



FOUNDATION FOR TRADITIONAL CHINESE MEDICINE

ANNUAL REPORT

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Foundation for Traditional Chinese Medicine

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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 is 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 been an important area of research for the Foundation, and a survey of practitioner's reports of adverse events has been recently published in the *British Medical Journal*. A second survey, recording patients' experiences of adverse events following acupuncture is nearing completion. An exploratory randomised controlled trial of acupuncture for menorrhagia is also a key project. We also have a new project exploring acupuncture as a treatment for depression. In addition we are also involved in a range of smaller projects related to promoting good quality research into acupuncture for the benefit of patients.

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). The Foundation works closely with a number of university based researchers, particularly Kate Thomas, Deputy Director of the Medical Care Research Unit in the Faculty of Medicine at Sheffield University and Professor Trevor Sheldon who heads the Department of Health Sciences at University of York. 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. A literature review revealed that acupuncture can be an effective treatment though there is a lack of high quality research trials. In preparation for a randomised controlled trial, a feasibility study was carried out in 1994 in which GPs referred four patients with chronic low back pain to an acupuncture clinic in York for a course of ten treatments (Fitter & MacPherson, 1995). These results were encouraging in terms of procedures, end-point measures and outcomes. A full pilot study was undertaken with twenty patients being referred to two acupuncture clinics in York by local GPs and also by consultants from the Pain Clinic at the NHS hospital in York (MacPherson et al 1999).

In collaboration with Kate Thomas of the Medical Care Research Unit at Sheffield University, this project was developed into a successful application for funding from the Department of Health R & D Health Technology Assessment Programme. The research design is that of 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). Lucy Thorpe is managing the day-to-day aspects of this trial. The full number of 241 patients were referred by 39 GPs from the Selby & York Primary Care Trust and then randomised to the offer of acupuncture or to normal GP management. The acupuncture group received up to 10 treatments from 6 acupuncturists based at three centres in York. In-depth interviews with selected patients' focussed on strategies for coping with low back pain and patient's experience of acupuncture. The trial started in the summer of 1999 and the twelve-month results were collected by April 2002. Funding has been granted for an additional 12 months follow up and the project will be completed by April 2003. Results will be published in 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 been published in the British Medical Journal (MacPherson et al 2001a), followed by longer versions (MacPherson et al 2001b, MacPherson et al 2002).

As an extension of this work, the British Acupuncture Council funded a follow-up survey of adverse events as experienced by patients. Julie Elwick and then Tony Scullion have been the researchers working on this project, which started in January 2001. With over 9,000 patients completing consent forms and over 6,000 reporting on reactions to treatment over a three months period, it will be the first large scale study on what patients experience in terms of the type and frequency of adverse events associated with acupuncture. This study is breaking new ground both in terms of its patient perspective and in the range of adverse consequences being explored. Results will be reported in 2003.



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 Foundation has designed the ACUMEN Project in collaboration with the Department of Health Sciences at the University of York and the Medical Care Research Unit, University of Sheffield.

The Project has two phases: phase one is an exploratory trial, designed to explore a possible role for acupuncture in the treatment of menorrhagia, and to establish the feasibility of a full scale randomised controlled trial. In the first phase, 40 patients were invited to join a trial, half of whom 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 2003. This research has established the acceptability of such a trial for patients, as well as testing referral and other procedures, assessing outcome measures, and monitoring costs and safety. The bid for the full scale multi-centre trial will be made in 2003.

The ACUMEN Project is run by Alison Gamon, a researcher and acupuncturist who graduated from the Northern College of Acupuncture with an MSc in May 2000. Funding has come from an independent grant-making trust and the Department of Health Sciences, York University where Alison has been DPhil student.



Acupuncture for Depression Project (ADEPT)

Depression is a common psychiatric disorder with a prevalence of approximately 5% in the general population. It is estimated that one-third of the population will have experienced an episode of depression during their lifetime. For the individual, depression results in high personal, social and economic costs through social exclusion, disability, deliberate self-harm and the need for health care provision. The effectiveness of acupuncture in the treatment of depression has been recently reviewed with a strong suggestion of benefit. However there is a need for further research involving randomised controlled trials before firm conclusions can be drawn.

The Acupuncture for Depression Project involved a pilot study to assess the feasibility of further research in this area. In this pilot study, a total of 10 patients were recruited and referred for up to 10 acupuncture treatments. A variety of psychological outcome measures were used to measure changes in psychological well-being over time. The results have paved the way for a Phase II randomised controlled trial which will provide the platform for full-scale Phase III multi-centre trial. This will provide an evaluation of the clinical and economic benefits of offering acupuncture to patients with mild/moderate depression assessed as suitable for management in primary care. To date there have been no cost-effectiveness studies of acupuncture for depression.

Funding for the Phase II trial is being sought from the Community Fund with the bid being headed by Rebecca Rea of York & District MIND. Lucy Thorpe will be coordinating the research for this project and we are also working in close collaboration with Kate Thomas of the Medical Care Research Unit, Sheffield University. Dr David Geddes, General Practitioner and mental health lead in the Selby & York Primary Care Trust is an advisor to the project. Ethical approval has been attained. This research is planned to commence in May 2003.



Chinese Herbs Safety Project

With the aim of providing information about adverse events associated with Chinese herbal medicine, we have established 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 two prospective surveys involving the 400 practitioners who are members of the Register of Chinese Herbal Medicine, who each year deliver an estimated 200,000 prescriptions of Chinese herbs to patients in the UK. First there will be a prospective practitioner survey modelled on an equivalent survey of acupuncture practitioners (MacPherson et al 2001). A prospective survey of patients' reports of adverse events will follow, and this will be based on our research with acupuncture patients. We are working closely with the Natural Medicines Society to attain funding for this project.

Research related activities

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

Promoting acupuncture research in the UK

Over the years, the Foundation has made a number of contributions to national debates and forums on complementary and alternative medicine and particularly on acupuncture research. We contributed to Prince of Wales Foundation for Integrated Health Care and the 1997 publication of “Integrated healthcare: a way forward for the next five years”. Hugh MacPherson works on their research strategy group and contributed to their position paper on research into complementary medicine “Towards a National Strategy”. Hugh also submitted both written and oral evidence on acupuncture research to the House of Lords Sub-Committee on the Science and Technology Committee for their influential report on complementary and alternative medicine.

In supporting the work of the acupuncture profession, Hugh MacPherson has been Chair of the British Acupuncture Council’s Research Committee. In this role he helped write their position paper on a research strategy for the acupuncture profession. He continues to support the development of research awareness and activity among acupuncturists. This has led to ongoing work with the acupuncture schools and colleges. Hugh MacPherson also contributes to the Department of Health’s new Advisory Panel on complementary and alternative medicine which aims to boost the research infrastructure in the field. He also is a member of the Royal College of Physicians Committee on Complementary & Alternative Medicine.



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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.

Fenella Jeffers has recently completed a Masters in Women's Studies at York University.

Sato Liu (Chair of the Trustees) is Executive Director of the Natural Medicines Society - the largest consumer group representing users of complementary medicine.

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 Principal of the Northern College of Acupuncture, also based in York. He has also worked for the Foundation for Traditional Chinese Medicine as its first Research Director 1992 to 1993 and since then has been an consultant.

Dr. Mike Fitter is Research Director for the MSc in Acupuncture at the Northern College of Acupuncture. He was Research Director of the Foundation from 1993 to 1997 and has been a consultant since then.



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.

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 Deputy Director of the Centre for Care And Primary Health at the University of Westminster, Research Director of Marylebone Centre Trust and a trustee of the Research Council for Complementary Medicine.

Dr. Kim Jobst is a physician working at the Glasgow Homeopathic Hospital and University Department of Medicine and Therapeutics and he is editor of the Journal of Alternative and Complementary Medicine.

Dr. Julian Kenyon is a physician and researcher who has worked as Co-Director of the Centre of Complementary Medicine, Southampton and is Director of The Dove Healing Trust.

Dr George Lewith is Honorary Senior Research Fellow and Honorary Consultant Physician at the University of Southampton.

Dr. David Reilly is Consultant Physician, Glasgow Homeopathic Hospital and Honorary Senior Lecturer in Medicine, Glasgow Royal Infirmary.

Dr. David St. George is Senior Lecturer in Clinical Epidemiology and Consultant in Public Health Medicine at the Royal Free Hospital in London.



Foundation And Project Staff

Julie Elwick ran the second phase of the Acupuncture Safety Project for 12 months while also studying for an MSc in acupuncture at the Northern College of Acupuncture. [Until 20/11/2001]

Alison Gamon is a Project Research Worker on the Acupuncture for Menorrhagia Project (ACUMEN), and is midway through her PhD at the Department of Health Sciences at York University. She graduated with an MSc in Acupuncture in May 2000.

Dr Hugh MacPherson has been Research Director of the Foundation for Traditional Chinese Medicine since 1997. He is also founder and President of the Northern College of Acupuncture and an Honorary Senior Research Fellow in the Faculty of Medicine, University of Sheffield.

Tony Scullion is a Research Administrator who joined the Foundation in November 2002. He is co-ordinating the research for the Acupuncture Safety Project, with its large database of patient records. He will also be taking a central role in the Chinese Herbs Safety Project. [From 20.11.02]

Lucy Thorpe is a Research Associate working with Sheffield University and the Foundation for Traditional Chinese Medicine on the York Acupuncture for Back Pain Project. She has an MSc in Social Research Methods from Leicester University. She has also developed the Acupuncture for Depression Project (ADEPT).

Helen Wilkinson was the office manager and personal assistant to the Research Director through 2002. [Until 31.10.2001]