

Out of the laboratory and into the clinic: acupuncture research in the real world

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INTRODUCTION

The UK's National Health Service (NHS) took the decision in 1998 to fund two pragmatic randomized controlled trials (RCTs), the first evaluating acupuncture for migraine and the second for chronic low back pain. That the NHS is willing to fund large scale trials in complementary medicine is itself an exciting development, but what is more remarkable is that both of these are designed as pragmatic rather than explanatory trials. While an explanatory (or experimental) trial is used to evaluate a scientific hypothesis, for example that acupuncture is better than placebo, a pragmatic trial is used to inform decisions about procedures and interventions in normal clinical practice. This distinction has fundamental implications for acupuncture, for acupuncturists and for the acupuncture profession. The aim of what follows is to draw out some of the implications of these two types of research design and to describe in more detail the recent development towards pragmatic research funding in the UK.

THE EXPLANATORY TRIAL: A THEORETICAL QUESTION, AN EXPERIMENTALLY DERIVED ANSWER

Over the last three decades, the history of research into the clinical benefits of acupuncture in the West has been dominated by the explanatory (or experimental) randomized controlled trial (RCT). Within this context, the challenge has been to determine the efficacy of acupuncture for a range of diseases and conditions. The central concern has been to separate the specific effects of acupuncture needling from

what are called the non-specific effects. They are known as non-specific because it is assumed that the benefits from acupuncture treatment result from a wide range of factors in addition to the needling. Such factors include the therapeutic relationship, the expectations of the patient, the quality of the clinical environment, and many other subtle influences.

A key feature of most explanatory trials has been the utilization of a formula of acupuncture points for the treatment group, and some form of 'sham' acupuncture for the control group. The requirement of a strict protocol for point selection has been dictated by the nature of the explanatory trial and the related desire to test a scientific hypothesis. Evidence for this rigid adherence to treatment formulae comes from the systematic review by Linde et al. (1996) who examined the trials of acupuncture for asthma in the literature. They found that in the 15 trials that met their selection criteria, all but one of the trials specified treatments based on a formula of acupuncture points. In the trial that was the exception (Jobst et al. 1986), the point selection was based on the principles of traditional Chinese medicine, an approach that incorporates a differentiation of syndromes or patterns and individualized treatments for patients. The overall results of these 15 trials will therefore have limited implications when drawing conclusions on the effectiveness of acupuncture in everyday practice.

A central feature of the explanatory RCT is that it is designed to elicit the effect of the active ingredient of an intervention. This design is based on the assumption that the patient group is reasonably homogenous, such that similar treatments will deliver results which can be averaged. As practising acupuncturists however, we see similar types of patients with different diseases and similar types of diseases

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with different patients. Individualized treatment should take into account the uniqueness of the patient as well as the particularity of their disease and the presenting signs and symptoms. For the researcher wedded to the explanatory RCT, differences between patients are not assumed to have a significant bearing on the outcome of the patient group as a whole. Yet in practical terms, if the appropriate treatment for one sub-group of patients is different from the appropriate treatment for another sub-group, then a methodology utilizing appropriate (rather than standardized) treatments will deliver the best benefits for the treatment group as a whole. Standardized interventions based on a formula of points will result in some mismatches and therefore will not deliver results based on optimum practice.

This line of reasoning can be extended to the issue of participation. Convention RCTs are based on the assumption that patients have no preference for a particular treatment. However, where preferences do exist, such a trial design can result in a selective and, in population terms, biased sample (Fitter & Thomas 1997). This issue becomes particularly important where there is a participatory element to receiving treatment, for example through discussions with the practitioner the patient will choose to make changes in lifestyle or diet, or perhaps engage with issues of life's meaning and purpose. In contrast, for other patients receiving acupuncture, it is a one-way process where the patient expects to be 'cured' and takes little or no responsibility for actively helping with the healing process other than turning up for treatment. In a patient preference trial, of which there are a number of alternative designs (Thomas & Fitter 1997), a higher proportion of the treatment group will be actively participating in their treatment process. Such a trial will demonstrate more representative results clinically, because patient choice is a real factor in primary care. And, assuming that patients benefit from their active involvement, such a trial will also deliver outcomes that reflect optimum practice unlike trials that ignore patient preferences (Brewin & Bradley 1989).

For academics and scientists, explanatory trials have always held the high ground in terms of methodological rigour. The obsession with the placebo question, namely aiming to determine whether acupuncture is more than just placebo, has been the research question of choice for most researchers. The risk-benefit argument has been made, namely that unless we can determine that acupuncture is better than placebo, then there is an ethical case for not using acupuncture because we already know that acupuncture has the potential to cause harm. A

consequence of this focus on the explanatory trial has been the debates on the various types and credibility of the 'sham' interventions that are needed for the control group. The aim of these 'sham' interventions is to ensure that the control group receives all the effects of acupuncture treatment with the exception of the 'real' acupuncture. For the credibility of this design, the patients should not be able to tell the difference between the 'real' and the 'sham' acupuncture. Such a methodology assumes that the specific and the non-specific effects can be separated, a reductionist assumption which has been questioned on the basis that there could be a synergy between specific and non-specific influences, whereby the sum is more than the parts (Kaptchuk 1998).

The problem with explanatory trials is that their focus is on trying to answer what is essentially a theoretical question (does acupuncture result in more than a placebo response?) and, as with all theoretical questions, the method for determining the answer requires an artificial laboratory type of environment. All unwanted variables should be controlled so that the one variable under question can be monitored and evaluated. Few of the explanatory controlled trials of the last 30 years have come close to laboratory conditions, but nevertheless their methodology has more closely matched scientific and academic expectations. That so many of these trials are far removed from clinical reality has been of little concern. Methodological rigour has ruled at the expense of real world research.

The quality of clinical trials needs to be assessed from more than the point of view of methodological rigour based on scientific criteria of 'objectivity'. The clinician's perspective is crucial. The practice of acupuncture involves many complex and interacting components which include careful diagnosis based on signs and symptoms, appropriate matching of points to the patient, subtle needle insertion and manipulation, and professional judgements about the overall care and management of the treatment process (MacPherson & Kaptchuk 1997). These factors are all important to the outcome, and to exclude their influence in an explanatory trial is to limit its applicability to real world clinical practice, to reduce the measurable benefits and to minimize the learning opportunities. So what is the alternative?

THE PRAGMATIC TRIAL: A PRACTICAL QUESTION, A REAL WORLD ANSWER

While 'efficacy' is the word usually used to describe the benefits of acupuncture over and above the non-specific effects, 'effectiveness' is more commonly

used to describe the overall benefits of an acupuncture service. It is through utilizing the pragmatic RCT that such benefits can best be determined. Instead of a strict adherence to treatment protocols to equalize the placebo effect, pragmatic trials aim for a flexible approach by the practitioner in order to maximize both the placebo effect and the treatment effect. An acupuncture service includes moxibustion, cupping and auxiliary techniques; it incorporates dietary and lifestyle advice; and it includes all the non-specific ingredients of treatment such as expectations and belief, and the quality of the therapeutic relationship. The pragmatic RCT is not designed to separate out the different components that contribute to the overall effect. Rather it is designed to evaluate the overall effectiveness, and in some trials the cost-effectiveness. This information can be used to determine choices between interventions, procedures or practices. Ideally, pragmatic trials should be conducted under conditions as close as possible to normal clinical practice.

The practical relevance of the pragmatic RCT is one of its strengths (Fitter & Thomas 1997, Thomas & Fitter 1997). Pragmatic trials are often used to compare a new intervention with the best existing one; the primary comparison then is not between acupuncture and placebo but between acupuncture and the currently accepted treatment. For example, in the condition of tennis elbow, knowing whether acupuncture is better than steroid injections is more useful than knowing whether it is better than placebo. Just because acupuncture is better than placebo does not mean that acupuncture is better than the best available treatment. Pragmatic trials can be designed to incorporate patient preferences which would lead to a higher proportion of more motivated patients in the treatment group, resulting in acupuncturists being able to optimize their practice for these patients. For the treatment group as a whole, this would also deliver a more realistic result than if patient preferences had been ignored.

For an acupuncture trial to serve professional acupuncturists, it should inform practice. A trial can be a useful learning tool such that practitioners can learn more about diagnosis, improve treatment and be more accurate with prognosis. The explanatory trials, with their formulaic treatment protocols, have failed to deliver in this regard. Linde et al. (1996) write 'In the case of negative results such (explanatory) trials have no impact on acupuncturists, and in the case of positive results it is questionable if clinically useful strategies are provided'. Pragmatic trials that evaluate acupuncture as it is practised have the advantage that they can build on existing good practice, providing detail on the patterns of disharmony, the clinical strategies and the related outcomes. On

the basis that clinical trials can answer useful questions, it is encouraging in the UK to have the NHS funding two large-scale pragmatic trials in acupuncture.

TWO MAJOR ACUPUNCTURE TRIALS START IN THE UK

The NHS has made a strategic decision to fund research into acupuncture in primary care. The NHS Research & Development Health Technology Assessment Programme wanted to evaluate the value to general practitioners (GPs) and their patients of having an acupuncture service available for patients with chronic pain. The aim was to commission research in order to establish the evidence on whether an integrated acupuncture service should be provided by GPs as an adjunct to normal primary care. Based on the bids for funding within this programme, the NHS chose to prioritize the methodology of the pragmatic RCT and two trials have been funded along these lines.

In the first of these two trials, where the bid came from the Research Council for Complementary Medicine (RCCM), acupuncture is being evaluated for migraine. The protocol for this trial, recently published by Vickers et al. (1999), outlines how 400 patients will be randomized to one of two groups, one of which will receive acupuncture. Both groups will continue to receive normal primary care from their GP. Acupuncture will be delivered by physiotherapists (physical therapists), who will provide up to 12 treatments within the NHS, and will be members of the Acupuncture Association of Chartered Physiotherapists (AACCP) with 'advanced' status which requires a minimum training of 200 h. The primary outcome measure will be the change in mean daily headache score between baseline and one year follow-up.

In the second of these two trials funded by the NHS, acupuncture is evaluated as a treatment for chronic low back pain. Initiated by the Foundation for Traditional Chinese Medicine based in York, England, this trial is a collaboration with the Medical Care Research Unit based at Sheffield University and GPs from York's Primary Care Group. The research project started six years ago with a feasibility study (Fitter & MacPherson 1995) followed by a pilot study (MacPherson et al. 1999). The protocol for the full trial has also recently been published (Thomas et al. 1999). The primary aim of the trial is to evaluate the longer-term clinical benefits of providing an acupuncture service for patients with chronic low back pain. There will be 240 patients in the trial, all receiving normal primary care treatment

at the discretion of their GP. Two thirds (160 patients) will be randomized to the offer of acupuncture. Because patients have the option of not accepting the offer, patients' preferences are incorporated. Up to ten sessions of acupuncture will be provided in independent clinics by professional members of the British Acupuncture Council (membership is based on a minimum of three years full-time training), with at least three years' post-qualification experience. Outcome measures include the Oswestry Back Pain and Disability Questionnaire, and the general health status SF-36. Cost effectiveness and safety will also be evaluated. Outcomes will be measured at three and 12 months from entry to the trial. Within the trial there will also be three sub-analyses: the first will explore the common low back pain syndromes, such as Qi and Blood Stagnation and Kidney Deficiency, evaluating variations in treatment and outcome; the second will be a qualitative investigation of the patients' experience of acupuncture; and the third will assess adverse and positive reactions to treatment from both the practitioners' and the patients' perspectives.

TOWARDS REAL WORLD RESEARCH

In drawing some lessons from 30 years of acupuncture research in the West, we have an opportunity to question whether we need to continue the past emphasis on explanatory trials. Such trials have investigated whether acupuncture is better than placebo, i.e. whether there is an active mechanism or effect. Is it not time to move acupuncture research from the laboratory to the clinic? Instead of asking 'is acupuncture better than placebo?', shouldn't we be asking 'is acupuncture of better value than what is currently on offer?' Is there not a compelling case for research designs to shift away from artificial treatment protocols and towards designs where practitioners can use individualized treatments? Does it not make sense for us to move beyond research that prioritizes rigorous methodology linked to the values of 'objective' science and invest our energy in research that evaluates acupuncture with a rigorous methodology that also supports treatment under conditions of optimum practice? A crucial aspect of research is the overall goal of helping deliver better treatment and care to patients. As acupuncturists, we need to focus on research that supports this goal, and this means building collaborative links with researchers who want to help us evaluate what we actually do in practice.

The explanatory clinical trial can help medical scientists answer scientific hypotheses. However, such trials tend to deliver sub-optimum results with limited generalizability to normal practice. In contrast, the pragmatic trial can help acupuncturists evaluate the value of their work in the real world, can aid decision-making when there are choices to be made between different clinical interventions, and has the potential to provide learning opportunities for improving practice.

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