



FOUNDATION FOR TRADITIONAL CHINESE MEDICINE

ANNUAL REPORT

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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, publishing over 50 articles and reports over the last ten years. Currently the largest project is a pragmatic randomised controlled trial evaluating the cost effectiveness of acupuncture in the treatment of low back pain. The trial, which has taken four years to complete, shows that acupuncture is beneficial for patients with low back pain, and the results will be published soon.

The evidence on the safety of acupuncture has also been an important area of research for the Foundation. Our first survey of practitioner's reports of adverse events was published in the British Medical Journal, and our second survey, recording patients' experiences of adverse events following acupuncture will be published soon.

Research Director Hugh MacPherson has recently taken up a joint appointment as a Senior Research Fellow at the University of York where he will continue in his role with the Foundation for Traditional Chinese Medicine. Working closely with Head of Department, Professor Trevor Sheldon, and in conjunction with key partners at the Medical Care Research Unit, University of Sheffield and York & District Mind, Hugh MacPherson will be taking forward as his primary project the clinical evaluation of acupuncture for patients with depression.

The Foundation for Traditional Chinese Medicine is research charity (no: 702083) with a Patron, Lord Colwyn, a Board of Trustees and a Board of 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 ‘orthodox’ 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, the FTCM carried out a feasibility study in 1994 in which four patients with chronic low back pain were referred for a course of ten acupuncture treatments (Fitter & MacPherson, 1995) followed by a full pilot study with twenty patients (MacPherson et al 1999).

With Kate Thomas 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, this project developed into a pragmatic randomised controlled trial to evaluate the evidence for the clinical benefits and the cost effectiveness of acupuncture for chronic low back pain (Thomas et al 1999). A total of 43 general practitioners referred 241 patients for up to 10 acupuncture treatments at six local clinics. Patients were randomised in a ratio of two to an acupuncture group or to a control group. Both groups continued to receive conventional primary care from their general practitioner. The key outcome measure was the SF-36 Bodily Pain, as measured at 12 and 24 months after randomisation. The results were in favour of the acupuncture group at 12 months with the acupuncture patients being in significantly less pain at 24 months. There was no significant difference in improvement between the patients of the six acupuncturists. 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 by the National Coordinating Centre for Health Technology Assessment (Thomas et al 2003).

A sub-study explored diagnostic concordance among 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%). For patients that 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 is soon to be published (MacPherson et al 2003)

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 longer versions targeted at different audiences (MacPherson et al 2001b, MacPherson et al 2002a, MacPherson et al 2002b).

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 1044 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 conclusion was that acupuncture is a relatively safe intervention when practised by regulated practitioners. These results are soon to be published, along with additional papers on related sub-studies.

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 suggest 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 of the Department of Health Sciences at the University of York, in collaboration with the Foundation and Kate Thomas of the Medical Care Research Unit, University of Sheffield. Funding has come from an independent grant-making trust and the Department of Health Sciences, University of York where Alison has been a PhD student.

The initial phase of this project has 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 either to the offer of acupuncture in conjunction with normal GP care or to 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 2004. This research has established the acceptability of acupuncture for patients with menorrhagia, as well as testing referral and other procedures, assessing outcome measures, and monitoring costs and safety.

Chinese Herbs Safety Project

With the aim of providing information about adverse events associated with Chinese herbal medicine, we have designed a 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,

The project has at its core a prospective survey where we hope to involve one third of the 400 practitioners who are members of the Register of Chinese Herbal Medicine, who between them deliver an estimated 200,000 prescriptions of Chinese herbs a year. These practitioners will help us recruit patients who in turn will then monitor adverse events over a three month period. We are being advised by Kate Thomas of the University of Sheffield and we are working closely with our key partner, the Natural Medicines Society, to attain funding for this project so that work can commence.

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 has been 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 five 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. Over time, it is hoped that the STRICTA recommendations will lead to better trial design.

This project has attracted considerable international interest and it is hoped that a small working group will meet in 2004 and work towards developing better methods for judging the appropriateness of the acupuncture used in clinical trials and establishing, through consensus, criteria for assessing their quality.

Acupuncture for Depression Programme

The Research Director has recently awarded a Department of Health post-doctoral award to develop a programme of research with the aim of determining acupuncture's potential role as a treatment modality for depression. This programme will be run jointly by the Foundation for Traditional Chinese Medicine and the Department of Health Sciences at the University of York who are hosting the award. Partners in this work include York & District Mind and the Medical Care Research Unit at the University of Sheffield.

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. However the evidence on the clinical effects of acupuncture is weak, in contrast to its increasing popularity. Studies of acupuncture under experimental conditions are not always easily generalised to the real world, while clinical research of routine practice has often lacked scientific rigour. For credibility among policy makers, practitioners and the public, research must be scientifically rigorous, respectful of the integrity of acupuncture as a system of medicine, and take into account what patients experience and value about acupuncture.

This programme will initially tackle a series of five 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 mild to moderate major depression.

A broader aim is to develop specific methodological tools for the evaluation of acupuncture in real life settings. We also hope to generate meaningful and credible evidence that can inform decision-making on acupuncture for patients with depression in primary care.

The five methodological challenges in phase 1 are:

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

The Department of Health support for this programme, which includes funding for Research Fellow Sylvia Schroer, will cover the four-year period from 2003 to 2007. The Department of Health Sciences is also funding a PhD student, Beverley Lawton, who will work within this programme.

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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. From 1993 to 1997 he worked as Research Director at the Foundation for Traditional Chinese Medicine and then from 1997 to 2003 as Research Director at the Northern College of Acupuncture.

Fenella Jeffers has a Masters in Women's Studies from the University of York and has recently undertaken a training in counselling at York St John, College of the University of Leeds.

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, is currently Principal of the Northern College of Acupuncture. He worked for the Foundation for Traditional Chinese Medicine as its first Research Director 1992 to 1993 and since then has taken the role of a consultant.

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

Kate Thomas is Deputy Director of the Medical Care Research Unit at the University of Sheffield. She collaborates with the Foundation on a number of projects and has co-authored many of the Foundation's publications.

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.

Prof. 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 School at the School of Integrated Health, University of Westminster and a Trustee of the Research Council for Complementary Medicine.

Dr. Kim Jobst is a physician and Visiting Professor of Healthcare and Integrated Medicine at the School of Healthcare, Oxford Brookes University. He also is editor of the Journal of Alternative and Complementary Medicine.

Dr. Julian Kenyon, a physician and researcher, is Medical Director of the Dove Clinic for Integrated Medicine.

Dr George Lewith is Clinical Senior Research Fellow and Honorary Consultant Physician at the University of Southampton where he heads the Complementary Medicine Research Unit.

Dr. David Reilly is a consultant physician who is Director of the Glasgow Homeopathic Hospital and Honorary Senior Lecturer in Medicine, Glasgow Royal Infirmary.

Dr. David St. George is Director of Research & Clinical Effectiveness, with the Research & Development Team of Southampton University Hospitals NHS Trust based at Southampton General Hospital.

Foundation Staff

Dr Hugh MacPherson has been Research Director of the Foundation for Traditional Chinese Medicine since 1997. He currently has a joint appointment as Senior Research Fellow at the Department of Health Sciences, University of York. An acupuncturist for twenty years, he also works part-time as an acupuncturist at the York Clinic for Complementary Medicine. He founded the Northern College of Acupuncture in 1988, and after working there as Principal for ten years, he then served as Honorary President until recently.