the University of York.

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	Page
1. Introduction	3
2. Research Projects	
□ York Acupuncture for Back Pain Project (YacBac)	4
□ Acupuncture Safety Project	5
□ Acupuncture for Menorrhagia Project (ACUMEN)	6
□ Chinese Herbal Medicine Safety Project	6
□ Standards for Reporting Controlled Trials of Acupuncture: the STRICTA Project	7
□ Acupuncture for Depression Project	7
□ Acupuncture for Non-cardiac Chest Pain	8
□ Acupuncture for Chronic Neck Pain	9
□ Acupuncture for Irritable Bowel Syndrome	10
□ Acupuncture for Osteoarthritis of the Knee	10
□ Neuroimaging Acupuncture Project	11
3. List of Publications	11
4. List of Recent Presentations	17
5. Who's Who in the Foundation (Appendix 1)	18



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 carrying out and promoting research into traditional acupuncture. Our primary goal 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 appointment of the current Research Director, Hugh MacPherson, to a post at the Department of Health Sciences, University of York, we now have an expanded range of new projects exploring acupuncture's potential for several conditions, as well as a neuroscience project 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). Financial support 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. Adjusting for baseline score and for any clustering by acupuncturist, the estimated intervention effect was +5.6 points (95% CI -0.2 to 11.4, $p=0.06$) in favour of acupuncture at 12 months, increasing to +8.0 points (95% CI 2.8 to 13.2 $p=0.003$) 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. These results will be published soon in a major medical journal. The full report has now been 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 also 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 BAcC 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). Two sub-studies, one on the short-term reactions to treatment that they experienced (MacPherson et al 2005) and one on the profiles of these patients (MacPherson et al 2006) have recently been published.



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 involved 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 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. The results are now being written up for publication.

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 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 have recently been published. (MacPherson & Liu 2005, MacPherson & Liu 2006).



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, 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. We are currently conducting a review of how well the STRICTA items have been reported over time, as well as receiving feedback from authors of acupuncture trials. Our goal is to review STRICTA in the context of updating it if necessary.

Acupuncture for Depression Programme

This research programme was initiated by the Foundation and is currently being conducted at 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. An initial small study the Foundation conducted with an uncontrolled case series of 10 patients has been published (MacPherson et al 2004). However, robust evidence on the clinical effects of acupuncture is weak, in contrast to its increasing popularity.



Associated with design and implementation of a full-scale trial of acupuncture for depression, this research programme is initially tackling a series of methodological challenges (Phase 1), leading to the implementation of an exploratory (pilot) 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. Our Phase 1 has included:

- (i) *Selection of the target patient group(s) and the relevant treatment for the comparator arm of the clinical trial.* A qualitative study has been conducted to determine the potential therapeutic niche of acupuncture in primary care, and to inform the choice of patient group(s) and comparator arm intervention for a randomised controlled trial. We have conducted 30 in-depth interviews with a purposive sample of patients with depression, GPs and acupuncturists, and explored GPs' willingness to refer, the potential role of acupuncture, and patient choice. The results of this qualitative study are being written up in three papers which are currently being prepared for submission.
- (ii) *Design and assessment of acupuncture trial treatment protocol.* Using the Nominal Group Technique we have developed a trial treatment protocol with a representative group of 15 acupuncture practitioners. The protocol combines sufficient standardisation to allow replicability, with legitimate flexibility to accommodate expected patient variability. A paper describing the nominal group process and results has been submitted for publication.

The design of the Phase II pilot study is now complete and an application for ethics approval had been submitted to York Local Research Ethics Committee. The pilot will have three arms: acupuncture plus usual GP care, non-directive counselling plus usual GP care, and usual GP care alone. We will start recruitment in September 2006. This programme of research is supported Sylvia Schroer who is a Department of Health award-holder.

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 hearts. The causes of non-cardiac chest pain are not always clear, although there is evidence that they could be musculo-skeletal, gastrointestinal, 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, 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, Bob Lewin, Professor of Cardiac Rehabilitation and statistician Dr Jeremy Miles. 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 Gemma Salter, an MRC funded MSc student has conducted a small pilot in which we recruited 24 patients and provided those randomised to acupuncture with 10 sessions of acupuncture. We have completed the three month follow-up for this study, and we have submitted a paper outlining the findings in the context of designing and conducting a large scale trial.



Acupuncture for Irritable Bowel Syndrome (IBS)

Irritable bowel syndrome (IBS) is the most common bowel disorder seen by primary care physicians and gastroenterologists. It is a gastrointestinal disorder that is believed to affect approximately 15%-20% of the adult population and is characterised by an array of symptoms including “abdominal distension, abdominal pain, and bowel dysfunction, characterised by loose bowels, constipation or a fluctuation between these two extremes”. Treatment consists of pharmacological and psychological therapies that aim to manage and alleviate the symptoms. However, these have been found to have limited acceptability and effectiveness, and as a consequence many patients have been led to seek alternative therapies such as acupuncture to treat their IBS. Although a Cochrane systematic review of acupuncture for IBS is currently underway, the lack of good quality trials will almost certainly mean that it is inconclusive in its findings, although it is expected to show that further investigation is warranted.

The aim of the pilot study is to develop a trial platform for a full-scale randomised controlled trial to evaluate the clinical and economic benefits of offering acupuncture to patients being treated for irritable bowel syndrome. This research is based on the framework of the Medical Research Council’s guidelines for complex interventions. The co-ordinator for this project is Julie Reynolds, an MRC funded student at the University of York. We are also supported by Professor Peter Whorwell, Consultant Gastroenterologist at the IBS clinic in the South Manchester Hospitals Trust. The project is based in South Birmingham and involves primary care referrals of patients with IBS to receive either a course of acupuncture or normal GP care alone.

Acupuncture for Osteoarthritis of the Knee

Osteoarthritis (OA) is most commonly located in the knee and is a major cause of pain, activity limitation and health care utilisation, especially among older people. There appears to be an unmet need for treatment for this condition, while a systematic review and recent randomised trials have provided evidence that acupuncture is more effective than placebo for osteoarthritis of the knee. A number of substantive questions remain regarding the effectiveness and cost-effectiveness of acupuncture for OA of the knee.

The aim of the research is to pilot a full-scale cost-effectiveness study using a pragmatic randomised trial design. This will be a Phase II study based on the MRC’s guidelines for the evaluation of complex interventions and will enable us to determine the key parameters for a Phase III study or definitive RCT. Harriet Lansdown, a Medical Research Council funded MSc student, is



conducting this pilot with the support of GP Dr Mark Roman. Initial results are expected in the autumn of 2006.

Neuroimaging and acupuncture

Even with a growing body of evidence for acupuncture, there are many sceptics who would like to see evidence in the form of biological correlates of acupuncture. One new area of research where such 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 our understanding of the mechanisms underlying acupuncture, and potentially contribute 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 suggests exciting opportunities for mapping the impact of needling specific acupuncture points on brain structures.

We have been working closely with the York Neuroimaging Centre in a project to investigate the impact on brain images of needling Hegu (LI-4). Our primary aim is to compare the effect of deep and superficial needling on functional magnetic resonance images (fMRI). Secondary objectives were to explore variations in the brain images associated with the sensation experienced at the site of needling. We hope that the first publication will be in late 2006 or early 2007.

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Bell-Syer SEM, Thorpe LN, Thomas KJ, MacPherson H. Recruiting patients to trials in primary care: Lessons based on two RCTs and reports from participating GPs. (Submitted for publication, 2006.)

Salter G, Roman M, MacPherson H. Acupuncture for chronic neck pain: a pilot for a randomised controlled trial. (Submitted for publication, 2006.)



Recent conference presentations

12th October 2005: Inaugural Conference of the Foundation's GP Associates, St James Palace, London. Invited speaker: Developing the evidence base for integrated medicine.

14th Nov 2005: Department of Anthropology, University of Oxford. Invited speaker: Acupuncture and the RCT – developing the evidence.

17th Nov 2005: National Institutes of Health, USA. Invited poster presentation: Neuroimaging the response to acupuncture at LI-4 (Hegu): comparing superficial and deep needling.

9th March 2006: Hull York Medical School Third Annual Research Conference, Hull. Invited presentation: Neuroimaging responses to acupuncture: comparing superficial and deep needling.

30th May 2006 Co-Sponsored by Harvard Medical School, Osher Institute and Martinos Center for Biomedical Imaging, Massachusetts General Hospital, Boston USA. Invited speaker: "Neuroimaging acupuncture at LI-4 (Hegu): is superficial needling a control for deep?"

8th June 2006, Cheltenham Science Festival. Invited speaker: Alternative Medicine - Acupuncture - How does it work? A joint presentation with Professor Kathy Sykes of University of Bristol and neuroscientist Dr Mark Lythgoe of University College London with a focus on acupuncture and its effect on the brain.

17th June 2006, Annual Acupuncture Research Symposium. Invited speaker: Neuroimaging and acupuncture: implications for clinical practice.



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.

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

Mark Tempest is a solicitor based in York with a special interest in 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 Professor of Complementary and Alternative Medicine Research at the University of Leeds. 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 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.