

A RESEARCH STRATEGY FOR THE ACUPUNCTURE PROFESSION

INTRODUCTION

The acupuncture profession has in recent years begun to recognise that research into the clinical effectiveness, patient demand and satisfaction, safety and the economic benefits of acupuncture is central to wider acceptance in the United Kingdom. With patients' demand for acupuncture rising, with the development of Primary Care Groups and with the increasing number of acupuncturists working within the health service, the British Acupuncture Council (BAcC) recognises the growing need to promote research as a tool to inform and improve standards of practice and to develop the evidence profile of acupuncture for use by policy makers and general public alike. To this end, this research strategy discussion document has been drafted to highlight areas of progress in meeting these needs, to outline a coherent strategy for the future and to encourage wider debate within the profession.

HISTORY

The profession has had to contend with a number of major challenges in pursuing its research strategy. The first has been the challenge of accessing the scientific and medical literature from East Asia, much of which has not been translated into English, and the resultant difficulty in interpreting the research evidence from the Peoples Republic of China and other Far Eastern countries. Critics of this research evidence have pointed to the widespread use of inadequate trial designs, particularly the absence of control for the natural course of the disease (i.e. which may include spontaneous recovery) and of validated outcome measures. Often insufficient detail is specified to enable the work to be replicated. The most common criticism of these studies is that very few of these studies are randomised controlled trials RCT, a requirement for statistically significant results. Often overlooked however has been the very large number of patients in many of the studies and the generally positive outcomes for a wide range of conditions.

The second of these challenges has been that acupuncture research in the West, which has largely been undertaken by scientists and doctors, seems to be of limited relevance to the work of most acupuncturists. It has tended not to inform practice nor lead to innovative developments that benefit patients. Most acupuncture trials have attempted to separate the active effect of the needles from the non-specific effects of the treatment as a whole. The methodology used has been the explanatory randomised controlled trial with the aim of determining the efficacy of acupuncture over and above the placebo response. Trial designs have often been based on treatment protocols that are rigid and formulaic which has therefore limited the practical relevance and the generalisability of the results, given that most acupuncturists in practice individualise their treatments. In addition, sample sizes in the trials have almost always been small, outcome measures have not always been validated, and often there has been no long-term follow up. Attempts to combine the data from a number of trials in the form of meta-analyses have usually been undermined by the weaknesses in the available data.

The third of these challenges has to do with the marginalisation of acupuncturists because they predominantly work outside the state sector. Since acupuncturists have not been in the mainstream of scientific research, and specifically the institutions such as universities that support academic research, they have been marginalised in terms of access to funding from the Medical Research Council and the National Health Service. Another primary source of funding in medical research lies in the pharmaceutical companies and it is clearly not in the interests of such companies to fund research into alternatives to drug treatment. The resultant lack of access to funding has created a vicious circle reinforcing the difficulties of getting research off the ground. There are signs, however, that this climate is changing, and as we will discuss below, there is now one significant initiative in acupuncture research that has gained mainstream funding.

The fourth of these challenges for the acupuncture profession has been the lack of research awareness among its practitioners. Many acupuncturists have come to the profession with strong feelings that a techno-rationalist approach to health care has its limitations. Some acupuncturists are even hostile to science *per se*. The colleges that have trained acupuncturists have not until recently had research awareness as part of their curricula. There is, therefore, a challenge within the profession to articulate what role research could have in extending both personal and professional standards, in better meeting the needs of patients and in developing a coherent agenda for acupuncture research that meets the requirements of a maturing profession.

Faced with these challenges, the BAAC and its precursor body, the Council for Acupuncture (CfA), invested its limited funding in the provision of a research centre providing database information and support through the Acupuncture Research Resource Centre (ARRC), currently based at the Faculty of Health and Human Sciences at Thames Valley University, and in supporting the work of other small trusts and foundations established by members of the profession to pursue research into acupuncture, including the Foundation for Traditional Chinese Medicine in York and the Oriental Medicine Research Trust in Reading. It has also maintained close liaison with other research bodies in the field, such as the Research Council for Complementary Medicine and the Foundation for Integrated Medicine, and established contact with the formal research bodies such as the Medical Research Council and the departments of several universities.

Within its own field the BAAC has also been the primary funder of the British Acupuncture Accreditation Board (BAAB), an independent body established to accredit the increasing number of acupuncture schools and colleges within the UK, and through this encouraged research-mindedness among new entrants to the profession.

CURRENT RESEARCH PRIORITIES AND DEVELOPMENTS

The BAAC's current research priorities have included the following five main strands all of which aim to inform and improve the standards of practice of acupuncturists working in the UK. These are:

1) To encourage research-mindedness among the members of the acupuncture profession and to provide support and guidance on research matters both for the profession and for the general public.

The activities in this area include:

- a) Adoption by the British Acupuncture Accreditation Board (BAAB) of a requirement for research-mindedness in the curricula of acupuncture schools and colleges
- b) Development of a research database, search facilities and information service through ARRC, who are now based at Thames Valley University
- c) Organisation of annual research symposia by ARRC in London
- d) Production by ARRC of a Research Directory detailing members of the profession directly or indirectly involved in research.

2) To develop the evidence base for acupuncture through promoting research into the clinical effectiveness of acupuncture.

The British Acupuncture Council recognises that developing the evidence profile for acupuncture is a research priority. However there are two well-established approaches to clinical evaluation, both of which involve randomised controlled trials. First there is the explanatory trial that is used to determine the efficacy of acupuncture (i.e. if there is an acupuncture effect over and above the placebo) in conditions as near as possible to a laboratory environment. Second there is the pragmatic trial that is used to determine the clinical effectiveness of acupuncture in conditions as near as possible to everyday clinical practice. While both types of research are important, the British Acupuncture Council has a strong interest in ensuring that the research is relevant to normal practice so that the results can influence decision-making on the wider availability of acupuncture.

An example of a pragmatic trial is the York Back Pain Trial that commenced in 1999 and is being undertaken by the Foundation for Traditional Chinese Medicine at York in collaboration with Sheffield University's Medical Care Research Unit. They have been granted £184,000 through the R&D Health Technology Assessment Programme of the NHS. As a pragmatic randomised controlled trial, the clinical benefits to patients receiving acupuncture will be compared with patients in the control group under normal GP management. Based on a range of outcome measures assessed at 3 months and at 12 months, this trial will evaluate the effectiveness of acupuncture for chronic low back pain when delivered under optimal clinical conditions. The trial will also explore patient choice, cost effectiveness, safety, the patient's experience of acupuncture, and the variations in treatment strategies and outcomes for the different back pain syndromes of traditional Chinese medicine.

3) To develop innovative research models, both quantitative and qualitative, which reflect better the interactive and dynamic elements of traditional acupuncture and the patient-centred nature of the therapeutic relationship.

Research can be designed to meet the needs of an external audience, where the profession may want to demonstrate effectiveness, cost savings and safety. However, many practitioners are interested in how research can improve (rather than prove) practice, and here the audience is internal to the profession. Innovative research is needed for both external and internal research, bringing both quantitative and qualitative approaches together in a way that can add depth to our understanding of acupuncture. Social research methods are an important resource and in this context several years ago the Council for Acupuncture, the forerunner of the BAaC, spent many months working with the British Holistic Medical Association on a social science orientated model of evaluation of patients' experience. There has been much discussion at the annual symposia of how best to utilise appropriate methodologies, particularly from social sciences, and how to bring in a stronger emphasis on qualitative research in order to better understand the very qualities of the acupuncture experience that have led to the dramatic increase in demand for treatment. These qualities include the value that patients put on the therapeutic relationship, the insights from Chinese medicine that are often acknowledged to be of value by patients, and the deeper and subtler changes in attitude, in behaviour and in relationship to self that can result from treatment.

4) To develop audit and outcome protocols that assess the range of acupuncture practice in the UK and the success of acupuncture treatment in clinical practice.

There have been many research-oriented audit and outcome studies carried out by BAaC members over the years. The aim of the audit cycle is to explore and improve an aspect of clinical practice through implementing change and evaluating the benefits. Outcome studies have been utilised to evaluate health gain, whether subjective or objective, resulting from acupuncture. These studies have enhanced our understanding of prognosis and patient benefits, including variability of response between patients.

With the goal of researching outcomes across the acupuncture profession more systematically, the BAaC is funding a pilot phase of the Dao-base Project in order to establish a national database of patient profiles and outcomes. The project is being co-ordinated by the Oriental Medicine Research Trust in Reading. The pilot phase will involve a relatively small patient sample while the full study will take in the whole membership of the British Acupuncture Council. This will be the first large-scale attempt in the UK to identify who is receiving acupuncture, which conditions are being treated and what outcomes are the result. Once the pilot phase is completed, the intention is for the full study to be undertaken in collaboration with a university based research group. The OMRT proposal, which draws on the published work of the FTaC, assesses patient outcomes utilising a general health status questionnaire (the SF-36) and other measures.

5) To assess the safety and risks of acupuncture through a nation-wide survey of all practitioners in order to both learn from current practice as well as provide better evidence on risk.

After several rounds of discussion with the British Medical Acupuncture Society (BMAS) and the Acupuncture Association of Chartered Physiotherapists (AACCP) on plans to jointly undertake a survey of adverse events, the BAaC decided to fund its own survey. Through

collecting data from the effects of 30,000 treatments, an estimate will be made of the frequency and severity of adverse reactions. This will take into account the nature of the acupuncture treatment itself, which can also result in short-term ‘healing crises’ and other positive post-treatment effects. The study is being conducted and co-ordinated by the Foundation for Traditional Chinese Medicine in York, and will involve practitioners from the BAAC monitoring their work with patients over a specific time period.

In addition to these five major aims, the BAAC committed itself to two pragmatic policies that reflect the piecemeal nature of the development of research into complementary medicine in the UK:

- To promote liaison between the various research bodies which have developed independently to meet the perceived needs of the profession
- To act as a forum and broker for research initiatives in acupuncture in the UK.

CLOSELY ALIGNED ACUPUNCTURE RESEARCH ORGANISATIONS

The BAAC has not itself undertaken any of its own research projects. In the medium to long-term the BAAC could plan to employ a Research Officer whose role would be to implement some of the design and development work involved in protocols and project management. In the short term, however, the BAAC has looked to three closely aligned research organisations to act as providers in the delivery of its priorities. These are:

1) Acupuncture Research Resource Centre (ARRC)

This is an information and support service based in the Faculty of Health and Human Sciences at Thames Valley University in Ealing. Through building an in-house database on research publications, known as ARRCbase, this centre provides information and support for the general public and many others including acupuncturists, doctors, and the media. ARRC also has a proactive role of interpreting research through publishing briefing papers on a range of topics and through challenging poor research in a scholarly and rigorous manner. ARRC is an important contact point for the media when researching the evidence on acupuncture, and as a result can help to shape and influence public opinion. In addition, ARRC provides direct support for practitioners involved in research by publishing a directory of researchers, by offering training sessions on research skills, by articulating appropriate methodologies and by outlining directions for future research. And finally, ARRC organises an annual acupuncture research symposium in London that is an important forum for debate and discussion within the profession. The BAAC is ARRC’s sole funder.

2) Foundation for Traditional Chinese Medicine (FTCM)

This is an acupuncture research organisation, registered as a charity, and based in York that aims to promote the role of acupuncture within the UK national healthcare system and to develop and improve the practice of traditional Chinese medicine. The Foundation has been active in the field of acupuncture research since 1992 with over thirty scientific and academic papers having been published in that time. Currently the Foundation is working on several research projects, including the York Back Pain Trial and the Adverse Events Survey, both of which are mentioned above, and also a study exploring a role for acupuncture for women with

menstrual disorders, a project being undertaken in collaboration with the Department of Health Sciences at York University. The Foundation also organises regular conferences. The FTCM is independent of the BAAC, but its Research Director, Hugh MacPherson, is a member of the BAAC Executive. ARRC was initially a joint BAAC/FTCM venture.

3) Oriental Medicine Research Trust (OMRT)

The OMRT is a research organisation based in Reading whose main aims are to initiate and fund research projects, develop appropriate research methodologies, increase the involvement of practitioners and other health professionals in research, and disseminate the results of research into Oriental medicine. Its main research activity at present is the Dao-base Project discussed above. As a registered charity, OMRT is independent of the BAAC, but most of its trustees and advisors are BAAC members.

PROPOSALS FOR A BAAC RESEARCH STRATEGY

Given the history of research both within and outside the acupuncture profession, a number of proposals have emerged as consistent with what has worked well in the past and in accord with the emergent reality that research will be one of the key issues facing the profession in the next decade. The stage has been set, therefore, for drawing together the various strands of the BAAC's involvement in research into a coherent and achievable strategy. These proposals have been brought together here to stimulate debate, encourage wider discussion and help the BAAC move towards a relevant and robust strategy on research. These proposals for a research strategy are:

1) Encouraging research-mindedness

The BAAC has already been proactive in this area for many years, and so the work of developing research-mindedness among practitioners will necessarily build on past activities. The following three strands to this work will be maintained, extended and developed:

- a) Funding the work of ARRC which supports acupuncturists in developing research awareness, provides a search service, commissions and disseminates briefing papers within and outside the profession, organises annual research conferences and runs training seminars in research methods
- b) Funding the BAAB and supporting its work with acupuncture schools and colleges in developing curricula that emphasise research awareness
- c) Developing a framework for Continuing Professional Development (CPD) which encourages members to use practitioner-based research activities, such as audit and reflective practice, to improve the quality and skill of their professional work.

2) Developing research priorities for the profession

The BAAC's role of setting strategy for the profession will include a more detailed assessment of research priorities. While these priorities have yet to be firmly established, the following have been identified as of considerable value:

- exploring the patient perspective, what patients value about acupuncture, how patient

satisfaction could be improved, and what barriers there are to use of acupuncture

- investigating acupuncture on its own terms through basic science projects, most likely where there are active collaborations with institutions that have access to the appropriate resources
- identifying research methodologies that are congruent with the patient-centred and holistic dimensions of the work of acupuncturists, where possible drawing on existing qualitative research models, on single case study methods, and on various cohort and RCT research designs
- determining the effectiveness, the cost-effectiveness and the safety of acupuncture treatment in normal clinical practice
- developing the reliability and validity of clinical decision-making processes, including pulse and tongue diagnosis and the interpretation of patterns of disharmony
- translating, collating, interpreting and disseminating high-quality research from East Asia.

The BAAC will identify appropriate areas for commissioning research starting with small-scale projects and feasibility studies. The BAAC supports the publication of research studies, whether the outcome for acupuncture is positive or not, the wider dissemination of the results of these studies, and the development of clinical guidelines where appropriate.

3) Liaison with existing closely aligned research organisations

Given the existence of closely aligned research organisations, currently ARRC, FTCCM and OMRT, and that these organisations are already working well with the BAAC, the “arm’s length” relationships with these bodies, and others when they are established, will be retained. Although each provider has its own specific goals, the BAAC will have a facilitating role in bringing these organisations together and in ensuring liaison, mutual support and synergy between them. At some point the BAAC may propose that it has a stronger interlinking and co-ordinating role in order to enhance the infrastructure and the overall research effort of the profession.

4) Building links, developing collaborations

The BAAC will build stronger links with the research organisations and universities departments that have a particular interest in acupuncture research as well as maintaining and extending the acupuncture profession’s research links with individual scientists, academics and doctors. These relationships will be encouraged to develop naturally around shared interests, through collaborations on research projects and through jointly organising conferences, study days and workshops. The BAAC will aim to be well represented in the research forums that promote greater liaison between the practitioners of the orthodox and complementary health care systems.

5) Fund-raising for acupuncture research

The BAAC will have a pro-active role in arguing for increases in the current low level of funding for acupuncture research. Key institutions will be targeted, including the Department of Health, the Medical Research Council and the large medical charities with a view to

negotiating for funding for research projects identified and developed by research providers. The BAcC will also argue for the ring-fencing of a percentage of their total grant allocations for acupuncture research.

6) Raising the research profile of the profession

The BAcC's strategy will include a strong research emphasis in PR activities. Issues around evidence-based medicine, safety and risk, and potential costs and/or savings will continue to feature in the media. The profession's representatives need to be well-versed in the current debates, and present well-argued key points on acupuncture research.

Appendix

The members of the Research Committee who have been involved in writing and editing this document are Mark Bovey, Carol Horner, Hugh MacPherson, Mike O'Farrell, Nicola Robinson and John Wheeler.

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