

Meeting Report

Acupuncture Research: Strategies for Clinical Evaluation: Workshop Report, York, July 5–8, 2006

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This report summarizes a ground-breaking workshop on the strategic direction of acupuncture research which was held in York in early July 2006. Three days were spent discussing the history, the philosophy and the practicalities of researching acupuncture. Attending the workshop were an international group of researchers with varied backgrounds, including acupuncturists, physicians, physiotherapists, sociologists and anthropologists. Supported by the Medical Research Council's Health Services Research Collaboration, Elsevier and others, this workshop was an opportunity to brainstorm the issues and the concerns in the field and set out directions for research that would tackle some of the major challenges facing the acupuncture research community.

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Introduction

A ground-breaking workshop on the strategic direction of acupuncture research was held in York in early July 2006. Three days were spent discussing the history, the philosophy and the practicalities of researching acupuncture. Attending the workshop were an international group of researchers with varied backgrounds, including acupuncturists, physicians, physiotherapists, sociologists and anthropologists. Supported by the Medical Research Council's Health Services Research Collaboration, Elsevier and others, this workshop was an opportunity to brainstorm the issues and the concerns in the field and set out directions for research that would tackle some of the major challenges facing the acupuncture research community. Linked to the workshop was the plan that presenters at the workshop would also take the lead in

writing chapters that would contribute to a book to be published by Elsevier.

This workshop consisted of a series of presentations from acupuncture researchers each of which had input from two or three others. Underpinning these presentations were several themes that, to a lesser or greater extent, informed the strategic direction taken by those attending the workshop including:

- (i) an understanding that the field of acupuncture research is a developing one; we have come so far already, but we have much further to go
- (ii) an excitement about the opportunities to learn from what has gone before, rather than having to always reinvent the wheel
- (iii) a commitment to inclusivity—in the styles of acupuncture to be investigated, in the breadth of appropriate methods that might be suitable, and in the range of investigators that we encourage to engage in research
- (iv) a sensitivity to the medicine, the tradition, and the orientation to acupuncture being a unique and person-centered approach

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- (v) a respect for good 'orthodox' research practices
- (vi) a creativity that identifies current challenges and opportunities as well as possible future strategic directions
- (vii) an enthusiasm for improving clinical practice such that research is not an end in itself.

History of Acupuncture Research

Stephen Birch outlined the background to acupuncture research, particularly as it pertains to the West. He offered a brief history of acupuncture as a way of introducing the diversity of current practice. He then explored some key philosophical differences between oriental and western approaches to developing a knowledge base, and how there could be a mismatch in the evaluation of a holistic medicine when using a reductionist methodology. Following on from a brief introduction to acupuncture research; his presentation concluded by identifying some useful perspectives for understanding the complexity of acupuncture and its diversity. These included the need for research studies to be designed in a way that the data collected accurately reflected the patients, the practitioners and the style of acupuncture being tested.

Patients' Perspectives and Utilization of Acupuncture

Claire Cassidy set out research strategies used to map the patterns of utilization and experience of acupuncture patients. The aim of this is to explore not just who is using acupuncture but also to tease out from patients their reasons why. This calls for more in-depth investigation, where qualitative methods such as interviews can reveal patients' perceptions and experiences, and what they particularly value about the treatment process. Claire Cassidy set out the case for multiple perspectives; with no one research method providing answers to all the research questions. Strategies for research may involve collecting either qualitative data or quantitative data, or perhaps some mixture of both. In this presentation she particularly stressed the importance of the patient's perspective and the value this has for all types of acupuncture research.

The Safety of Acupuncture

Hugh MacPherson then explored approaches to researching acupuncture safety. We have to assume that acupuncture can only be shown to be safe when we have robust evidence. In this context he set out the key methods that have been used to identify and quantify the levels of risk associated with acupuncture. Given the current level of evidence, it is increasingly accepted that

acupuncture can be considered safe in competent hands. There remain however a number of challenges. These include exploring the inherent variability and sensitivity of patients in their reactions to acupuncture. We also know little about the relationship between short-term reactions, which may be aggravations to treatment, and their association with health outcomes. The goal of many of these types of research endeavours is to improve the safety of routine practice, and further research is likely to enhance this process.

The Practice of Acupuncture

Rosa Schnyer in her presentation described acupuncture as a complex treatment intervention which has developed from its rich and diverse history. She set out the breadth of current approaches and styles of acupuncture based on the traditions from Asia. Such diversity raises unique challenges when conducting to evaluate the clinical impact. This presentation addressed a range of questions such as how specific are the actions of the acupuncture points, how reliable are acupuncturists' diagnoses, and how far can acupuncture be standardized without compromising the integrity of the intervention. Then Rosa suggested some useful pointers for developing research strategies that combine an intellectual rigour of good science with a focus on evaluating the impact of acupuncture as a dynamic and interactive intervention.

Patient Centered Outcomes from Acupuncture

Charlotte Paterson then opened up the question of how best to measure the outcomes and processes of acupuncture from the patient's perspective. First the case was made that the patient should be central to the measuring process. Then she moved on to the need to identify what patients actually value about treatment, which often includes broader changes, that is, changes to more than the presenting symptom. These broader changes can include whole person effects, and even a shift in social and personal identity. This presentation explored how these measures of broader change can be captured by specific outcome measures. This creates the opportunity of mapping change in this broader way in larger-scale studies and clinical trials.

Treatment Effects: Non-Experimental Designs

Adrian White, in the first of three presentations on 'effectiveness' of acupuncture, focused on non-experimental studies, those where we can explore treatment effects and outcomes from routine care yet without the benefit of a control group for comparative purposes. He set out an array of non-experimental research methods that range from single and multiple case series through to surveys and qualitative studies.

Also included in this presentation were an overview of the potential of pilot studies to assess feasibility of larger scale analyses and clinical trials. While non-experimental studies are not 'definitive' in the way that randomized controlled trials can be said to be, nevertheless there are some challenging aspects to these endeavours. There is a need to maintain the quality of the non-experimental research methods while at the same time identifying the building blocks for treatment effects and outcomes.

Comparing Acupuncture with Other Healthcare Interventions

Karen Sherman then talked about comparing treatment effects of acupuncture with other types of health care. She identified the methods by which we can ascertain whether acupuncture is more or less effective when compared with a reasonable comparison. She set out a field guide for such research, clarifying the differences between effectiveness and efficacy, and between pragmatic and explanatory trials. With the focus of this presentation more on pragmatic and effectiveness, she provided good examples of how these studies have contributed to the evidence base for acupuncture. This approach lends itself well to analyses of cost-effectiveness, an important concern when there are limited resources and decisions be made about their allocation. We also explored some of the challenges, for example the potential limitations imposed when the acupuncture is constrained in a trial treatment protocol.

Efficacy of Components of Acupuncture

Peter White set out the research methods to investigate the efficacy of components of acupuncture. In contrast to the previous presentation, these methods are more about establishing efficacy *per se* using explanatory trials. As in effectiveness studies, efficacy studies require researchers to ensure the design will lead to as little bias as possible. Potential sources of bias were explored, and in particular for efficacy the role of a sham or placebo arm for comparative purposes was presented. Peter White then reviewed a range of sham techniques that have been used in placebo-controlled studies, as well as an assessment of their limitations. One concern is that placebo or sham acupuncture seems not to be physiologically inert, as would be ideal in a control. We moved on to question whether it is actually possible to fully control for 'placebo' effects, especially when acupuncture is practiced as a dynamic and interactive intervention. Nevertheless there continues to be a need for rigorous methods that minimize bias, for establishing how well acupuncture works and for identifying what components of acupuncture to which any putative benefit can be ascribed.

Biological Correlates and Mechanisms

Richard Hammerschlag presented research into the biological correlates and physiological mechanisms of acupuncture. He started by explaining the differences between correlations and mechanisms. Correlations are simply associations between some aspect of acupuncture and a biological measure, and they will occur at some stage along the causal pathway. Mechanisms however are the fundamental processes of acupuncture that initiate and drive physiological change, and knowledge of these can be helpful for many reasons. He showed how clinical practice can inform the direction of research into physiological mechanisms. He also showed how mechanism research can inform clinical practice. In this presentation he provided an overview of the types of mechanisms that have been identified, assessed the strength and limitations of these approaches and provided suggestions for moving the field forward. The importance of this work was stressed, since it may well provide a challenge to the dominant biomedical model of health and disease, with the potential for furthering credibility for acupuncture.

Evidence Synthesis: Systematic Reviews and Meta-Analyses

Klaus Linde presented how it is to bring the evidence together and synthesize it in systematic reviews and meta-analyses. First he set out how systematic reviews are done, with clear research questions, explicit methods for identifying and selecting relevant studies from literature and critically appraising them. He provided a short history of systematic reviews of acupuncture and highlighted how differing interpretations can lead to different conclusions. This leads us into several challenges, such as the variability of study designs used in acupuncture trials, as well the variability in the styles of acupuncture that have been under scrutiny. Given the diversity of current acupuncture practice, assessing the adequacy of acupuncture in clinical trials was flagged as a major concern. Nevertheless there continues to be an important role for synthesizing clinically relevant evidence in systematic reviews.

Engaging Practicing Acupuncturists in Research Activity

On behalf of Peter Wayne, who was unable to attend to workshop, Karen Sherman invited the workshop to consider the process by which acupuncturists and others can become involved in research. Research can be daunting, and so in this presentation it was emphasized how research can be tackled by working in collaboration with others. Research projects can for example be initiated at acupuncture schools and colleges, and a

number of examples were cited where small-scale projects have led to a useful understanding and perspective. The workshop attendees stressed the need for some useful guidelines for conducting such studies, including having a clear research question, building a team of collaborators and obtaining the necessary ethics permissions. Acupuncturists have an essential role in supporting projects initiated by established research groups. The expertise of practicing acupuncturists can inform research designs and help establish appropriate treatment protocols so that the acupuncture evaluated is clinically relevant. In conclusion, clearly acupuncturists have an essential role in promoting acupuncture research that respects the integrity of the medicine.

Research Strategies for of the Future

George Lewith concluded the workshop with a 'blue skies' session where he asked for everyone's ideas and thoughts about acupuncture research. In particular he focused attention on the need for a clearer strategic direction if we are to move the field forward. A number of key dimensions emerged which include the importance of the patient's perspective, the need to consider both qualitative and quantitative methods, and the imperative of seeing acupuncture as a dynamic and interactive treatment modality. A number of challenges lie ahead,

not least the challenge of seeing acupuncture as a complex intervention so as not to lose important aspects of care in the process of evaluating it. Another challenge is that of establishing a placebo control that is sufficiently inert to unequivocally establish which components of acupuncture work. The need to see acupuncture research as an emerging discipline was also stressed, with many debates and discussions ahead that will shape the field.

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